SAMSKRUTI COLLEGE OF PHARMACY
Kondapur, Ghatkesar, Hyderabad-501 301.

TIME TABLE (2021-2022)
III YEAR 1st Sem. B.PHARMACY SECTION –A

DAY	9:30 -10:25	10:25-11:20	11.20–12.15	12 :15 01 :15	01:15 - 2:10	2:10 – 3:05	03.05-04.00
	1	2	3		4	5	6
MON	IP	GPD	MC	L U N C H	EMV.SC	SEMINAR	
TUE	P.COLOGY	ENV.SC	GPD		P.COG	IP	MC
WED	MC	P.COG	IP		P.COLOGY	LIB	SPORTS
THU	IP BATCH-I P.COLOGY BATCH-II				MC T/L	P.COLOGY	P.COG T/L
FRI	P.COLOGY BATCH-I P.COG BATCH-II				LIB	P.COG	P.COLOGY
SAT	P.COG BATCH-I IP BATCH-II				IP T/L	GPD	LIB

TEACHING FACULTY

S No	Name of the subject	Abbreviation	Faculty Name
1	MEDICINAL CHEMISTRY	MC	T.VIJAYA LAXSHMI
2	INDUSTRIAL PHARMACY I	IP	K MANISHA
3	PHARMACOLOGY II	P.COLOGY	T.SWATHI
4	PHARMACOGNOSY AND PHYTOCHEMISTRY II	P COG	B.KRISHNA
5	GENERIC PRODUCT DEVELOPMENT	GPD	M.SHIVA PRASAD
6	ENVIORNMENTAL SCIENCES	EMV.SC	L.SUNIL

CLASS INCHARGE:MR: L.SUNIL

Principal

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

ENVIORNMENTAL SCIENCE COURSE FILE

PREPARED BY
DR.B.SUDHAKAR

Contents

1. Syllabus copy
2. Vision of the Department
3. Mission of the Department
4. PEOs and POs
5. Course objectives and outcomes
6. Brief importance of the course and how it fits into the curriculum
7. Prerequisites if any
8. Instructional Learning Outcomes
9. Course mapping with PEOs and POs
10. Class Timetable
11. Lecture schedule with methodology being used / adopted
12. Detailed notes
13. Additional topics
14. University previous Question papers of previous years
15. Question Bank
16. Assignment Questions
17. Unit-wise quiz questions
18. Tutorial Problems
19. Discussion topics if any
20. References, Journals, websites, and E-links if any

SYLLABUS COPY

JAWAHARLAL NEHRU TECHNOLOGIVAL UNIVERSITY HYDERABAD

SYLLABUS FOR ENVIRONMENTAL STUDIES

B.Pharm. III Year I Sem. **L T/P/ C -1 0/0/ 0**

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

UNIT – I :The Multidisciplinary nature of environmental studies
Natural Resources Renewable and non-renewable resources:
Natural resources and associated problems
a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources.
e) Energy resources; f) Land resources:
Role of an individual in conservation of natural resources.

UNIT – II : **Ecosystems Concept of an ecosystem**. Structure and function of an ecosystem.
Introduction, types, characteristic features, structure, and function of the ecosystems:
Forest ecosystem; Grassland ecosystem; Desert ecosystem.
Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

UNIT – III : Biodiversity and Biotic Resources: Introduction, Definition, genetics, species and ecosystem diversity. Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic, and optional values.
India as a mega diversity nation, Hot spots of biodiversity. Field visit.
Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts.
conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

Unit – IV : Environmental Pollution: Air pollution; Water pollution; Soil pollution, Noise Pollution.

Definition, Cause, effects, and control measures of a) Air pollution: Primary and secondary pollutants, Automobile and industrial pollution, Ambient air quality standards.

b. Water pollution: Point and non-point sources of pollution, Major pollutant of water and their sources, drinking water quality standards, Wastewater treatment methods, ETP, STP, CETP.

c. Soil pollution: Soil as a sink of pollutants, Impacts of modern agriculture on soil, degradation of soil.

d. Marine pollution: misuse of international water for the dumping of hazardous waste, coastal pollution due to sewage and marine disposal of industrial effluents

e. Noise pollution: Sources, Industrial Noise occupational health hazards, standards, Methods of noise control

f. Thermal pollution: Heat Island effect, Radiation effects

g. Nuclear pollution: nuclear power plants, nuclear radiations, disasters and impacts, genetical disorders.

Solid waste Management: types, collection, processing and disposal of municipal solid waste and industrial waste, composition and characteristics of e waste and its management.

UNIT – V: Environmental Policy, Legislation & EIA: Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wildlife Act.

ENVIRONMENTAL IMPACT ASSESSMENT AND ENVIRONMENTAL MANAGEMENT PLAN:

Definition of an Impact: Classification of impacts, positive and negative impacts, reversible and irreversible, light, moderate and severe, methods of baseline data acquisition, Impacts on different components such as human health resources, air, water, flora, fauna and society. Prediction of impacts and impact assessment methodologies.
Environment Management Plan: technological solutions, Preventive methods Control technologies, greenbelt development, rainwater harvesting, remote sensing and GIS methods.

ENVIRONMENTAL POLICY, LEGISLATION, RULES AND REGULATIONS:

-Environment Protection Act. – Air (Prevention and Control of Pollution) Act. –
Water (Prevention and control ofPollution) Act,
Wildlife Protection Act –Forest Conservation Act , Municipal solid waste management and Handling rules, biomedical waste management and handling rules, hazardous waste management and handling rules.

Towards Sustainable Future: Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human health, Environmental Ethics, Concept of Green Building, Ecological Footprint, Life Cycle assessment (LCA), Low carbon life

TEXT BOOKs:

1. Textbook of Environmental Studies for Undergraduate Courses by Erach Bharucha for University Grants Commission.

2. Environmental Studies by R. Rajagopalan, Oxford University Press.

REFERENCE:

- Textbook of Environmental Sciences and Technology by M. Anji Reddy, BS Publica
- Environmental Studies by Anubha Kaushik C.P. Kaushik
- Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
- Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
- Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
- Clark R.S., Marine Pollution, Clanderson Press Oxford

Vision of the Department

Mission of the Department

VISION:

"To be a center of excellence by redefining Pharmacy Education and nurture Globally Competent Professional Pharmacists."

MISSION:

To train and develop students into Professional Pharmacists so as to fulfill the Industrial and Community needs.

To shoulder the responsibility of reducing the suffering of mankind by providing Pharmaceutical care.

VISION,MISSION OF DEPARTMENT

VISION OF THE DEPARTMENT :

To be a recognized global leader in developing solutions for evolving healthcare challenges.

MISSION OF THE DEPARTMENT:

To improve healthcare quality and outcomes through educating the next generation of pharmacists and pharmaceutical scientists in an environment foresting intellectual curiosity,through pursuing impactful basic and applied research,and developing and evaluating bmodels of clinical practice.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PEOs and POs

PEO 2: To train students with problem solving capabilities such as analysis and design with adequate practical skills wherein they demonstrate creativity and innovation that would enable them to

PEO 1: To prepare students with excellent comprehension of basic sciences, mathematics and engineering subjects facilitating them to gain employment or pursue postgraduate studies with development.

PEO 3: To inculcate positive attitude, professional ethics, effective communication and interpersonal skills which wouldfacilitate them to succeed in the chosen profession exhibiting creativity and innovation through research and development both as team member and as well as leader.

Program Outcomes

At the end of the program graduate is expected to acquire

PO1: An ability to apply knowledge of Mathematics, Science, to solve complex problems of Pharmacy

PO2: An ability to model, simulate and design systems, conduct experiments, as well as analyze and Interpret data and prepare a report with conclusions.

PO3: An ability to design , component, or process to meet desired needs within the realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability.

PO4: An ability to function on multidisciplinary teams involving interpersonal skills

PO5: An ability to identify, formulate and solve engineering problems of multidisciplinary nature.

PO6: An understanding of professional and ethical responsibilities involved in the practice of Pharmacy profession.

PO7: An ability to communicate effectively with a range of audience on complex problems of multidisciplinary nature both in oral and written form.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PO8: The broad education necessary to understand the impact of Pharmacy solutions in a global, economic,environmental and societal context.

PO9: A recognition of the need for, and an ability to engage in life-long learning and acquire the capability forthe same.

PO10: A knowledge of contemporary issues involved in the practice of Pharmacy profession.

PO11: An ability to use the techniques, skills and modern engineering tools necessary for Pharmacy practice.

.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Course Objectives and Outcomes

Course Objectives (as per JNTU-H)

- Understanding the importance of ecological balance for sustainable development.
- Understanding the impacts of developmental activities and mitigation measures.
- Understanding of environmental policies and regulations.

Course Objectives (as per college plan)

- To understand the importance of ecosystem.
- To understand natural resources and their usage in day-to-day life.
- To understand the concepts of concept of biodiversity and their values.
- To gain knowledge about different types of pollution and their control technologies.
- To study global environmental problems and global efforts.

Course Outcomes

After the completion of the course, the student would be able to

CO 1: Get the information about ecosystem and about its functions like Food chain, Ecological pyramids etc.,

CO 2: Get the knowledge about the different types of resources like land, water, mineral and energy and About the effects of environment by the usage of these resources.

CO 3: Gain knowledge about ecosystem diversity, its values and also about the importance of endemic species.

CO 4: Get the complete information about the different methods of protecting the environment.

CO 5: Gain knowledge about the different types of pollution and their control technologies.

CO 6: Gain the knowledge about different types of pollution and their treatment techniques like wastewater treatment, Bio medical waste management etc.,

CO 7: Get the complete information about EIA- Environmental Impact Assessment in which the student will get the knowledge about the projects and the process involved in getting the projects.

CO 8: Gain knowledge about the present resources and different techniques involved in its conservation.

1. Brief Importance of the Course and how it fits into the curriculum

- Environmental studies are the sciences which includes the improvement of the natural environment, to providehealthy water, air, and land for human habitation and for other organisms, and to clean up pollution sites.
- Environmental studies can also be described as a branch of applied science that addresses the issue of energy preservation, production assets and control of waste from human and animal activities.
- Furthermore, it is concernedwith finding plausible solutions in the field of public health, such as waterborne diseases, implementing laws which promote adequate sanitation in urban, rural and recreational areas.
- It involves wastewater management and air pollutioncontrol, recycling, waste disposal, radiation protection, industrial hygiene, environmental sustainability, and public health issues as well as a knowledge of environmental engineering law. It also includes studies on the environmental impact of proposed construction projects.

Prerequisites if any

- The domain of environmental science is not completely defined and includes many smaller disciplines. Our existence, lifestyles and growth depend entirely on the sun and the earth.
- The energy from the sun iscalled solar capital. In the same way, the planets, air, water, fertile soil, forests, grasslands, wetlands, oceans, lakes, wildlife, minerals and natural purification and recycling process are treated as Earth's capital.
- We use the term 'environment to describe, in the language of G.T Miller, The Plant's fife -support system for us and for all other forms of life'.
- In effect, the environment is me sum-total of solar capital and earth capital.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

2. Instructional Learning Outcomes

Learning outcomes are the key abilities and knowledge that will be assessed

UNIT – I
ECOSYSTEMS :

- scope and importance of ecosystem, Concept of ecosystem
- structural components of an ecosystem
- Function of ecosystem like, Food chains ,food webs, And ecological pyramids. Flow of energy
- Homeostasis / Cybernetics
- ecosystems value, services and carrying capacity.

UNIT – II

NATURAL RESOURCES:

- Renewable and non-renewable resources
- Forest resources
- Land as a resource,
- Mineral resources
- Food resources:
- Energy resources
- Water resources

UNIT - III

BIODIVERSITY AND ITS CONSERVATION

- Definition: genetic, species and ecosystem diversity
- Value of biodiversity
- Hot sports of biodiversity
- Threats to biodiversity
- Conservation of biodiversity

- Timber and non-timber forest products.
- Food and fodder resources

UNIT – IV

ENVIRONMENTAL POLLUTION

Definition, Cause, effects and control measures of:

- Air pollution
- Water pollution
- Soil pollution:
- Marine pollution
- Noise pollution
- Thermal pollution
- Nuclear pollution

- Solid waste Management
- Global environmental problems and global efforts

UNIT – V

ENVIRONMENTAL IMPACT ASSESSMENT AND ENVIRONMENTAL MANAGEMENT PLAN:

Environmental policy, Legislation, Rules and regulation

Environment Protection Act

Biomedical waste management

Hazardous waste management

Towards sustainable future

Course mapping with PEOs and Pos

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Mapping of Course with Programme Educational Objectives: (Sample)

S.No	Course component	code	course	Semester	PEO 1	PEO 2	PEO 3
1	Environmental Studies	*Mc500	Environmental Studies	1	✓	✓	✓

*When the course outcome weightage is < 40%, it will be given as moderately correlated (1).
*When the course outcome weightage is >40%, it will be given as strongly correlated (2).

POs	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Engineering Chemistry															
CO 1: Get the information about ecosystem and also about its functions like Food chain, Ecological pyramids etc.,			**2**					**2**		**2**	**1**			2	**Environmental studies**
CO 2: Get the knowledge about the different types of	**2**	**2**	**1**					**1**	**2**	**2**				2	

Principal

resources like land, water, mineral and energy and also about the effects of environment by the usage of these resources.															
CO3: Gain the knowledge about the ecosystem diversity, its values and also about the importance of the endemic species			**2**						**1**						
CO 4: Get the complete information about the different methods of protecting the environment.			**2**						**1**						
CO 5: Gain the knowledge about the different types of pollutions and their control technologies.			**1**				**1**		**1**					2	
CO 6: Gain the knowledge about different types of pollution and their treatment techniques like waste water	**1**		**1**				**2**		**1**					2	

treatment, Bio medical waste management etc.,															
CO 7: Get the complete informationabout EIA- Environmental Impact Assessment in which the student will get the knowledge about the projects and the process involved in getting the projects.			**2**						**1**					1	
CO 8: Gain the knowledge about the present resources and different techniques involved in its conservation.			**2**						**2**					1	

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

3. Time table of concerned class

Individual time table

4. Lecture schedule with methodology being used / adopted

SL.No.	Unit No.	Week No.	Topic to be covered in One lecture	Regular/ Additional	Teaching aids used LCD/OHP/BB	Remarks
1	I	WEEK 1	Scope and Importance of an Ecosystem	Regular	BB	
2			Classification of Ecosystem	Regular	BB	
3			Structure and Structural components	Regular	BB	
4			Forest, Grassland and desert ecosystem	Regular	BB	
5			Biogeochemical cycles, Nitrogen cycle and carbon cycle, Phosphorous cycle and hydrological cycle			
6	II	WEEK 2	Carrying capacity & homeostasis	Regular	BB	
7			Classification of Resources	Regular	BB	
8			Water Resources	Regular	BB	
9			Mineral Resources, Land Resources	Regular	BB	
10			Energy resources – Reneweble, Solar energy applications	Regular	BB	

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

11		WEEK 3	Nonrenewable resources- Fossil fuels, Nuclear energy, Chernobyl Nuclear disaster	Regular	BB	
12	III		Types of Diversity, Alpha, Beta and Gamma	Regular	BB	
13			Value of Biodiversity,			
14			Red list categories- Red Data book,	Regular	BB	
15			Food and fodder resources, Timber and Non timber resources.	Regular	BB	
16	IV	WEEK 4	Threats to Biodiversity.	Regular	BB	
17			Hot spots	Regular	BB	
18			Conservation of Biodiversity			
19			Classification of Pollution	Regular	BB	
20			Air Pollution.	Regular	BB	
21		WEEK 5	Soil Pollution, Noise Pollution	Regular	BB	
22			Nuclear Pollution & Disasters			
23			Water pollution, Waste water treatment technologies	Regular	BB	
24			Solid waste, Thermal Pollution	Regular	BB	
25			Marine Pollution	Regular	BB	
26		WEEK 6	Green house Effect & Global Warming	Regular	BB	
27			Ozone Layer Depletion	Regular	BB	
28			International Conventions			
29			Deforestation Desertification	Additional	BB	

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

30			Desertification	Regular	BB	
31	V	WEEK 7	Impact and Types of Impact	Regular	BB	
32			Steps involved in EIA	Regular	BB	
33			Prediction of Impacts and methodologies	Regular	BB	
34			EIS	Regular	BB	
35			EMP	Regular	BB	
36		WEEK 8	Treatment technologies	Regular	BB	
37			National Environmental Policy	Regular	BB	
38			Air Conservation Act	Regular	BB	
39			water Conservation Act	Regular	BB	
40			Forest Conservation Act	Regular	BB	
41		WEEK 9		Regular	BB	
42			Municipal Solid waste management	Regular	BB	
43			Biomedical waste management	Regular	BB	
44			Hazardous waste management	Regular	BB	
45			Water Cess Act	Regular	BB	
46	V	WEEK 10	Concept of Sustainable Development	Regular		
47			Over-exploitation of Natural Resources	Regular	BB	
48			Conservation of Resources	Regular		
49			Green building technologies	Regular		
50			Types of Human diseases	Regular		
51		WEEK 11	Sustainable future	Regular		

53			Slip Test	Regular	BB	
54			Revision	Regular	BB	
55			Revision	Regular	BB	
56			Crazy Consumerism	Regular	BB	
57		WEEK 12	Over exploitation of resources	Regular	BB	
58			Strategies for Achieving Sustainable	Regular		
59			Environmental Education	Regular	BB	
60			Conservation of Resources	Regular	BB	
61	V		Urban sprawl, Sustainable Cities and communities	Regular	BB	
62		WEEK 13	Human health	Regular	BB	
63			Role of IT in Environment	Regular	BB	
64			Environmental Ethics	Regular	BB	
65			Environmental Economies	Regular	BB	
66			Concept of green building	Regular	BB	
67		WEEK 14	Clean development Mechanism	Regular	BB	
68			Environmental Economies	Regular	BB	
69			Concept of green building	Regular	BB	
70			Clean development Mechanism	Regular	BB	

72		WEEK 15	Revision			
73			Previous Question paper Discussion			
74			Previous Question paper Discussion			

S.No	Topic to be covered in One lecture	Dates
	UNIT-I	
	ECOSYSTEM	
1	**ECOSYSTEM:** Introduction about Environmental studies&Ecosystem	Lec1
2	Scope and Importance of an Ecosystem	Lec 2
3	Classification of Ecosystem	Lec3
4	Structure and Structural components	Lec4
5	Forest, Grassland, and desert ecosystem	Lec5
6	Biogeochemical cycles, Nitrogen cycle and carbon cycle, Phosphorous cycle, and hydrological cycle	Lec6
7	Carrying capacity & homeostasis	Lec7
	UNIT-II	
	NATURAL RESOURSES	
8	Classification of Resources	Lec8
9	Water Resources	Lec9
10	Mineral Resources, Land Resources	Lec10

11	Energy resources – Renewable, Solar energy applications	Lec11
12	Nonrenewable resources- Fossil fuels, Nuclear energy, Chernobyl Nuclear disaster	Lec12
	UNIT-III	
	BIODIVERSITY&BIOTIC RESOURSES	
13	Types of Diversity, Alpha, Beta and Gamma	Lec13
14	Value of Biodiversity,	Lec14
15	Red list categories- Red Data book,	Lec15
16	Food and fodder resources, Timber and Non timber resources.	Lec16
17	Threats to Biodiversity.	Lec17
18	Hot spots	Lec18
19	Conservation of Biodiversity	Lec19
	UNIT-IV	
	ENVIRONMENTAL POLLUTION ,GLOBAL WARMING& GLOBAL ENVIRONMENTALPROBLEMS	
20	Classification of Pollution	Lec20
21	Air Pollution.	Lec21
22	Soil Pollution, Noise Pollution	Lec22
23	Nuclear Pollution & Disasters	Lec23
24	Water pollution, Waste water treatment technologies	Lec24
25	Solid waste, Thermal Pollution	Lec25
26	Marine Pollution	Lec26
27	Green house Effect & Global Warming	Lec27
28	Ozone Layer Depletion	Lec28
29	International Conventions	Lec29
30	Deforestation Desertification	Lec30

31	Desertification	Lec31
	UNIT-V	
	TOWARDS SUSTAINABLE FUTURE	
32	Impact and Types of Impact	Lec32
33	Steps involved in EIA	Lec33
34	Prediction of Impacts and methodologies	Lec34
35	EIS	Lec35
36	EMP	Lec36
37	Treatment technologies	Lec37
38	National Environmental Policy	Lec38
39	Air Conservation Act	Lec39
40	water Conservation Act	Lec40
41	Forest Conservation Act	Lec41
42	Municipal Solid waste management	Lec42
43	Biomedical waste management	Lec43
44	Hazardous waste management	Lec44
45	Water Cess Act	Lec45
46	Concept of Sustainable Development	Lec46
47	Over-exploitation of Natural Resources	Lec47
48	Conservation of Resources	Lec48
49	Green building technologies	Lec49
50	Types of Human diseases	Lec50
51	Sustainable future	Lec51
52	Crazy Consumerism, Over exploitation of resources	Lec52
53	Strategies for Achieving Sustainable, Environmental Education	Lec53

54	Conservation of Resources, Urban sprawl, Sustainable Cities, and communities	Lec54
55	Human health, Role of IT in Environment, Environmental Ethics	Lec55
56	Environmental Economies, Concept of green building, clean development Mechanism	Lec56
57	Environmental Economies	Lec57
58	Concept of green building	Lec58
59	Clean development Mechanism	Lec59
60	Revision	Lec60
61	Previous Question paper Discussion	Lec61
62	Previous Question paper Discussion	Lec62

Detailed Notes

UNIT – I: ECOSYSTEM

Contents:

Introduction

Scope & concept of Ecosystem
Kinds of Ecosystem
Structure & Function of
EcosystemFood Chain
Food Web
Ecological
Pyramid
Energy flow/ Transfer of energy in the Ecosystem
Bio-geo-chemical cycles.. Water cycle
Carbon cycle
Oxygen cycle
Nitrogen cycle
Potash cycle
Phosphorous cycle
Aquatic
Ecosystem

Forest Ecosystem
Desert Ecosystem
Meanings
References

Introduction of ecology:

The term "Ecology" was derived from Greek words viz., **Oikes** means house or place and **logs** means a discussion or study.
So,ecology is the **scientific study of the distribution** and the **interactions** between organisms and their natural environment.
The environment (surroundings) consists of: **living organisms (** biotic **)** and **non-living things (** abiotic **)** such as physical components of wind, temperature, rainfall, water, humidity , light, soil etc and chemical components of C,H,N,K,P,S etc..(in-organic components) and carbohydrates, proteins (organic components).Hence, Ecology involves studying ecosystems.
According to **GEORGE JACKSON,** an Ecosystem is a natural unit consisting of all plants, animals and micro-organisms in an area functioning together with allof the non-living things.
An ecosystem is the smallest unit of the biosphere that has all the characteristics tosupport life.
Pond ecosystem, forest ecosystem, desert ecosystem, marine ecosystem, urban ecosystem are some of the examples for ecosystems.
An ecosystem varies in sizes from a few square kms to hundreds of square kms. Similarly, an ecosystem may be temporary like a fresh pool / agriculture field orpermanent like a forest / ocean.

Scope of ecosystem :

Ecology plays an important role in agriculture crop rotation, weed control (unwanted plant); management of grasslands, forestry etc., biological surveys, fishery surveys, conservation of soil, wild life, surveys of water bodies like rivers, lakes;ponds etc...

Concept of ecosystem:

In an ecosystem, the interaction of life with its environment take place at manylevels. A single bacteria in the soil interacts with water, air around it within a small space while a fish in a river interacts with water and other animals, rivals in a large space. .
Considering the operational point of view; the biotic and abiotic components of an ecosystem are so interlinked such that their separation from each other is practicallydifficult. So, in an ecosystem both organisms (biotic communities) and abiotic environment (rainfall, temperature, humidity) each influencing the properties with other for maintenance of life.

KINDS OF ECOSYSTEMS: Ecosystem may be natural or artificial.

Artificial Ecosystem: These are maintained or created artificially by man. The man tries to control biotic community as well as physico chemical environment.Eg: Artificial pond, urban area development.

Natural Ecosystem: It consists of Terrestrial and Aquatic Ecosystems which are maintained naturally.

Terrestrial Ecosystem:

This ecosystem relates to bioticcomponents living on the land.

Vegetation dominates the community

and the types of vegetation affect the climate, soil structure & a rapid exchangeof O2, water & CO2

Aquatic Ecosystem:

- This ecosystem relates to biotic community living in water. The types of water (fresh water, saline water, polluted water) dominate and affect the pH of water, depth of water, temperature of water etc..
- Aquatic ecosystem has been sub-divided into **fresh water** and **saline water** basedon the
- quality of water.

STURCTURE & FUNCTION OF ECOSYSTEM

- **NATURAL ARTIFICIAL TERRESTRIAL (LAND) ES :** eg: Forest ecosystem Grassland ecosystem Desert ecosystem
- **AQUATIC ECOSYSTEM :**Eg: River ecosystem Marine ecosystem Estuarine ecosystem
- **FRESH AQUATIC ES :** Eg: rivers, streams
- **MARINE AQUATIC ES** eg: seas ; oceans, salt lakes
- **LENTIC** :(stagnant waters) eg: ponds, wells, lakes
- **LOTIC :** (Running waters) eg: river streams

  Eg: Agricultural land, artificial pond ;

URBAN AREA

The two major aspects of an ecosystem are: (1) Structure and (2) Function together they illustrate the organization of an ecosystem.

The Structure of an ecosystem consists of:

- Abiotic structure includes the non-living things of the ecosystem such as
- physical factors (soil, temperature, light & water) and chemical factors consisting ofthe inorganic compounds (N,C, H, K, P,S) & organic compounds (carbohydrates, proteins).
- Biotic structure includes plants, animals & microorganisms present in an ecosystem form the biotic component. These organisms have different nutritionalbehavior and status in the ecosystem and are known as Autotrophs (Producers),
- Heterotrophs (Consumers) & Micro-consumers (Decomposers) based on howthey get their food.
- Hence, the structure of an ecosystem comprises:
- The composition of biological community species (plants, animals, microorganisms), their population, life cycles, distribution in space etc.
- The quantity and distribution of non-living things such as soil ; water etc .
- The range or intensity of conditions like temperature, light, rainfall, humidity,wind & topography plays a major role in the structure of ecosystem.
- **Function of ecosystem** means how an ecosystem works/ operates under naturalconditions. The rate of biological energy flow ; the rate of nutrient cycles ie Bio-
- Geo-Chemical cycles and Ecological regulation (means regulation of organisms
- by Environment and regulation of Environment by organisms) plays a major role inthe function of an ecosystem

1. Autotrophic components (Producers) :

- Autotrophic means self nourishing. Since these organisms are self nourishing, they are also called producers. Eg: Algae, Green plants, Bacteria of photo synthetic.
- Green plants prepare their food themselves by making use of CO2 present in the air& water in the presence of sunlight through the process of **photosynthesis.**

  $CO2 + 2H2O \; CH2O + O2 + H2O$

  (Carbon dioxide) (Water) (Carbohydrates) (Oxygen) (Water)
- A few micro-organisms which can produce organic matter (nutrients) to some extent through oxidation of certain chemicals in the absence of sunlight known as **chemo autotrophs.**
- Eg: In the Ocean depths, where there is no sunlight, chemo-autotrophic bacteria make use of the heat generated by the decay of radioactive elements for preparationof their food .

2. ***Hetero-trophic components (Consumers) :***

Hetero-trophic means dependent on others for nourishment directly or indirectly upon the autotrophs (producers) for their food. These are of the following types:

a. **Herbivores (Primary consumers) :** These animals feed directly on livingplants or remains of plants. Eg: Rabbits, Deer's, Insects.

b. **Carnivores (secondary consumers):** These carnivores (flesh eating) feed onthe herbivores. Eg: Snakes, birds, Lizards, fox.

c. **Tertiary consumers (or) Tertiary carnivores:** These feed on the primary &secondary consumers. Eg: Lions, Tigers.

d. **Omnivores:** These consumers feed on both plants & animals. Eg Humanbeings, Birds (hawk) etc…

3. **Decomposers or Micro consumers:** They feed on organic compounds of deador living plants and animals for their food and energy.

They absorb some of the products from decomposed material and release organic compounds (nutrients) making them available to producers.

Eg: Bacteria, Fungi, Flagellates. The decomposers are also called as"**Saprotrophs**".

Food chain:

The transfer of food energy from the producers (plants) through a series of organisms (Herbivores, Carnivores) successively with the repeated activities of eating and being eaten is known as food chain.

In an ecosystem(s), one organism is eaten by the second which in turn is eaten by the third and so on... This kind of feeding relationship is called food chain.

Examples of food chain:

1. Grass Grasshopper Frog Snake Hawk.
2. Grass Mouse Snake Hawk.
3. Grass Rabbit Man .
4. Grass Mouse Hawk.
5. Plant leaf Caterpillar Sparrow Hawk.

Explanation: A caterpillar eats a plant leaf, a sparrow eats the caterpillar, and a hawk eats the sparrow. When they all die, they are all consumed by micro organisms like bacteria (or) fungi which break down the organic matter and convertit into simple inorganic substances that can again be used by the plants.

In nature, there are two basic types of food chains viz:

1. Grazing food chain and (2) Detritus food chain

Grazing food chain: This food chain starts with green plants (primary producers)and goes to herbivores and on to carnivores.

1. Phytoplankton's Zooplanktons Small fish Tuna.
2. Phytoplankton's Zooplanktons Fish Man.
3. Grass Rabbit Fox Tiger.

Detritus food chain: This food chain starts from dead organic matter (dead leaves / plants / animals) and goes to Herbivores and on to Carnivores and so on. .Leaves or dead plants Soil mites Insects Birds . Dead organic matter Bacteria Insects .dead leaves Algae Fish Man

The dead remains of plants and animals, dead leaves and flowers & fruits are degraded by decomposers(Fungi, Bacteria) and convert the organic matter.

into simple substances whichare then taken up by the primary producers as nutrients.

FOOD WEB:

Food web is a net work of food chains where different types of organisms are connected at different trophic levels so that there are a number of options of eating and being eaten at each trophic level. (A trophic level refers to an organisms position in the food chain) .

In the above figure, it may be observed that there are 5 linear food chains in the foodweb of a grass land ecosystem.

1. Grass Grasshopper Hawk
2. Grass Grasshopper Lizard Hawk
3. Grass Rabbit Hawk
4. Grass Mouse Hawk
5. Grass Mouse Snake Hawk

ECOLOGICAL PYRAMID:

Ecological pyramids were first studied by a British ecologist **CHARLES ELTAN (1927).** An Ecological Pyramid is a graphical representation consisting various trophic levels with producers forming the base and top occupy the carnivores.In an ecological pyramid the huge number of tiny individuals form at the base and a few large individuals occupy the top / apex . This formation is known as ecological pyramid.

Hence, **all producers** (micro & macro plants) belong to the *I trophic level*; all primary consumers belong to *II trophic level* and **organisms feeding** on these consumers belong to the *III trophic level* and so on.

The ecological pyramids are of three types. They are :

The pyramid of Numbers (showing population).

The pyramid of Biomass (showing total mass of organisms).
The pyramid of energy (showing energy flow).
The pyramid of Number:
It shows the relationships among the producers, herbivores and carnivores at successive trophic levels in
terms
of their number. Mostly the pyramid of number isstraight (or) upright with number of individuals in
successive
higher trophic levels goes on decreasing from base to apex.
The maximum number of individuals occur at the producers level. They support a small number of herbivores.
The herbivores, in turn, support a fewer number ofprimary carnivores and so on….. Top carnivores are very
few in number.
For eg: (1) In a grass land ecosystem.
Grass Grasshoppers Frogs Snakes Peacock / Hawk.
For eg: (2) in a pond ecosystem:
Phytoplankton Zooplankton Fish Crane
The pyramids may be inverted in a few cases :
A single plant may support the growth of many herbivores and each herbivore in turn provides nutrition to several parasites which support many hyper-parasites. Thus, from the producer towards consumers, there is
a reverse
position i.e., the number of organisms gradually shows an increase making the pyramid inverted inshape.
For eg: (3) in a Forest ecosystem
Tree Birds / deer Parasites Hyper parasitesTree Birds eagle
The Pyramid of Biomass: The amount of organic matter present in the environment is called biomass.
In pyramids of biomass, the relationship betweendifferent trophic levels is mentioned in terms of weight of organisms.
The pyramid may be upright for grassland ecosystem and inverted for pond ecosystem.
Eg: A vegetation produces a biomass of 1000 kg. Out of this 100 kgs of biomassfor herbivores, which in
turn only 10 kg of biomass for primary.
carnivores that give rise 1 kg of biomass for second order carnivoresand so on…

1000 kgs 100 kgs 10 kgs 1 kg

Vegetation Herbivores primary carnivore's Secondary carnivores

HENCE, A VEGETARIAN DIET CAN SUPPORT A LARGER POPULATION THAN ANON – VEGETATION DIET.

The pyramid of energy: The amount of energy trapped per unit time andarea at different trophic levels of a food chain with producers forming the base and the top carnivore at the apex is called pyramid of energy.

The energy content is generally expressed as K cal /m2 / year or KJ /m2 / year

Large Fish ---126 KJ / m2 / year

Small Fish 840 – 126 KJ / m2 / year

Zooplankton 7980 KJ / m2 / year

Phytoplankton (producers) 31080 KJ / m2 / year

Energy flow /Transformation of energy in Ecosystem

The movement of energy (or) transfer of energy through a series of organisms in an ecosystem from the external environment and back to the external environmentagain is known as **energy flow.**

In the universe, the main source of energy is SUN that produces energy in the formof light or solar radiation.

Different ecosystems in the world receive variable quantities of solar energy depending upon their location on the globe.

The other chief factors that control the amount of solar energy received by an ecosystem are Latitude and Longitude ; Slope; Cloud formation; Pollutants in theatmosphere

The transformation of energy in an ecosystem begin first with the input of energy from the sun by the process of photosynthesis. Carbon dioxide is combined with hydrogen (derived from the splitting of water molecules) to produce carbohydrates(CH2O) and the energy is stored in the high energy bonds of Adenosine Tri Phosphate (ATP).

Herbivores obtain their energy by consuming plants or plant products, ***carnivores*** eat herbivores and **micro-organisms** consume the droppings and carcasses (dead bodies). In an ecosystem, the utility of energy is taken place inthe following manner:

The SUN provides heat to maintain the required temperature in which properPhysical and chemical processes can take place. Certain bacteria obtain usefulenergy by oxidation of a few elements such as sulphur and iron.

BIO – GEO-CHEMICAL CYCLES: In every ecosystem sunlight or solar radiant energy is accepted by producers (green plants) and the energydoesn't recycle through an ecosystem. But nutrients like Carbon; Nitrogen; Oxygen, Hydrogen; Water, Sulphur; Phosphorous etc move in circular paths through biotic and abiotic components and they are known as **Bio-geochemicalcycles.**

About forty chemical elements are considered to be essential for living organisms.
They are macronutrients of C, H, O, P, K, I, N, S , Mg, Ca etc.. and micro
nutrients of Cu, Fe, Co.....While all inorganic nutrients have cycles, we focus onthe following:

WATER CYCLE
CARBON CYCLE
OXYGEN CYCLE
NITROGEN CYCLE
POTASSIUM CYCLE
PHOSPHOROUS CYCLE

THE WATER CYCLE OR HYDROLOGIC CYCLE

Due to the solar heat, water evaporates or water is lost to the atmosphere as vapour from the seas / oceans
which is then precipitated back in the form of rain,snow, frost etc.. The evaporation and precipitation continues
for ever, and thereby a balance is maintained between the two. This process is known as Hydrologic cycle.

THE CARBON CYCLE:

All life is based on the element carbon and
hence carbon is the main constituent of living organisms.. Carbon may be present in most organic matter from
fossil fuels to the complex molecules (DNA& RNA). In fact, the lithosphere is only 0.032% carbon by weight.
In comparision, oxygen and silicon make up 45.2% and 29.4% respectively of the
earth's surface rocks.
Plants absorb CO2 during photosynthesis whereas animals emit CO2 during respiration. Animals obtain all their carbon through their food and thus, all carbonin biological systems ultimately comes from plants (autotrophs).
The dead bodies of plants and animals as well as the body wastes are decomposed by
micro-organisms which release carbon in the form of CO2.
Even plant debris if buried a longer time cause for the formation of coal, oil, natural gas and these releases carbon when they burned. Otherwise, the carbonin limestone or other sediments released to the atmosphere when they are subducted (using forces) or undergo chemical reactions. The weathering of rocks also contribute CO2 into the environment .

OXYGEN CYCLE: Oxygen is present in CO2, CH2O (carbohydrates) and H2O. Oxygen is released into the atmosphere by plants during
photosynthesis and taken up both autotrophs and Heterotrophs duringrespiration.
All the oxygen in the atmosphere is biogenic ie., it was released from waterthrough the process of photosynthesis.

Because of the vast amounts of oxygen in the atmosphere, even if all photosynthesis cease it would take 5000
million years to strip out more or less alloxygen.

NITROGEN CYCLE: Nitrogen is used by living organisms to produce a
number of complex organic molecules like Amino acids; Proteins ; Nucleic acids ;Enzymes; Chlorophyll etc..
he largest reservoir of nitrogen is the atmosphere where it exists as a gas mainlyN2. But atmospheric nitrogen
is not utilized directly. However, nitrogen gas undergoes many changes in the nitrogen cycle like: NITROGEN FIXATION; AMMONIFICATION; NITRIFICATION
Nitrogen fixation or conversion of free nitrogen into biologically acceptableform is referred to as Nitrogen
Fixation.
$N_2 + 2(O)$ electric discharge $2\ NO$
Nitrogen gas oxygen radical nitrogen oxide
In physico chemical process; nitrogen combines with oxygen during lightning orelectrical discharges in the clouds and produces different nitrogen oxides (N_2O_5).
These nitrogen oxides get dissolved in rain water and react with mineralcompounds to form Nitrates and
Nitrogenous compounds on the earth.$N_2O_5 + H_2O\ 2HNO_3$
$2HNO_3 + CaCO_3\ Ca(NO_3)_2 + CO_2 + H_2O$
Nitrogen fixation is also carried out by biological process by means of blue – greenalgae in the oceans. (1) Eg: rhizobium bacteria fix nitrogen in the roots of Leguminous plants (2) Eg: Blue – green algae (Nostoc, Anabena)
fix
Nitrogen.
Ammonification: when plants or animals die or release waste, the nitrogen is returned to the soil as ammonia. The bacteria (nitrite bacteria) in the soil and inthe water which take up ammonia and convert it to Nitrite (NO_2). Another bacteria (Nitrate bacteria) take nitrite and convert it to Nitrate (NO_3) which
can be taken up by plants to continue the cycle.
Nitrification means conversion of ammonia into nitrite by some of the bacteria such as Nitrosmonas, Nitrococcus
in oceans and soils.
POTASSIUM CYCLE: The major role of potassium in living organisms
is osmotic control and potassium is taken up, retained and excreted in ionic form(K^+). The amount of potassium
in soil solution is relatively small.
Soils contain potassium in more slowly exchangeable forms which act as sources for crops. In some soils, for example clays, this source of potassium is adequate to meet the requirements of cereals for decades without supplementation with fertilizers. The main pathways for potassium through the

plant and soil are mentioned below :

Plant K: Potassium is an essential nutrient in maintaining the osmotic regulation ofplant cells. It will constitute between I .6 and 2.5% of the leaf dry matter in healthyleaves.

Fertilizer and manure: The principle sources of potash are manures and sulphatesalts. In animal manures, the

potash is not biologically fixed to other compounds unlike nitrogen and phosphate, and thus is readily available to plants. Common fertilizers utilize the muriate (chloride) and sulphate salts of potassium. Chloride, which is not toxic at agronomic applications, should not be confused with chlorine which is a poisonous gas. Manure and fertilizer potassium contribute to potassium insoil solution.

Soil Solution (K+): Potassium in solution is immediately available to plants. The amount of potassium in solution varies with fertilizer application, and cropping history but the amount is generally not enough to meet the requirements of the crop.**Leaching**: Where the amount of potassium added to the soil in fertilizers or manures exceeds the exchange capacity of the soil, potassium can be lost by leaching.

THE PHOSPHOROUS CYCLE: Phosphorous is present in rocks

in the form of phosphate. When rocks containing phosphate are exposed to water, the phosphate goes into solution. Plants and Fungi have a symbiotic relationship . Plants get phosphates from fung and give them sugar in return. Phosphorous is an important constituent of cell membrane, DNA, RNA and ATP. Animals obtain phosphorous from plants through food. Phosphorous is acomponent of bones, teeth and shells. When animals or plants die, the phosphates are returned to the soil or water by the decomposers. Most of thephosphates escape into the sea through the waters, where part of phosphate is deposited in the sediments. This phosphorous will be released when the rock is brought to the surface and weathered.

Marine birds consume phosphorous containing fish from the oceans, their

guano (Guano is a natural manure composed chiefly of the excrement of sea birds) .which fallson land as a high content of phosphorous. Thus marine birds and fish play

an important role in returning phosphorous to the cycle.

Aquatic eco system

Eco system that exists in water is known as aquatic ecosystem . Water is the primary requirement for life in biological community. The aquatic ecosystems range from a small pond to a large ocean.

Varying quantities of nutrients are carried from terristrial (land) ecosystem by themovement of water and deposited in aquatic ecosystems. The life in aquatic communities is influenced mostly by physical factors like:

Water depth; amount light; temperature; salinity of water and

amount of oxygen and Carbondioxide.

Aquatic ecosystems are broadly classified into ***fresh water*** and ***marine water*** ecosystems. In some regions, the marine and freshwater environments overlaps creating "***Estuaries***".

AQUATIC ECOSYSTEM

FRESH WATER MARINE ESTUARIES

Eg: lakes, ponds, eg: salt lakes, seas eg: water bodiesstreams, rivers oceans mix of fresh & sea water

I. PONDS & LAKE ECOSYSTEMS: A pond is a small area of still water, especially is artificial whereas a lake is a large area of water body and the water isnatural. The life span of ponds range from a few weeks or months and whereas the life span for lakes depend upon their location, size and depth.

Depending upon temperature, the upper part of the lake becomes warm and iscalled ***eplimnion*** and the lower part of the lake becomes cold which is called as***hypolimnion.*** These two zones are separated by **thermocline zone** which acts as a barrier to exchange of material / nutrients within the pond.

During rainy season, entire water body gets same temperature due to mixing ofwater while in non-rainy season very small amount of mixing occurs by surface waves due to wind blow.

The ***non-living (abiotic) components*** of a pond include Heat; light, pH value of water; organic compounds (water, CO2, O2, Ca, N, P ..) and ***living (biotic) component***s of Autotrophs or producers (green plants, bacteria, rootedplants of Trapa, Typha, Sagi Haria) ; Consumers (Herbivores, insects and large fish) and micro cosumers (bacteria, fungi,…).

STREAM & RIVER ECOSYSTEMS: Rivers and streams are flowing fresh waterbodies. Out of all

natural ecosystems, rivers are the most intensively used ecosystems by man. The organization of river and stream ecosystem include: ABIOTIC COMPONENTS include volume of water, speed of water flow,

dissolved oxygen content, temperature etc.. The energy flow usually the organicmatter which is being imported from adjacent terrestrial ecosystems.

BIOTIC COMPONENTS include Producers (algae, grass, amphibians); consumers (leaches, water insects, snails, fishes, crocodiles, reptiles) andDecomposers (bacteria, fungi, protozoa).

OCEAN OR MARINE ECOSYSTEMS: The marine environment is

characterized by its high concentration of salts and minerals. The major oceans of the world are Atlantic; Pacific; Indian, Arctic and Antarctic. These are deep and lifeextends to all its depths. The sea water contains salt content in the form of NaCl and rest are Mg, Ca, K . Temperature ranges from 0o to 30o C and pressure

of 1 ATM at surface and 1000 ATM at bottom of oceans.The ocean ecosystem consists of the following;

Biotic components of Producers (phytoplanktons, marine plants , Ruppia,

Zostera, Halophile are true marine angiospers); Consumers of Molluscas, fishesetc and Decomposers of bacteria and Fungi.

Abiotic components include Na, Cl, Mg, Ca, Sulphur, Dissolved oxygen content,light , temperature , pressure variations etc.

IV. ESTUARINE ECOSYSTEM: Estuary is the area at the mouth of the river joins the sea and continents. It has a free connection with the open sea and is thus strongly affected by tidal action. Estuaries are mixed with fresh water from landdrainages. River mouth, coastal bay etc are the examples for estuarine ecosystem.

Estuaries are one among the naturally fertile in the world. The components ofEstuarine ecosystem are given below:

Abiotic components: Estuaries have their own ecological characteristics. Physical factors such as salinity, temperature, tidal activity etc are variable inestuaries when compared to the sea or ocean.

Biotic components include Producers, consumers and Decomposers. Producers: Three major life

forms of Autotrophs play a significant role in grassproduction. They are (a) macrophytes (sea weeds, sea grass, spartina, Thalassia, marsh grass, nagrove trees) (b) Phytoplankton and (c) Benthic flora(algae).

Consumers include a number of zooplankton, oysters, crabs and some species offishes capable of surviving in estuarine conditions form primary, secondary, tertiary consumers of the estuarine ecosystem.

Decomposers include bacteria and fungi which actively take part in the breakingdown the complex and dead organic matter (Fungi of actinomycites).

Forest ecosystem

Introduction: Forest is a type of terrestrial (land) ecosystem. It consists of f trees, shrubs or woody vegetation occupying an extensive area of land. Forestsare important renewable resources.

A different types of forests are seen on this earth. The type of forest depend upon its geographical location and environment factors (Temperature and moisture) that influence the kind of vegetation that occur in an area.Types of forests:

Savannas: These forests develop where a seasonal rainfall occurs. The grass lands of North Africa are known as savannas. Eg: North Africa, America, Burma &India.

Tropical forests: These exits in areas of good rainfall (>200cm per year) with uniform warm temperature. The Soils found in there forests are old, acidic in nature& poor in nutrients. Eg: Amazon rain forest (South America, India).

Deciduous forests (or) Temperate forests: Deciduous forests consists of Broad leaved trees & occur where rainfall is plenty (750 - 1000 cms per year). Eg:Europe & North-East America.

Coniferous forest: These occur in areas with long winters with heavy snowfall.

In other words, where moisture is limited & rainfall is low. Herbivores (animals eatingplants) & insects exist in these forests. Eg: Moscow.

(5) Tundras: These are the large flat Arctic regions of Northern Europe, Asia and North America where no trees grow and where the soil below the surface ofthe ground is always frozen. The growing season is short and plants grow very slowly.

Following are the types of forests present in INDIA:

Tropical, forests present in Western Ghats of Maharashtra, Karnataka,Kerala.

Deciduous forests present at Dehradun, Eastern Ghats of AndhraPradesh, Tamil Nadu, M.P., U.P.

Littoral and swamp forests present at Sunderbans in West Bengal andAndaman islands.

Tropical Thorn forests present in New Delhi, Punjab and Gujarat.

Mountain wet temperature forests present at Nilgiri and Palani hills.

Alpine scrub forests present at Ladakh and Sikkim.

The characteristic features of a forest ecosystem are as follows:

Abiotic components include inorganic and organic compounds and dead organic debris. Further, the natural light conditions are different in forests due to complexstratification in the vegetation.

Biotic components include Producers, consumers and Decomposers. Producers: These are plants and trees and produce the food through photosynthesis. The dominant species of trees are Quercus, Acer, Betula,Thuja, Picea, Abies, Pinus, Cedrus etc…

Consumers: The primary consumers are Ants, beetles, leaf hoppers, bugs,spiders, deers, squirrels etc. The secondary consumers are Snakes, birds, lizards, foxes etc are the examples. The tertiary consumers are lion, tiger,hawk etc.

Decomposers include micro organisms like bacteria, fungi etc.. consume thedead or decayed bodies.

Tropical rain forests are found in the hot and humid regions near the equator: These regions have abundant rainfall (2000 – 4500 mm per year) that occurs almost daily. These forests are found in South and Central America, Western andCentral Africa , SE Asia and some islands of the Indian & Pacific Oceans.

These rain forests are marked by a variety of tall trees and a dense canopy. Thesoils are thin and acidic with poor nutrients. A team of Brazilian scientists

Conducted a research and found that a forest could return as much as 75% of the moisture it received back into atmosphere. Hence, more trees are meant for morerain.

Temperate forests are very cold in winter and warm or humid in summer. Theseforests grow where the annual rainfall is about 750 – 2000 mm per year and arefound in Western and Central Europe, Eastern Asia, Eastern America.

Soil is rich in temperate forest areas. oaks, maples, beech, pine trees, ferns,lichens, mosses etc are found in these forests.

Temperate forests contain abundant micro – organisms and mammals (squirrels,porcupines, chipmunks, raccoons, hares, deer, foxes, coyotes, bears. Birds like warblers, wood peckers, owls, hawks are seen. Snakes, frogs are also common these forests.

Coniferous forests derive the name from the abundance of coniferous trees like spruce, fir, pine, hemlock etc. Coniferous tree produces dry fruits called cones. Inconiferous forests, winters are usually long and cold. The soil in these forests is acidic and humus rich.

The main animals found in these forests are deer, moose, elk, caribon, mice,hares, squirrels, foxes, bears and birds.

Status of Forests in India:

Forest Survey of India (FSI) , Dehradun estimated, the country's forest coveras 6,76,000 sq km . Of this 6,76,000 sq km; 259000 sq km is open forest,

417000 sq km is covered by dense forest and mangroves occupied 4490 sq kms. Madhya Pradesh accounts for the largest forest cover of the country with 77265 sqkm followed by Arunachal Pradesh 68045 sq km and Chhattisgarh with 56448 sq km.

Desert ecosystem

Deserts occur in regions when the annual rainfall is in the range of 250 to 500mm and **evaporation rate is high.** Deserts occupy about 30% of land area on the globe. Deserts are found 30 above north and below south of the equator.

Deserts are characterized by extremely hot days and cold nights. The largest

deserts are found in the interiors of continents where moisture bearing winds do notreach. The desert soils has very little organic matter but rich in minerals. The

desert plants have adapted to the dry conditions and conserve water by having fewor no leaves.

eg: (1) A plant namely Saguaro cactus has a stem that can expand to storewater

Many desert plants have thorns or toxins to protect themselves frombeing grazed by animals.

Some desert plants have wax – coated leaves that minimize the loss

of moisture.

Some desert plants have deep roots that reach the ground water.

A few desert plants have shallow roots that collect water after any rainand store it in spongy tissues.

Desert ecosystem is characterized by scanty flora and fauna. The organisms which with stand the extreme temperatures can survive here. Desert animals areusually small in size and come out during the nights for food.

Human impact on deserts.:

Slow rate of growth of vegetation if topsoil is eroded due to a heavy vehicle transportation across the desert. Desert cities, depletion of ground water, landdisturbance, pollution from mining, storage of toxic wastes are some of the human activities that cause damage.

Abiotic components include temperature, rainfall, soil, water etc plays a major roleto control the desert ecosystem.

Biotic components include **producers** (shrubs, bushes, grasses, a few trees and plants namely Cacti Acacias, Euphorbias); **Consumers** of insects, reptiles,

rodents of rats & rabbits; birds, camels which are capable of living under desert conditions and **Decomposers** include Bacteria, Fungi due to poor vegetation andthe less quantity of dead organic matter. .

A Case study of Desert ecosystem:

The Thar desert (the Great Indian Desert) is spread over four states in India

____Punjab; Haryana; Rajasthan and Gujarat and two states in Pakistan. Thardesert covers an area of about 4,46,000 sq kms.

Though the Thar desert is smaller than the Sahara desert in Africa and the Gobidesert in Russia, the Thar desert is most populated in the world with about 13 million people.

The average rainfall is between 100 mm and 500 mm. The only river in the regionis the **Ghaggar** which enters Rajasthan from Punjab and dries up in the forest.

The Thar desert has no Oasis. Flowering plants like shrubs, grasses, trees (Khejra, Babul, Rohida); fruit trees (Ber; Pilu) are found in Thar desert.

Sheep, goats, camels are the common animals found in the Thar desert. Inaddition, wild ass, black

buck deer, hare, red lynx, Jackal, Wild dog etc..

About 23 species of Lizard and 25 species of snakes are found in Thar desertregion.

ECOSYSTEM (UNIT - I) meanings

Abiotic Non – living organisms (soil, temp, light, water, inorganiccomponents of N,C,H,K,P,S)

Algae Simple plant with no leaves. Stems or roots that grow in waterBacteria Simple and smallest form of life exist in water, air, soil and

Causes of diseases

Biomass An organic material from living beings or its residues (wood,animal manure)

Biome A characteristic plants & animals that exist in a particular type ofenvironment

Biotic Living organisms

Carnivores (sec consumers) Dependent on herbivores (snakes, birds, lizards) Chemo autotrophs Micro organisms produce organic matter through oxidation ofchemicals in the absence of sunlight.

Consumers (Heterotrophs) Depends on others for nourishing food Decomposers Feed on organic compounds of dead or living plants & animalsEcological Succession Development of ecosystem

Fauna Animals

Feeding levels (Trophic levels) A trophic level refers to an organisms position in the food chain

Flora Plants

Fungi (mushrooms,Mildew) Any plant without leaves, flowers or green colouring growing onother plants or decaying matter

Herbivores Depends on plants (rabbit, deers)

Humus A substance made from dead leaves & plants added to soil tohelp plants grow

Inorganic Not consisting of or coming from any living substancesLentic Standing water

Lotic Running water

Nourishing To keep a person / animal or plant alive with foodOasis An area in the desert where there is water

Omnivores Depends on plants & animals (human beings, birds)

Organic Produced by or from living things (proteins, carbohydrates, fats)Plankton Very small plants / insects

Producers (Autotrophs) Self nourishing (algae, green plants)Puddle A small place where rain water accumulates

Sea weed A plant that grows in the sea or ocean or on rocks at the edgeof the sea.

Tertiary consumers Depend on primary & secondary consumers (lions ,, tigers)

Weed control To remove unwanted plants

osmosis The tendency of fluids to diffuse in such a manner DIFFERENCE BETWEEN HABITAT AND NICHE

In ecology, a **niche** is a term describing the relational position of a species in its ecosystem to each other. A definition of niche is how an organism makes living.A niche is the totality of all biological and environmental factors that affect a Population. It encompasses everything one can think of that allows populations to live,grow, and reproduce.

The niche of an animal is all the conditions it can tolerate and where it lives. There are two types of niches. A broad and narrow niche. An animalthat has a broad niche can tolerate more conditions rather than an animalthat has a narrow niche. An example of an animal that has a broad niche is an opposum. An example of an animal that has a narrow niche is a panda bear.

The ecological niche describes how an organism or population responds to thedistribution of resources and competitors.

A niche is the functional role of a species in a community—that is, its occupation, orits living. For example, the tanager lives in a deciduous forest habitat. Its niche, its part, is gleaning insects. The community provides the habitat—the place where particular plants or animals live. Within the habitat, organisms occupy different niches.Habitat - is the specific place where something lives.

Niche - is the role of a specie plays in a community suchas feeding relationships, space, and what the organism needs to survive in the environment. It includes how a species uses and affects its environment.

Encompasses - (to enclose within a circle; surround) Gleaning - To gather (grain) left behind by reapers andto collect bit by bit

Opossums - live in the tree canopies, feeding solely onfruits .

Tanager is a type ofbird

Different species of organisms may appear to have the same habitat but each has adifferent niche so that they can survive in that habitat.

A frog generally tends to have a broad niche. It can live in areas that havelittle water sources to areas that have a vast region as water sources.

Unit 2-Natural resources

Non-renewable resource

A coal mine in Wyoming. Coal, produced over millions of years, is a finite and non-renewableresource on a human time scale.

A **non-renewable resource** (also known as a finite resource) is a resource that does not renew itself at a sufficient rate for sustainable economic extraction in meaningful human timeframes. An example is carbon-based, organically-derived fuel. The original organic material, with the aid of heat and pressure, becomes a fuel such as oil or gas. Fossil fuels (such as coal, petroleum, and natural gas), and certain aquifers are all non-renewable resources.

Metal ores are other examples of non-renewable resources. The metals themselves are present in vast amounts in the earth's crust, and are continually concentrated and replenished over millions of years. However their extraction by humans only occurs where they are concentrated by natural processes (such as heat, pressure, organic activity, weathering and other processes) enough to become economically viable to extract.

These processes generally take from tens of thousands to millions of years. As such, localized deposits of metal ores near the surface which can be extracted economically by humans are non-renewable in human timeframes, but on a world scale, metal ores as a whole are inexhaustible, because the amount vastly exceeds human demand, on all timeframes.

Though they are technically non-renewable, just like with rocks and sand, humans could never deplete the world's supply. In this respect, metal ores are considered vastly greater in supply to fossil fuels because metal ores are formed by crustal scale processes which make up a much larger portion of the earth's near-surface environment than those that form fossil fuels, which are limited to areas where carbon-based life forms flourish, die, and are quickly buried. These fossil fuel-forming environments occurred extensively in the Carboniferous Period.

In contrast, resources such as timber (when harvested sustainably) and wind (used to power energy conversion systems) are considered renewable resources, largely because their localized replenishment can occur within timeframes meaningful to humans.

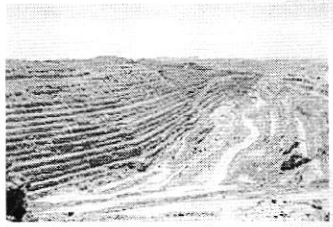
FOSSIL FUEL

Natural resources such as coal, petroleum (crude oil) and natural gas take thousands of years to form naturally and cannot be replaced as fast as they are being consumed. Eventually it is considered that fossil-based resources will become too costly to harvest and humanity will need to shift its reliance to other sources of energy. These resources are yet to be named.

An alternative hypothesis is that carbon based fuel is virtually inexhaustible in human terms, if one includes all sources of carbon-based energy such as methane hydrates on the sea floor, whi are vastly greater than all other carbon based fossil fuel resources combined. These sources of carbon are also considered non-renewable, although their rate of formation/replenishment on the sea floor is not known. However their extraction at economically viable costs and rates has yet to be determined.

At present, the main energy source used by humans is non-renewable fossil fuels. Since the daw of internal combustion engine technologies in the 17th century, petroleum and other fossil fuels have remained in continual demand. As a result, conventional infrastructure and transport systems, which are fitted to combustion engines, remain prominent throughout the globe. The continual use of fossil fuels at the current rate is believed to increase global warming and cause more severe climate change.[1]

Radioactive fuel



An open pit uranium mine in Namibia

annual release of uranium and thorium radioisotopes from coal combustion, predicted by ORNL t cumulatively amount to 2.9 million tons over the 1937-2040 period, from the combustion of an estimated 637 billion tons of coal worldwide.

Further information: Uranium depletion

The use of nuclear technology requires a radioactive fuel. Uranium ore is present in the ground at relatively low concentrations and mined in 19 countries. This mined uranium is used to fuel energy-generating nuclear reactors with fissionable uranium-235 which generates heat that is

ultimately used to power turbines to generate electricity.

Nuclear power provides about 6% of the world's energy and 13–14% of the world's electricity. The expense of the nuclear industry remains predominantly reliant on subsidies and indirect insurance subsidies to continue. Nuclear energy production is associated with potentially dangerous radioactive contamination as it relies upon unstable elements. In particular, nuclear power facilities produce about 200,000 metric tons of low and intermediate level waste (LILW) and 10,000 metric tons of high level waste (HLW) (including spent fuel designated as waste) each year worldwide.

The use of nuclear fuel and the high-level radioactive waste the nuclear industry generates is highly hazardous to people and wildlife. Radiocontaminants in the environment can enter the food chain and become bioaccumulated. Internal or external exposure can cause mutagenic DNA breakage producing teratogenic generational birth defects, cancers and other damage. TheUnited Nations (UNSCEAR) estimated in 2008 that average annual human radiation exposure includes 0.01 mSv (milli-Sievert) from the legacy of past atmospheric nuclear testing plus the Chernobyl disaster and the nuclear fuel cycle, along with 2.0 mSv from natural radioisotopes and 0.4 mSv from cosmic rays; all exposures vary by location. Some radioisotopes in nuclear waste emit harmful radiation for the prolonged period of 4.5 billion years or more, and storage has risks of containment. The storage of waste, health implications and dangers of radioactive fuel continue to be a topic of debate, resulting in a controversial and unresolved industry.

Renewable resources

Natural resources, called renewable resources, are replaced by natural processes and forces persistent in the natural environment. There are intermittent and reoccurring renewables, and recyclable materials, which are utilized during a cycle across a certain amount of time, and can be harnessed for any number of cycles.
The production of goods and services by manufacturing products in economic systems creates many types of waste during production and after the consumer has made use of it. The material is then either incinerated, buried in a landfill or recycled for reuse. Recycling turns materials of value that would otherwise become waste into valuable resources again.

The natural environment, with soil, water, forests, plants and animals are all renewable resources, as long as they are adequately monitored, protected and conserved. Sustainable agriculture is the cultivation of plant materials in a manner that preserves plant and animal ecosystems over the long term. The overfishing of the oceans is one example of where an industry practice or method can threaten an ecosystem, endanger species and possibly even determine whether or not a fishery is sustainable for use by humans. An unregulated industry practice or method can lead to a complete resource depletion.

The renewable energy from the sun, wind, wave, biomass and geothermal energies are based on

renewable resources. Renewable resources such as the movement of water (hydropower, tidal power and wave power), wind and radiant energy from geothermal heat (used for geothermal power) and solar energy (used for solar power) are practically infinite and cannot be depleted, unlike their non-renewable counterparts, which are likely to run out if not used sparingly.

The potential wave energy on coastlines can provide 1/5 of world demand. Hydroelectric power can supply 1/3 of our total energy global needs. Geothermal energy can provide 1.5 more times the energy we need. There is enough wind to power the planet 30 times over, wind power could power all of humanity's needs alone. Solar currently supplies only 0.1% of our world energy needs, but there is enough out there to power humanity's needs 4,000 times over, the entire global projected energy demand by 2050.

Renewable energy and energy efficiency are no longer niche sectors that are promoted only by governments and environmentalists. The increasing levels of investment and that more of the capital is from conventional financial actors, both suggest that sustainable energy has become mainstream and the future of energy production, as non-renewable resources decline. This is reinforced by climate change concerns, nuclear dangers and accumulating radioactive waste, high oil prices, peak oil and increasing government support for renewable energy. These factors are commercializing renewable energy, enlarging the market and growing demand, the adoption of new products to replace obsolete technology and the conversion of existing infrastructure to a renewable standard.[15]

Economic models

In economics, a non-renewable resource is defined as goods, where greater consumption today implies less consumption tomorrow. David Ricardo in his early works analyzed the pricing of Exhaustible resources, where he argued that the price of a mineral resource should increase over time. He argued that the spot price is always determined by the mine with the highest cost of extraction, and mine owners with lower extraction costs benefit from a differential rent. The first model is defined by Hotelling's rule, which is a 1931 economic model of non-renewable resource management by Harold Hotelling. It shows that efficient exploitation of a nonrenewable and nonaugmentable resource would, under otherwise stable conditions, lead to a depletion of the resource. The rule states that this would lead to a net price or "Hotelling rent" for it that rose annually at a rate equal to the rate of interest, reflecting the increasing scarcity of the resources. The Hartwick's rule provides an important result about the sustainability of welfare in an economy that uses non-renewable source.

However, nearly all metal prices have been declining over time in inflation adjusted terms, because of a number of false assumptions in the above. Firstly, metal resources are non-renewable, but on a world scale, largely inexhaustible. This is because they are present throughout the earth's crust on a vast scale, far exceeding human demand on all time scales. Metal ores

however, are only extracted in those areas where nature has concentrated the metal in the crust to a level whereby it is locally economic to extract. This also depends on the availabletechnology for both finding the metal ores as well as extracting them, which is constantly changing. If the technology or demand changes, vast amounts of metal previously ignored can become economically extractable. This is why Ricardo's simplistic notion that the price of a mineral resource should increase over time has in fact turned out to be the opposite, nearly all metal ores have decreased in inflation adjusted prices since well before the early 20th century.
The main reason he was wrong is that he assumed that metals are exhaustible on a world scale, and he also misunderstood the effect of globally competing markets; in human terms the amountof metal in the earth's crust is essentially limitless. It is only in localized areas that metal ores can become depleted, as these local areas compete with extraction costs of resources elsewhere, which does have ramifications for the sustainability of local economies.

UNIT III:
BIODIVERSITY

CONTENTS

Topic Content

Introduction: Genetic diversity
Species diversity
Ecosystem diversity
Value Biodiversity Consumptive valueProductive value
Social value
Ethical value
Aesthetic value
India as a mega diversity Biogeographic regionHot spots of Biodiversity
Major threats to Biodiversity Bio geographical classificationFactors to control the biogeographical classification climate Wetlands
Marine environment Endangered & endemic speciesAsiatic Lion description.
Conservation of biodiversity In-situ conservationEx-situ conservation
Food & fodder resources Timber & non-timber forest

The word biodiversity is a combination of two words: "*biological and diversity*" and refers to the variety of life on the Earth which includes many livingthings that exist in a certain area (in the air, on land or in water). The area may beconsidered as small as a heap or as big as the whole planet. Hence, Biodiversity
means " the existence of a large number of different kinds of animals andplants which make a balanced environment" (or)
" ***the totality of all species and ecosystems in a region***" is called biodiversity. Biodiversity deals

with a large variety of flora and fauna on this earth. For eg: a wide variety of plants and animals are find in a part of forest. The plant life range from a small herb to a large tree and the animal life vary from a tiny insect to a large mammal in addition to micro-organisms (algae, bacteria, fungi etc)

Biodiversity is usually considered at three different levels:

Genetic diversity means the variation of genes within the species. For eg: in human species, genetic variation between an Indian and African and genetic variations within a population (eg: within the Indian population) can be seen . In simple terms, genetic matter dictates whether the persons have blue or brown eyes, brown or black hair and tall or short..

Genetic diversity can be identified by using a variety of DNA based and other techniques. One estimate is that there are 1000 crores of different genes distributed across the worlds biota though they do not all make an identical contribution to overall genetic diversity.

Species diversity means the richness of species in all ecosystems. It
is measured on the basis of number of species in a region. So far 1.75 million
Species have been described world wide.

Warmer areas tend to support more species than colder ones and wetter areascontain more species than drier ones. Topography and climate of the areas support and control the species of a region. .

Ecosystem diversity means the study of difference between ecosystem types. Ecosystem diversity is difficult to measure since the boundaries of varioussub ecosystems are overlap each other. An example for ecosystem diversity is Godavari – Delta ecosystem which consists of grassland ecosystem, , river ecosystem, estuarine ecosystem, fresh water aquatic ecosystem, marine water aquatic ecosystem .

Importance of biodiversity: Biodiversity performs a number of ecological seriesfor human kind that have economic, and aesthetic values. As an example, the contribution of biodiversity to human health is given below:

One out of 125 plant species produce a major drug as per Herb Research Foundation. Of the 118 drugs in the US, 74% are based on plants; 18% on fungi;05% on bacteria and 03% on vertebrates. 80% of the world population relies ontraditional plant medicine.

Value of biodiversity: The value of biodiversity (in terms of its commercial utility, ecological

services, social and aesthetic values) is

enormous. There are several ways that biodiversity and its various forms are valuable to humans. We get benefits from organisms in an innumerable ways. .Sometimes, one realize the value of the organism only after it is lost from this Earth.

Every year numerous species are lost before we have a chance to know anythingabout them. The biodiversity value may be classified as follows:

CONSUMPTIVE VALUE: Biodiversity is an essential requirement for the maintenance of global food supply. The main sources of human food includesanimals, fish and plant produces.

A large number of plants are consumed by human beings as food. A few animalspecies are consumed by people which comes from cattle, pigs, sheep, goats, buffaloes, chickens, ducks, geese and turkey species.

Fish: Many fresh water fish can be grown in ponds. Israel and China already getabout half of their fish from aqua culture.

Drugs & medicines: About 75% of the worlds population depends upon plants orplant extracts for medicines. The drug Penicillin used as an antibiotic is derived from a fungus called ***Penicillium.*** Likewise, Tetracycline from a bacteria which

is used to cure malaria is obtained from the bark of cinchona tree. .

Fuel: The fossil fuels like coal, petroleum products and natural gas are theproducts of biodiversity.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

MC400: GENDER SENSITIZATION LAB

B. Pharm. II Year II Sem

L	T	P	C
1	0	0	0

Course Objectives:

- To develop students' sensibility with regard to issues of gender in contemporary India.
- To provide a critical perspective on the socialization of men and women.
- To introduce students to information about some key biological aspects of genders.
- To expose the students to debates on the politics and economics of work.
- To help students reflect critically on gender violence.
- To expose students to more egalitarian interactions between men and women.

Course Outcomes:

- Students will have developed a better understanding of important issues related to gender in contemporary India.
- Students will be sensitized to basic dimensions of the biological, sociological, psychological and legal aspects of gender. This will be achieved through discussion of materials derived from research, facts, everyday life, literature and film.
- Students will attain a finer grasp of how gender discrimination works in our society and how to counter it.
- Students will acquire insight into the gendered division of labour and its relation to politics and economics.
- Men and women students and professionals will be better equipped to work and live together as equals.
- Students will develop a sense of appreciation of women in all walks of life.
- Through providing accounts of studies and movements as well as the new laws that provide protection and relief to women, the textbook will empower students to understand and respond to gender violence.

UNIT-I

UNDERSTANDING GENDER

Gender: Why Should We Study It? (*Towards a World of Equals*: Unit -1)

Socialization: Making Women, Making Men (*Towards a World of Equals*: Unit -2)

Introduction. Preparing for Womanhood. Growing up Male. First lessons in Caste. Different Masculinities.

UNIT-II

GENDER AND BIOLOGY

Missing Women: Sex Selection and Its Consequences (*Towards a World of Equals*: Unit -4)

Declining Sex Ratio. Demographic Consequences.

Gender Spectrum: Beyond the Binary (*Towards a World of Equals*: Unit -10)

Two or Many? Struggles with Discrimination.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

UNIT-III

GENDER AND LABOUR

Housework: the Invisible Labour (*Towards a World of Equals*: Unit -3)

"My Mother doesn't Work." "Share the Load."

Women's Work: Its Politics and Economics (*Towards a World of Equals*: Unit -7)

Fact and Fiction. Unrecognized and Unaccounted work. Additional Reading: Wages and Conditions of Work.

UNIT-IV

ISSUES OF VIOLENCE

Sexual Harassment: Say No! (*Towards a World of Equals*: Unit -6)

Sexual Harassment, not Eve-teasing- Coping with Everyday Harassment- Further Reading: "*Chupulu*".

Domestic Violence: Speaking Out (*Towards a World of Equals*: Unit -8)

Is Home a Safe Place? -When Women Unite [Film]. Rebuilding Lives. Additional Reading: New Forums for Justice.

Thinking about Sexual Violence (*Towards a World of Equals*: Unit -11)

Blaming the Victim-"I Fought for my Life...." - Additional Reading: The Caste Face of Violence.

UNIT-V

GENDER: CO - EXISTENCE

Just Relationships: Being Together as Equals (*Towards a World of Equals*: Unit -12)

Mary Kom and Onler. Love and Acid just do not Mix. Love Letters. Mothers and Fathers. Additional Reading: Rosa Parks-The Brave Heart.

TEXTBOOK

All the five Units in the Textbook, ***"Towards a World of Equals: A Bilingual Textbook on Gender"*** written by A. Suneetha, Uma Bhrugubanda, Duggirala Vasanta, Rama Melkote, Vasudha Nagaraj, Asma Rasheed, Gogu Shyamala, Deepa Sreenivas and Susie Tharu and published by **Telugu Akademi, Hyderabad**,Telangana State in the year **2015**.

Note: Since it is an Interdisciplinary Course, Resource Persons can be drawn from the fields of English Literature or Sociology or Political Science or any other qualified faculty who has expertise in this field from engineering/pharmacy departments.

REFERENCE BOOKS:

1. Menon, Nivedita. Seeing like a Feminist. New Delhi: Zubaan-Penguin Books, 2012
2. Abdulali Sohaila. *"I Fought For My Life...and Won."*Available online at: http://www.thealternative.in/lifestyle/i-fought-for-my-lifeand-won-sohaila-abdulal/

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

GENDER SENSITIZATION

COURSE FILE

PREPARED BY

DR.K.NAGASREE

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

VISION MISSION OF INSTITUTION

VISION:

"To be a center of excellence by redefining Pharmacy Education and nurture Globally Competent Professional Pharmacists."

MISSION:

- To train and develop students into Professional Pharmacists so as to fulfill the Industrial and Community needs.
- To shoulder the responsibility of reducing the suffering of mankind by providing Pharmaceutical care.

VISION,MISSION OF DEPARTMENT

VISION OF THE DEPARTMENT :

- To be a recognized global leader in developing solutions for evolving healthcare challenges.

MISSION OF THE DEPARTMENT:

- To improve healthcare quality and outcomes through educating the next generation of pharmacists and pharmaceutical scientists in an environment foresting intellectual curiosity,through pursuing impactful basic and applied research,and through developing and evaluating bmodels of clinical practice.

SAMSKRUTI COLLEGE OF PHARMACY
Kondapur (V)
Ghatkesar (M)
R.R. Dist. Hyd.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PROGRAM OUTCOMES:

UNIT -1: SELF-EXPLORATION

UNIT –II :ROOT CAUSES FOR GENDER DISCRIMINATION

UNIT-III: EVE TEASING

UNIT-IV: NIRBHAYA ACT

UNIT-V: THE PROTECTION OF WOMEN FROM DOMESTIC VIOLENCE ACT, 2005

PROGRAM INCOMES:

Complete knowledge and guided throroughly the following contents

Self- Exploration As The Process Of Value Education

Content of Self-Exploration

Realization and Understanding:

Continuous Happiness and Prosperity

Prevailing notions of Happiness and Prosperity

Lack of Employment Facilities

Harms or injures or endangers the health, safety, life, limb or well-being

UNIT-1: Self-Exploration

Self- Exploration As The Process Of Value Education

Self-Exploration:

It is the process of finding out what is valuable to me by investigating within myself.

Exploration = Observing Outside

Self-Exploration = Observing Inside

Purpose of Self-Exploration:

- It is a process of dialogue between 'what you are' and 'what you really want to be'.
- It is a process of self evolution through self-investigation.
- It is a process of knowing oneself and through that, knowing the entire existence.
- It is a process of recognizing one's relationship with every unit in existence and fulfilling it.
- It is a process of knowing human conduct, human character and living accordingly.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301.

- It is a process of being in harmony with oneself and in harmony with entire existence.
- It is a process of identifying our innateness(Svatva) and moving towards Self-Organization(Swantantrata) and Self-Expression(Swarajya)

Content of Self-Exploration:

It involves finding answers for the following –

- My Desire (Aspiration)
- My Program (Process to fulfill my aspirations)

Process of Self-Exploration:

The following points are to be kept in mind regarding the process of Self-Exploration:

- Whatever is stated is a proposal
- Don't start by assuming it to be true or false
- Verify it on your own right
- Don't just accept or reject it on the basis of scriptures, instruments or on the basis of others.
- The following two steps are involved in the process of Self-Exploration.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

- Firstly, verify the proposal on the basis of your natural acceptance

- Secondly, live according to the proposal to validate it experientially.

Natural Acceptance: It is the process of seeing and observing attentively and then using your inner conscience to get the answer from within. It is a way to bring out the goodness in everything naturally.

- It does not change with time/age
- It doesn't depend on place
- It does not depend on our beliefs or past conditioning
- It is always there within us
- It is the same for all of us.

Realization and Understanding:

The process of Self-Exploration results in 'Realization' and 'Understanding' in us. This realization and understanding leads to the following answers –

- Assuring
- Satisfying
- Universal with respect to Time, Space and Individual.

Continuous Happiness and Prosperity

All human beings basically aspire for/ want the following in their life:

i. Continuous Happiness

ii. Prosperity

- If all of us happen to prepare a list of our aspirations, we will find that all our aspirations have an underlying basic desire – the basic aspiration to be happy. Through his life, every human being is continuously trying to do things that make him/her happy. In other words, we always look for continuous happiness in our life.
- In addition to happiness, we also aspire for adequate fulfillment of our bodily needs i.e. the need for physical facilities. These Physical Facilities are the material things we use in order to fulfill the needs of our body. Having enough physical facilities gives us a feeling of prosperity. We want to have a continuity of this feeling too. Hence prosperity is another basic aspiration of every human being.

Exploring Happiness and Prosperity:

Happiness: Happiness may be defined as being in harmony/ synergy in the states/ situations that we live in. Happiness is being in a state of liking. Unhappiness is a lack of this synergy or harmony. To be in a state of disliking is unhappiness.

Happy situations comprise of feelings such as trust, respect, confidence etc. All these feelings carry an element of harmony in them. Hence they make us feel relaxed and happy.

On the other hand, feelings like failure, disrespect, lack of confidence, doubt etc. lack the element of harmony and hence make us unhappy.

Prosperity: It is the feeling of having more physical facilities than required. Prosperity creates a desire to share what one possesses. However, since the need for physical facilities is limitless, the feeling of prosperity cannot be assured.

Wealth: Wealth is a physical thing. It means having money, or having a lot of physical facilities, or having both.

Prosperity Vs Wealth: Wealth means possessing more number of physical things while Prosperity is a feeling of possessing more than required physical facilities.

Following are the possibilities:

- A person may not possess required physical facilities, so he may not feel prosperous.
- A person may accumulate more and more wealth but still he may be deprived of the feeling of prosperity.
- A person may have required wealth and feel prosperous.

Prevailing notions of Happiness and Prosperity: In the modern world, the desire for physical facilities has become unlimited. The physical facilities are no longer seen as objects fulfilling bodily needs but as a means of maximizing happiness. This unlimited desire for physical facilities has become anti-ecological and anti-people endangering human survival itself.

The false notions of happiness and Prosperity have affected human living at all four levels:

At the level of Individual: Problems of depression, psychological disorders, suicides, stress, insecurity, psycho-somatic diseases, loneliness etc.

At the level of family: Breaking of Joint families, mistrust, conflict between older and younger generations, insecurity in relationships, divorce, dowry tortures, family feuds, wasteful expenditures in family functions etc.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

At the level of Society: Terrorism, naxalism, communism, casteism, racial, ethnic struggles, wars between nations, genocide, nuclear genetic warfare.

At the level of Nature: Global Warming, pollution, depletion of mineral resources, deforestation, loss of soil fertility.

Right Understanding: Right Understanding helps us to maintain proper relationships with other human beings and also helps us to make a proper choice of physical facilities. Hence the needs of all human beings consist of the need for – Right Understanding, Relationships and Physical Facilities in the right order.

Following is a set of three Proposals based on the need for Physical Facilities:

- Physical Facilities are necessary for human beings
- Physical Facilities are necessary for human beings and they are necessary for animals

For e.g. : Human Beings need food, water, TV, bike, MBA degree, Relationships with family and society etc.

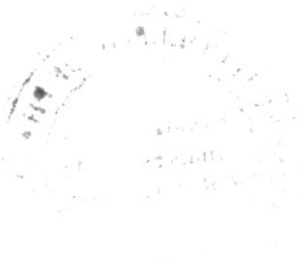
For e.g.: Animals need food, water, shelter from extreme climatic conditions etc.

- Physical Facilities are necessary and complete for animals, while they are necessary but not complete for human beings

For e.g.: Animals need food to survive. Once an animal receives the necessary grass or fodder, its need is complete. But for human beings, the needs are incomplete. If they are hungry they want food, but they look for something tasty. Once their hunger is satisfied, they need some recreation/ physical facilities, followed by the need for relationships etc. This list of human needs is almost endless and mostly incomplete.

SAMSKRUTI COLLEGE OF PHARMACY
Kondapur (V)
Ghatkesar (M)
R.R. Dist. Hyd.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301



Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Solution to Our Present State – The Need for Right Understanding:

The three basic requirements to ensure happiness and prosperity for human beings are –

i. Right Understanding
ii. Relationships
iii. Physical Facilities

(Living only with Physical Facilities is Animal Consciousness and living with all these three is Human Consciousness)

In the modern times, we are mostly not paying attention to(i) and (ii) and are focusing largely on (iii) most of the time. As human beings, all the three are needed for us.

Importance/ Need for Right Understanding:

Right Understanding helps to create harmony at all four levels of human living. Right Understanding enables us to –

- Resolve the issues in human relationships
- Be prosperous
- Work out our requirements for physical facilities
- Correctly distinguish between wealth and prosperity
- Understand the harmony in Nature

Right Understanding forms the basis on which we can work for relationships and also acquire Physical Facilities.

Two kinds of people in the world today:

1. **SVDD** – Sadhan Viheen Dukhi Daridra

(Materially deficient, unhappy and deprived)

2. **SSDD** – Sadhan Sampann Dukhi Daridra

(Materially affluent, but unhappy and deprived)

These two states are unwanted by all human beings. With the help of Right Understanding, human beings can move to a third category:

3. **SSSS** – Sadhan Sampann Sukhi Samridh

(Materially affluent, happy and prosperous)

Priority Order:

Hence for a continuous happy living, we need to work for all the three in the given order:

i. Right Understanding

ii. Relationships

iii. Physical Facilities

Right Understanding + Relationship = Mutual Fulfillment

(gives a feeling of satisfaction and happiness)

Right Understanding + Physical Facilities = Mutual Prosperity

(leads to enrichment of our lives as well as enrichment of Nature)

Living in Harmony at all levels of living with the help of Right Understanding:

1. **At the level of Myself:** Self-Exploration with the help of Natural Acceptance and Experiential Validation helps to develop a sense of Right Understanding. This right understanding helps me to understand myself clearly, and helps me to develop a feeling of Satisfaction , Prosperity and Happiness(Harmony) in Myself.
2. **At the level of Family:** Right understanding helps me to understand others feelings and expectations in a better way. This ensures harmony in family.

   t the level of Society: Our family is a part of a large group of people called the Society. As we understand our relationships with others in our family, we also start understanding others in the society and can maintain fulfilling relations with everyone.
3. **At the level of Nature/ Existence:** We live in a large eco-system called Nature. Existence refers to all the things that exist in Nature. Once we learn to maintain harmony with the society, we also develop a feeling of concern towards the plants, trees, animals etc. in Nature. Hence right understanding leads to mutual fulfillment with Nature.

Role of Natural Acceptance for developing Harmony at all Levels of our Living

Harmony In The Family – Understanding Values In Human Relationships

Family is the Basic Unit of all Interaction: Each of us is born into a family which includes a number of relationships. These relationships are the reality of our life. We recognize and identify these individuals. We share our feelings, tastes, interests and understanding with these people and have an affinity for them.

Beginning with our family as the basic unit of interaction, we extend our interactions to the immediate neighbourhood such as the shopkeepers, servants, classmates, teachers, colleagues etc. Thus we extend our interactions from beginning from our family to a bigger social order and then move further to a still bigger web of interdependency.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Set of proposals to verify Harmony in the Family:

1. **Relationship IS and it exists between the Self ('I') and the other Self ('I'):** In a family, we do not create relationships. Instead we are embedded into relationships that are already there and all that we need to do is to recognize them and understand them.

2. **The Self ('I') has feelings in a relationship. These feelings are between ('I') and ('I'):** In any relationship, it is the person's Self (I) that is related to the other person's Self (I). The body is only a means to express our relationship. For example, in a mother and a child, it is the Self of the mother and the Self of the child who feel connected. Their bodies are incapable of understanding or having feelings.

3. **These feelings in the ('I') are definite. i.e. they can be identified with definiteness:** The feelings in a relationship between "I" and "I" such as Trust, Respect, Affection etc., can be identified with clarity. These feelings are the values which characterize any relationship.

4. **Recognizing and Fulfilling these feelings lead to Mutual Happiness in a relationship**: Once we recognize the values essential for any relationship, we start working and behavingaccording to these feelings. We begin evaluating ours' and others' feelings in the relationship. Thus living with these values leads to mutual fulfillment and happiness in all our relationships.

Justice (Nyaya): Justice is the recognition of values (the definite feelings) in relationship, their fulfilment, the right evaluation of the fulfilment resulting in mutual happiness. Justice concerns itself with the proper ordering of things and people within a society. There are four elements: Recognition of values, fulfilment, evaluation and mutual happiness ensured. When all the four are ensured, justice is ensured. Mutual fulfilment is the hallmark of justice. And justice is essential in all relationships. Justice starts from family and slowly expands to the world family. The child gets the understanding of justice in the family. With this understanding, he goes out in the society and interacts with people.

If the understanding of justice is ensured in the family, there will be justice in all the interactions we have in the world at large. If we do not understand the values in relationships, we are governed by our petty prejudices and conditionings. We may treat people as high or low based on their body (particular caste, or sex or race or tribe), on the basis of wealth one possesses or the belief systems that one follows. All this is source of injustice and leads to fragmented society while our natural acceptance is for an undivided society and universal human order. Having explored the harmony in the human beings, we are able to explore the harmony in the family. This enables us to understand the harmony at the level of society and nature/existence. And this is the way, the harmony in our living grows. We slowly get the competence to live in harmony

with all human beings.

Present Scenario: Differentiation (Disrespect) in relationships on the basis of body, physical facilities, or beliefs –

Respect means accepting individuality and doing right evaluation (to be evaluated as I am). Our basis for respect today is largely quite contrary to our discussion above. Instead of respect being a basis of similarity or one of right evaluation, we have made it into something on the basis of which we differentiate i.e. by respecting you mean you are doing something special, because you are special or have something special or are in some special position. Thus, all of us are running around seeking respect from one another by trying to become something special.

Today, we are differentiating in the name of respect. We either differentiate people on the basis of their body, on the basis of their wealth and possessions or on the basis of their beliefs. There is no notion of respect in terms of right evaluation. Thus, there is no real feeling of relationship, only one of differentiation.

On the basis of body

- ***Sex/gender:*** We ignore the fact that being male or female is an attribute of the body, and not an attribute at the level of 'I'. And differentiate in giving respect on the basis of gender called male and females. In many countries, people even prefer a male child to a female child, and in some other societies, the other way round.
- ***Race*:** If the person is of the same race as oneself, then we treat them differently. For example, we differentiate on the basis of skin colour – white, brown, black etc. or on the basis of whether the person is of Aryan race, Mongolian race etc. or on the basis of caste. Again here, we don't do the evaluation on the basis of 'I', but on the basis of the body
- ***Age:*** We have notions such as 'one must respect elders'. There is no such notion as respect youngsters. Here, we see that we are again evaluating at the level of the body – age is related to the body, and not to 'I'.
- ***Physical strength:*** If someone is stronger, we again treat him/her differently. This is again at the level of the body. In fact, we think that we are respecting the other while it is fear; the fear that if we do not treat them like this, we will be harmed.

On the basis of physical facilities

- ***Wealth:*** We differentiate people because some have wealth than others. What we term

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

as a "rich person" gets idolized. We don't even bother to find out whether such people are feeling prosperous, or if they just have wealth. This way, we are over-evaluating physical facilities first, which are just meant to fulfil the needs of the body, and then on this basis, we are wrongly identifying our relationship.

- *Post:* We try to respect on the basis of a person's position. The post is wrongly evaluated as the mark of a person's excellence and differentiation sets in. The post is considered important either on the basis that it gives more physical facilities or on the basis that certain positions are assumed to be important. In our education, we are trained directly or indirectly to earn posts for us to fetch respect.

On the basis of beliefs *'Isms'*: 'Ism' means any belief in terms of a 'thought-system' that we have, or that we have adopted. There are also many modern 'isms' such as capitalism, socialism, communism, etc. The people following these sets of beliefs are called capitalists, socialists, communists, and so on. The people that have adopted them or are following them have been exposed to them since childhood. Believing theirs to be the right belief. However, all beliefs, as we have seen are at the level of desires, thoughts and expectations (selections) in 'I'. There is no definiteness at this level, and hence, this becomes a cause for differentiation.

- *Sects*: People of one sect only consider those with a similar belief system to be their 'own' and worthy of respect. Following a particular tradition, or what we call as religion, becomes the basis of respect and disrespect in relationship.

The Problems Faced Due To Differentiation In Relationships:

Differentiation based on sex/gender: Issue of women's rights, and women protesting and demanding for equality in education, in jobs, and in peoples' representation. People are insecure and afraid of one another based on their gender.

Differentiation based on race: there are many movements and protect against racial discrimination and demands for equality, racial attacks, movements against cast discrimination has people living in fear of such racism, racist attacks, casticism and discrimination.

Differentiation based on age: Protests and movements demanding for equal rights for children on the one hand and for rights for elderly people on the other, generation gap

Differentiation based on wealth: Class struggle and movements to do away with class-differentiation. Many people suffering from a lack of self-esteem and some even committing suicide,

Differentiation based on post: Protests against high handed government officials. At the level of the individual, leads to depression, etc.

Differentiation based on 'isms: Fights, turmoil, terrorism and war, people converting from one Ism to another in order to be able to get more respect.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Differentiation based on sects: Countless religions and sects and each sect has its own movement to ensure that there is no discrimination against people of their belief and demands for special provisions in jobs and in education.

Foundation Value and Complete Value in Human Relationship:

There are certain basic and important values in maintaining relationship. These values, we all know, are the backbone of health and happy family relations. The feelings, emotions, sentiments and respect all are of real importance. These values lead to elimination of friction and establishment of total harmony in relationship on long term basis. Values that are important in any relationship are:

Feelings / Values in Relationships	
S.No.	**Feeling**
1	Trust / Visvasa
2	Respect / Sammana
3	Affection / Sneha
4	Care / Mamata
5	Guidance / Vatsalya
6	Reverence / Shraddha
7	Glory / Gaurava
8	Gratitude / Kritagyata
9	Love / Prema

1. Trust: Trust or vishwas is the foundational value in relationship. "**To be assured that each human being inherently wants oneself and the other to be happy and prosperous.**" If we have trust in the other, we are able to see the other as a relative and not as an adversary.

There are two aspects in trust:

i. Intention (wanting to – our natural acceptance)

ii. Competence (being able to do)

Both intention and competence are the aspects of trust. Intention is what one aspires for (our natural acceptance) and competence is the ability to fulfil the aspiration. In intention every human being wants to do what is right, only the competence may be lacking which needs to be developed through proper understanding and practice. But what we are doing today is that when

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

we are judging ourself we are judging on the basis of our intention, whereas, when we are judging the other we are judging him on the basis of his competence.

" If you trust everybody, people will take undue advantage of you". What is the basic error

in this statement?

The basic error is that if we trust everybody people will not take undue advantage of me. On the contrary, it gives us inner strength and we become far more effective in interacting with and "dealing with different people". This is simply because, we already are sitting with the knowledge of what the person truly wants, truly intends, even though the person may not know this himself/herself! Hence, our ability to interact with people becomes far more effective and in the process, we don't get hurt, we don't get disturbed, we end up becoming an aid to the other. In other words, becoming aware, having the right understanding, living with the assurance in relationship does not mean becoming "stupid"! It only makes us, more competent. Further, what is being said here is that we have trust on the intention of everyone, but, when it comes to making a program with someone, I evaluate my competence, I evaluate his competence and make the program accordingly. This makes me more effective.

2. **Respect: Respect means individuality.** The sense of individuality is prime object. This is the first basic step towards respect (sammana). Once we realized that we are individual then only we can see our self different from others. In other words, **respect means right evaluation, to be evaluated as I am.**

Difference between Respect and Differentiation / Disrespect:

Respect	Differentiation
1. Respect is right evaluation.	1. Differentiation is lack of understanding of respect.
2. Respect for others is generated by the right evaluation and understanding which leads to fulfilment in relationships. This further creates a sense of respect among people	2. This differentiation can take the form of: o Gender bias o Generation gap o Caste struggle o Power play and domination o Communal violence o Clash of race, religion, etc. o class struggle

	society which further lowers the respect shown to others in society.

3. **Affection: Affection is the feeling of being related to the other.** Affection comes when I recognize that we both want to make each other happy and both of us are similar.

4. Care: **The feeling of care is the feeling to nurture and protect the body of our relative.** Or in other words a state of mind in which one is troubled; worry, anxiety, or concern is called care.

5. **Guidance: The feeling of ensuring right understanding and feelings in the other (my relative) is called guidance.** We understand the need of self ('I') for right understanding and feelings. We also understand that the other is similar to me in his/her faculty of natural acceptance, desire of wanting continuous happiness and the program of living in harmony at all the four levels.

6. **Reverence: The feeling of acceptance of excellence in the other is called reverence.** When we see that the other has achieved this excellence- which means to understand and to live in harmony at all the levels of living ensuring continuity of happiness, we have a feeling of reverence for him/her.

7. **Glory:** Each one of us wants to live with continuous happiness and prosperity. Each one of us has the similar faculty of natural acceptance, has the same goal and program and we have the same potential to realize this. **Glory is the feeling for someone who has made efforts for excellence.**

8. **Gratitude: Gratitude is the feeling of acceptance for those who have made efforts for my excellence.** Gratitude is an emotion that occurs after people receive help, depending on how they interpret the situation.

9. **Love: Love is the emotion of strong affection and personal attachment. In other words, love is a feeling of warm personal attachment or deep affection, as for a parent, child, or friend.** This feeling or value is also called the complete value since this is the feeling of relatedness to all human beings. It starts with identifying that one is related to the other human

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

being (the feeling of affection) and it slowly expands to the feeling of being related to all human beings.

The word *love* can refer to a variety of different feelings, states, and attitudes, ranging from generic pleasure ("I loved that meal") to intense interpersonal attraction ("I love my wife"). "Love" can also refer specifically to the passionate desire and intimacy of romantic love, to the sexual love of Eros (cf. Greek words for love), to the emotional closeness of familial love, or to the platonic love that defines friendship, to the profound oneness or devotion of religious love. This diversity of uses and meanings, combined with the complexity of the feelings involved, makes love unusually difficult to consistently define, even compared to other emotional states.

The above mentioned values are the core of all relations. One has to follow all to gain on the day to day problems. These values are intrinsic and available in every person. We need to find out in ourselves and implement. Without implementation, one cannot think of a strong family relation.

The Basis of Undivided Society (Akhanda Samaja) – The World Family:

The feelings of being related to every human being leads to our participation in an undivided society. By living in relationship in the family, we get the occasion to gain the assurance that the other person is an aid to me and not a hindrance. The family is a laboratory of sorts, in which we live our understanding and relationship. With the understanding of values in human relationship, we are able to recognize the connectedness with every individual correctly and fulfil it. On getting assured, it becomes easy to see that society is an extension of family and that it is possible to live in harmony with every human being- thus laying the foundation for an undivided society- from family to world family.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

UNIT-II

Root Causes for gender discrimination

Attaining gender justice is not an easy task in India. From time immemorial, a girl child has been considered as an unwanted entity and a burden whom the parents would not mind doing away with. Discrimination against women begins even before her birth. The gruesome evils of female feticide and infanticide prove how brutal the world could be to women.

Though the Indian constitution provides equal rights and privileges for men and women and makes equal provision to improve the status of women in society, majority of women are still unable to enjoy the rights and opportunities guaranteed to them.

Traditional value system, low level of literacy, more house hold responsibilities lack of awareness, non-availability of proper guidance, low mobility, lack of self confidence family discouragement and advanced science and technology are some of the factors responsible to create gender disparity in our society.

The most important causes of gender disparity such as poverty, illiteracy, unemployment, social customs, belief and anti-female attitude are discussed here.

1. Poverty:

In India of the total 30 percent people who are below poverty line, 70 percent are women. Women's poverty in India is directly related to the absence of economic opportunities and autonomy, lack of access to economic resources including credit , land ownership and inheritance, lack of access to education and support services and their minimal participation in the decision making process. The situation of women on economic front is no better and men still enjoy a larger share of the cake. Thus poverty stands at the root of gender discrimination in our patriarchal society and this economic dependence on the male counterpart is itself a cause of gender disparity.

2. Illiteracy:

Despite the notable efforts by the countries around the globe that have expanded for the basic education , there are approximately 960 million illiterate adults of whom two thirds are women .Educational backwardness of the girls has been the resultant cause of gender discrimination.

The disparities become more visible between male and female literacy rate, during 2001. The literacy rates for males increased from 56% in 1981 to nearly 76% in 2001. The corresponding

change in female literacy rate from 30 to 54%. On the whole the decline on gender gap peaked in 1981 at 26.6% and was 21.7% in 2001 is less impressive. The interstate variation in literacy rate for males was much lower in comparison to females. At the state level female literacy rate varies from 35% in Bihar to 88% in Kerala In states like Arunachal Pradesh, Assam, Bihar, Jammu and Kashmir and Rajasthan, the female literacy rate is below 50%.

The progress towards education by girls is very slow and gender disparities persist at primary, upper primary and secondary stage of education. Girl's account for only 43.7% of enrolment at primary level, 40 .9 % at upper primary level, 38.6% at secondary level and 36.9% at degree and above level. More over girl's participation in education is still below 50% Gender differences in enrolment are prevalent in all the state at all levels. They are not able to realize full identity and power in all spheres of life only due to illiteracy.

3. Lack of Employment Facilities:

Women are not able to resolve the conflict between new economic and old domestic roles. In both rural and urban India, women spend a large proportion of time on unpaid home sustaining work. Women are not able to respond to new opportunities and shift to new occupations because their mobility tends to be low due to intra-house hold allocation of responsibilities.

Rights and obligations within a house hold are not distributed evenly. Male ownership of assets and conventional division of labour reduce incentives for women to undertake new activities. In addition child bearing has clear implications for labour force participation by women. Time spent in bearing and rearing of children often results in de-Skilling, termination of long term labour contacts. Thus women are not being able to be economically self sufficient due to unemployment and their economic dependence on the male counterpart is itself a cause of gender disparity.

4. Social Customs, Beliefs and Practices:

Women are not free from social customs, beliefs and practices. The traditional patrilineal joint family system confines women's roles mostly to the domestic sphere, allocating them to a subordinate status, authority and power compared to men. Men are perceived as the major providers and protectors of a family while women are perceived as playing only a supportive role, attending to the hearth. Boys and girls are accordingly drained for different adult roles, status and authority. In Indian culture since very early periods, men have dominated women as a group and their status has been low in the family and society.

The preference for sons and disfavour towards daughter is complex phenomenon that still persists in many places. Sons especially in the business communities are considered to be economic, political and ritual assets where as daughters are considered to be liabilities. Thus anti female social bias is the main cause of gender disparity in our society.

The boy receives a ceremonial welcome on his birth where as everyone is sad at the birth of a girl child. The preference for male child is due to lower female labour participation, prevalence of social evils like dowry and many others causes. The typical orthodox mentality is present even in this modern era leading to sex determination tests and abortion in an illegal way.

Parents often think that teaching a girl child to manage the kitchen is more important than sending her to school. Many feel that it is an unnecessary financial burden to send a girl child to school as subsequently she will be married off and shifted to some other family. This orthodox belief of parents is responsible for gender disparity.

5. Social Altitude:

Though many social activists and reformers carried their crusade against all social odds to restore honour and dignity to women, attitudinal disparities still hunt our rural masses. Despite pronounced social development and technological advancement, women in our society still continue to be victims of exploitation, superstition, illiteracy and social atrocities.

The social stigma that women are housekeepers and should be confined to the four walls of the house is perhaps a viable cause of gender disparity. They should not raise their voice regarding their fortune for the sake of the prestige of the family. In patriarchal society a lot of weightage is given to men.

In the health and nutritional field, male members of family are supposed to take fresh and nutritious food in comparison to women because either they are earning members or head of the family or they are supposed to be more important than female members. This type of social attitude is conducive to create the problem of gender discrimination.

6. Lack of Awareness of Women:

Most of the women are unaware of their basic rights and capabilities. They even do not have the understanding as to how the socio-economic and political forces affect them. They accept all types of discriminatory practices that persist in our family and society largely due to their ignorance and unawareness.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Article 15 of the Indian constitution states that the state shall not discriminate any citizen on the grounds of only sex. The irony is that there still is widespread discrimination which is a form of injustice to women. Hence at the onset of the new millennium let this generation be a historic example by putting an end to the gender – based discriminations by unfurling the flag of gender justice in all our action and dealings.

What is a stereotype?

A stereotype is a fixed general image or set of characteristics that a lot of pople believe represent a particular type of person or thing.

What are gender stereotypes?

A gender stereotype is a widely held belief or generalisation about the behaviours, characteristics and roles performed by women and men. Female stereotypical roles include being emotional, caring and in need of protection. Male stereotypical roles include being rational, career driven and strong. These assumptions can be negative (eg women are irrational, men are insensitive) or seemingly benign (eg women are nurturing, men are leaders). However, all stereotyping can be limiting.

Where do gender stereotypes come from?

Gender stereotypes originate from local culture and traditions. Children learn what constitutes female and male behaviour from their family and friends, the media, and institutions including schools and religious bodies. The prevalence of gender stereotypes in our culture can have an adverse effect on both girls and boys, who are constantly bombarded with messages about how they should look, behave and play according to their gender. These socially accepted and often unconscious ideas start to form in infancy.

What are the negative impacts of gender stereotypes?

Gender stereotypes shape self-perception, affect wellbeing, attitudes to relationships and influence participation in the world of work. In a school environment they affect a young person's classroom experience, academic performance or subject choice. The assumptions we make about boys and girls may be conscious or unconscious and can result in different treatment of one group compared to another.

What is the difference between sex and gender?

Sex and gender are different concepts.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Sex is determined at birth, is based on physiological differences, and is usually fixed: a person is born as a man, woman or intersex.

Gender refers to sets of learned behaviours. These are socially defined characteristics and expectations attributed to being male or female. Gender is fluid and can change.

The challenge comes if we confuse sex and gender and start to view gender as innate. Gender is not fixed and should not prevent girls or boys from participating in an activity or making a life choice. In reality there are very few activities or choices that are not open to both boys and girls.

Dangerous models of masculinity

Masculinity to refer to certain cultural norms that are associated with harm to society and to men themselves.

Traditional stereotypes of men as socially dominant, along with related traits such as misogyny and homophobia, can be considered "toxic" due in part to their promotion of violence, including sexual assault and domestic violence. The socialization of boys often normalizes violence, such as in the saying "boys will be boys" with regard to bullying and aggression.

Self-reliance and emotional repression are correlated with increased psychological problems in men such as depression, increased stress, and substance abuse. Toxic masculine traits are characteristic of the unspoken code of behavior among men in American prisons, where they exist in part as a response to the harsh conditions of prison life.

Other traditionally masculine traits such as devotion to work, pride in excelling at sports, and providing for one's family, are not considered to be "toxic". The concept was originally used by authors associated with the mythopoetic men's movement such as Shepherd Bliss to contrast stereotypical notions of masculinity with a "real" or "deep" masculinity that they say men have lost touch with in modern society.

Toxic masculinity is thus defined by adherence to traditional male gender roles that restrict the kinds of emotions allowable for boys and men to express, including social expectations that men seek to be dominant (the "alpha male") and limit their emotional range primarily to expressions of anger. Some traditionally prescribed masculine behaviors can produce such harmful effects as violence (including sexual assault and domestic violence), promiscuity, risky and/or socially irresponsible behaviors including substance abuse, and dysfunction in relationships.

Gender binary

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Gender binary (also known as gender binarism, binarism, or genderism) is the classification of gender into two distinct, opposite, and disconnected forms of masculine and feminine, whether by social system or cultural belief.

In this binary model, *sex*, *gender*, and *sexuality* may be assumed by default to align, with aspects of one's gender inherently linked to one's genetic or gamete-based sex, or with one's sex assigned at birth. For example, when a male is born, gender binarism may assume the male will be masculine in appearance, character traits, and behavior, including having a heterosexual attraction to females. These aspects may include expectations of dressing, behavior, sexual orientation, names or pronouns, preferred restroom, or other qualities.

These expectations may reinforce negative attitudes, bias, and discrimination towards people who display expressions of gender variance or nonconformity or whose gender identity is incongruent with their birth sex.

The Pre-Natal Diagnostic Techniques (PNDT) Act & Rules 1994

- The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, was enacted and brought into operation from 1 st January, 1996, in order to check female foeticide. Rules have also been framed under the Act.
- The Act prohibits determination and disclosure of the sex of foetus . It also prohibits any advertisements relating to pre-natal determination of sex and prescribes punishment for its contravention.
- The person who contravenes the provisions of this Act is punishable with imprisonment and fine.

Offences and penalties.-

(1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or is employed in such a Centre, Laboratory or Clinic and renders his professional or technical services to or at such a Centre, Laboratory or Clinic, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

(2) The name of the registered medical practitioner who has been convicted by the court under subsection (1), shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

(3) Any person who seeks the aid of a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or of a medical geneticist, gynaecologist or registered medical practitioner for conducting prenatal diagnostic techniques on any pregnant woman (including such woman unless she was compelled to undergo such diagnostic techniques) for purposes other than those specified in clause (2) of section 4, shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

Cross references

clause (2) of section 4: *no pre-natal diagnostic techniques shall be conducted except for the purposes of detection of any of the following abnormalities, namely:-- (i) chromosomal abnormalities; (ii) genetic metabolic diseases; (iii) haemoglobinopathies; (iv) sex-linked genetic diseases; (v) congenital anomalies; (vi) any other abnormalities or diseases as may be specified by the Central Supervisory Board;*

Beti Bachao Beti Padhao

- Beti Bachao Beti Padhao (BBBP) Scheme was launched in January, 2015. The scheme is aimed at promoting gender equality and the significance of educating girls.
- ***The Scheme is targeted at improving the Child Sex Ratio*** through multi sectoral interventions including prevention of gender biased sex selection and promoting girls' education and her holistic empowerment.
- ***It is a tri-ministerial effort*** of Ministries of Women and Child Development, Health & Family Welfare and Human Resource Development.

Significance and the need for scheme:

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

The trend of decline in the Child Sex Ratio (CSR) has been unabated since 1961. The decline from 945 in 1991 to 927 in 2001 and further to 918 in 2011 is alarming. The social construct discrimination against girls on one hand, easy availability, affordability and subsequent misuse of diagnostic tools on the other hand, have been critical in increasing Sex Selective Elimination of girls leading to low Child Sex Ratio.

Child Sex Ratio is defined as number of girls per 1000 of boys between 0-6 years of age. Hence, a decline in the CSR is a major indicator of women disempowerment. The ratio reflects both, pre-birth discrimination manifested through gender biased sex selection and post birth discrimination against girls.

The government has formed a National Executive Committee to promote Beti Bachao Beti Padhao (BBBP) across the country. The committee is organising a number of programs to promote **"Save Girl Child"** and **"to Educate Girl Child"** since January 2015. Dr. Rajendra Phadke is the National Convener of BBBP Abhiyan.

Strategies employed to successfully carry out the scheme are:

- Implement a sustained social mobilization and communication campaign to create equal value for the girl child and promote her education.
- Place the issue of decline in child sex ratio/sex ratio at birth in public discourse, improvement of which would be an indicator for good governance.
- Focus on gender critical districts and cities.

UNIT-III

EVE TEASING

- Eve teasing is a euphemism used throughout South Asia, which includes (but is not limited to) India, Pakistan, Bangladesh and Nepal, for public sexual harassment or sexual assault of women by men.
- The name "Eve" alludes to the Bible's creation story concerning Adam and Eve. Considered a problem related to delinquency in youth, it is a form of sexual aggression that ranges in severity from sexually suggestive remarks, brushing in public places and catcalls, to groping.
- Eve teasing usually occurs in public spaces and streets and on public transport.

Remedial measures

Efforts were made to

- Sensitize the police about the issue, and police started to round up Eve teasers.
- The deployment of plain-clothed female police officers for the purpose has been particularly effective.
- Other measures taken in various states by the police
    - setting up of dedicated women's helplines in various cities,
    - police stations staffed by women
    - special police cells.

Legal redress

Although Indian law doesn't use the term *Eve teasing*, victims earlier usually seek recourse through

- Section 294 of the Indian Penal Code, which sentences a man found guilty of making a girl or woman the target of obscene gestures, remarks, songs or recitation to a maximum jail sentence of three months.
- Section 292 of the IPC clearly spells out that showing pornographic or obscene pictures, books or papers to a woman or girl results in a fine of ₹2,000 (US$29) with two years' imprisonment for first offenders. In the case of a repeated offense, the offender may have a fine of ₹5,000 (US$72) with five years' imprisonment imposed.
- Under Section 509 of the IPC, obscene gestures, indecent body language and negative comments directed at any woman or girl or exhibiting any object which intrudes upon the privacy of a woman, carries a penalty of imprisonment for one year or a fine or both.
- The Criminal Law (Amendment) Act, 2013 introduced changes to the Indian Penal Code, making sexual harassment an expressed offence under Section 354 A, which is punishable up to three years of imprisonment and or with fine. The Amendment also introduced new sections making acts like disrobing a woman without consent, stalking and sexual acts by person in authority an offense. It also made acid attacks a specific offence with a punishment of imprisonment not less than 10 years and which could extend to life imprisonment and with fine.

- The National Commission for Women (NCW) also proposed No 9. Eve Teasing (New Legislation) 1988. The Indian Parliament has passed the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013, which adds protections for female workers in most workplaces. The Act came into force from 9 December 2013.

Stalking is defined as harassing or threatening behavior that is engaged in repeatedly. Such harassment can be either physical stalking or cyber stalking.

Physical Stalking is committed when a person intentionally and for no legitimate purpose, engages in a course of conduct directed at a specific person, and knows or reasonably should know that such conduct is likely to cause fear of material harm to the physical, mental, or emotional health, safety or property of such person, a member of such person's immediate family or a third party with whom he or she is acquainted. This could include creating reasonable fear that such person's employment, business or career is being threatened. This is typically accomplished by following someone or appearing at their home, school or place of business, making harassing phone calls, leaving messages or objects, or vandalizing the person's property.

Cyber Stalking is similar behavior through the use of the internet or other electronic means to accomplish the same end. The fact that cyber stalking doesn't involve physical contact doesn't mean that it is less dangerous than physical stalking. An experienced Internet user can easily find the victim's personal information such as phone number, address or place of business to locate their whereabouts. This can then lead to more physical behavior. Stalking is defined as a crime

UNIT -IV

Nirbhaya Act

The Criminal Law (Amendment) Act, 2013 (Nirbhaya Act) is an Indian legislation passed by the Lok Sabha on 19 March 2013, and by the Rajya Sabha on 21 March 2013, which provides for amendment of Indian Penal Code, Indian Evidence Act, and Code of Criminal Procedure, 1973 on laws related to sexual offences.

This new Act has expressly recognised certain acts as offences which were dealt under related laws. These new offences like, acid attack, sexual harassment, voyeurism, stalking have been incorporated into the Indian Penal Code:

Section	Offence	Punishment	Notes

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

354A	Sexual harassment	Rigorous imprisonment up to three years, or with fine, or with both in case of offence described in clauses (i), (ii) or (iii) Imprisonment up to one year, or with fine, or with both in other cases	Only protects women. Provisions are: i. physical contact and advances involving unwelcome and explicit sexual overtures; or ii. a demand or request for sexual favours; or iii. forcibly showing pornographys; or iv. making sexually coloured remark; or v. any other unwelcome physical, verbal or non-verbal conduct of sexual nature.
354B	Act with intent to disrobe a woman	Imprisonment not less than three years but which may extend to seven years and with fine.	Only protects women against anyone who "Assaults or uses criminal force to any woman or abets such act with the intention of disrobing or compelling her to be naked."
354C	Voyeurism	In case of first conviction, imprisonment not less than one year, but which may extend to three years, and shall also be liable to fine, and be punished on a second or subsequent conviction, with imprisonment of either description for a term which shall not be less than three years, but which may extend to seven years, and shall	Only protects women. The prohibited action is defines thus: "Watching or capturing a woman in "private act", which includes an act of watching carried out in a place which, in the circumstances, would reasonably be expected to provide privacy, and where the victim's genitals, buttocks or breasts are exposed or covered only in underwear; or the victim is using a lavatory; or the person is

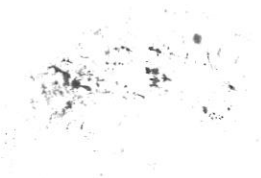
Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

		also be liable to fine.	doing a sexual act that is not of a kind ordinarily done in public."
354D	Stalking	Imprisonment not less than one year but which may extend to three years, and shall also be liable to fine	Only protects women from being stalked by men. The prohibited action is defined thus: "To follow a woman and contact, or attempt to contact such woman to foster personal interaction repeatedly despite a clear indication of disinterest by such woman; or monitor the use by a woman of the internet, email or any other form of electronic communication. There are exceptions to this section which include such act being in course of preventing or detecting a crime authorised by State or in compliance of certain law or was reasonable and justified."

Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013

The Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013 is a legislative act in India that seeks to protect women from sexual harassment at their place of work. It was passed by the Lok Sabha (the lower house of the Indian Parliament) on 3 September 2012. It was passed by the Rajya Sabha (the upper house of the Indian Parliament) on 26 February 2013.

The Act will ensure that women are protected against sexual harassment at all the work places, be it in public or private. This will contribute to realization of their right to gender equality, life and liberty and equality in working conditions everywhere. The sense of security at the



Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

workplace will improve women's participation in work, resulting in their economic empowerment and inclusive growth.

Major features

- The Act **defines sexual harassment** at the work place and creates a mechanism for redressal of complaints. It also provides safeguards against false or malicious charges.
- The Act also **covers concepts of 'quid pro quo harassment' and 'hostile work environment'** as forms of sexual harassment if it occurs in connection with an act or behaviour of sexual harassment.
- The definition of **"aggrieved woman",** who will get protection under the Act is extremely wide to cover all women, irrespective of her age or employment status, whether in the organised or unorganised sectors, public or private and covers clients, customers and domestic workers as well.
- An employer has been defined as any person who is responsible for management, supervision, and control of the workplace and includes persons who formulate and administer policies of such an organisation under Section 2(g).
- While the "workplace" in the Vishaka Guidelines is confined to the traditional office set-up where there is a clear employer-employee relationship, the Act goes much further to include organisations, department, office, branch unit etc. in the public and private sector, organized and unorganized, hospitals, nursing homes, educational institutions, sports institutes, stadiums, sports complex and any place visited by the employee during the course of employment including the transportation. Even non-traditional workplaces which involve tele-commuting will get covered under this law.
- The Committee is required to complete the inquiry within a time period of 90 days. On completion of the inquiry, the report will be sent to the employer or the District Officer, as the case may be, they are mandated to take action on the report within 60 days.
- Every employer is required to constitute an Internal Complaints Committee at each office or branch with 10 or more employees. The District Officer is required to constitute a Local Complaints Committee at each district, and if required at the block level.
- The Complaints Committees have the powers of civil courts for gathering evidence.
- The Complaints Committees are required to provide for conciliation before initiating an inquiry, if requested by the complainant.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

- The inquiry process under the Act should be confidential and the Act lays down a penalty of Rs 5000 on the person who has breached confidentiality.
- The Act requires employers to conduct education and sensitisation programmes and develop policies against sexual harassment, among other obligations.
- Penalties have been prescribed for employers. Non-compliance with the provisions of the Act shall be punishable with a fine of up to ₹ 50,000. Repeated violations may lead to higher penalties and cancellation of licence or deregistration to conduct business.
- Government can order an officer to inspect workplace and records related to sexual harassment in any organisation.
- Under the Act, which also covers students in schools and colleges as well as patients in hospitals, employers and local authorities will have to set up grievance committees to investigate all complaints. Employers who fail to comply will be punished with a fine of up to 50,000 rupees.

UNIT-V

The Protection of Women from Domestic Violence Act, 2005

The Protection of Women from Domestic Violence Act 2005 is an Act of the Parliament of India enacted to protect women from domestic violence. It was brought into force by the Indian government from 26 October 2006. The Act provides for the first time in Indian law a definition of "domestic violence", with this definition being broad and including not only physical violence, but also other forms of violence such as emotional/verbal, sexual, and economic abuse. It is a civil law meant primarily for protection orders and not for meant to be enforced criminally. Definition of domestic violence.—For the purposes of this Act, any act, omission or commission or conduct of the respondent shall constitute domestic violence in case it—

a) **Harms or injures or endangers the health, safety, life, limb or well-being**, whether mental or physical, of the aggrieved person or tends to do so and includes causing physical abuse, sexual abuse, verbal and emotional abuse and economic abuse; or

b) **Harasses, harms, injures or endangers the aggrieved person** with a view to coerce her or any other person related to her to meet any unlawful demand for any dowry or other property or valuable security; or

c) Has the effect of **threatening** the aggrieved person or any person related to her by any conduct mentioned in clause (a) or clause (b); or

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

d) Otherwise injures or causes harm, whether physical or mental, to the aggrieved person.

Explanation I.—For the purposes of this section,—

(i) **"Physical abuse"** means any act or conduct which is of such a nature as to cause bodily pain, harm, or danger to life, limb, or health or impair the health or development of the aggrieved person and includes assault, criminal intimidation and criminal force;

(ii) **"Sexual abuse"** includes any conduct of a sexual nature that abuses, humiliates, degrades or otherwise violates the dignity of woman;

(iii) **"Verbal and emotional abuse"** includes—

(a) Insults, ridicule, humiliation, name calling and insults or ridicule specially with regard to not having a child or a male child; and

(b) Repeated threats to cause physical pain to any person in whom the aggrieved person is interested.

(iv) **"Economic abuse"** includes—

a) ***Deprivation of all or any economic or financial resources*** to which the aggrieved person is entitled under any law or custom whether payable under an order of a court or otherwise or which the aggrieved person requires out of necessity including, but not limited to, household necessities for the aggrieved person and her children, if any, stridhan, property, jointly or separately owned by the aggrieved person, payment of rental related to the shared household and maintenance;

b) ***Disposal of household effects, any alienation of assets*** whether movable or immovable, valuables, shares, securities, bonds and the like or other property in which the aggrieved person has an interest or is entitled to use by virtue of the domestic relationship or which may be reasonably required by the aggrieved person or her children or her stridhan or any other property jointly or separately held by the aggrieved person; and

c) ***Prohibition or restriction to continued access to resources or facilities*** which the aggrieved person is entitled to use or enjoy by virtue of the domestic relationship including access to the shared household. Explanation II.—For the purpose of determining whether any act, omission, commission or conduct of the respondent constitutes "domestic violence" under this section, the overall facts and circumstances of the case shall be taken into consideration.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

*MC600: HUMAN VALUES AND PROFESSIONAL ETHICS

B.Pharm. III Year II Sem.

L T/P/ C
1 0/0/ 0

Course Objective: To enable the students to imbibe and internalize the Values and Ethical Behavior in the personal and Professional lives.

Course Outcome: The students will understand the importance of Values and Ethics in their personal lives and professional careers. The students will learn the rights and responsibilities as an employee, team member and a global citizen.

UNIT - I

Introduction to Professional Ethics: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

UNIT - II

Basic Theories: Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

UNIT - III

Professional ethics in pharmacy: general introduction to code of pharmaceutical ethics, objectives, pharmacists in relation to his job, his trade, to his profession and relation to medicinal professions. Pharmacists oath.

UNIT - IV

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.

Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

UNIT - V

Global issues in Professional Ethics: Introduction – Current Scenario, Technology Globalization of MNCs, International Trade, World Summits, Issues, Business Ethics and Corporate Governance, Sustainable Development Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights.

TEXT BOOKS:

1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

REFERENCE BOOKS

1. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
2. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.
3. Forensic Pharmacy by Dr.Kokate
4. Forensic Pharmacy by Bhaskar Chaurasia

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PROFESSIONAL ETHICS

Subject Code: MC600
Regulations: R19 JNTUH
Class: III Year II Semester B.Pharmacy

Prepared By

Dr.Y.SIRISHA
PROFESSOR

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PROFESSIONAL ETHICS [MC600]
COURSE PLANNER

I. COURSE OVERVIEW

To enable the students to imbibe and internalize the Values and Ethical Behavior in the personal and Professional lives.

II. PREREUISITES.

a. Understand the professional Rules of conduct for Engineers.
b. Appreciate codes of conduct, professional Rules of conduct.
c. Recognize the conflict of interest and Develop strategies
d. Understand the importance of communication with all stakeholders.
e. Apply practical strategies for handling ethical dilemmas.

III. COURSE OBJECTIVE.

1	Students will understand the importance of Values and Ethics in their Personal lives and professional careers
2	The students will learn the rights and responsibilities
3	Responsibilities of employee, team member and a global citizen.

IV. COURSE OUTCOME

Sl.No	Description	Blooms Taxonomy level
1	Understanding basic purpose of profession, professional ethics and various moral and social issues.	Analyze (Level 4)
2	Awareness of professional rights and responsibilities of a Engineer, safety and risk benefit analysis of a Engineer	Analyze (Level 4)
3	Acquiring knowledge of various roles of Enbgineer In applying ethical principles at various professional levels	Analyze (Level 4)
4	Professional Ethical values and contemporary issues	Analyze (Level 4)
5	Excelling in competitive and challenging environment to contribute to industrial growth.	Analyze (Level 4)

V. HOW PROGRAMME OUT COME ARE ASSESSED.

PO's	Programme outcome PO	Level	Proficiency assessed by
PO1	***Engineering Knowledge:*** Apply the knowledge of mathematics, science, engineering fundamentals, and an engineering specialization to the solution of complex engineering problems.	3	Assignment
PO2	***Problem Analysis:*** Identify, formulate, review research literature, and analyze complex engineering problems reaching substantiated conclusions using first principles of mathematics, natural sciences, and engineering sciences.	3	Assignment
PO3	Design solutions for complex engineering problems and design system components or processes that meet the	2	Assignment

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

	specified needs with appropriate consideration for the public health and safety, and the cultural, societal, and environmental considerations.		
PO4	Conduct investigations of complex problems: Use research-based knowledge and research methods including design of experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions.	2	Assignment
PO5	Modern tool usage: Create, select, and apply appropriate techniques, resources, and modern Ethical Tools		-
PO6	The engineer and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety, legal and cultural issues and the consequent responsibilities relevant to the Computer Science and Engineering professional engineering practice.	1-	Assignment
PO7	Environment and sustainability: Understand the impact of the Computer Science and Engineering professional engineering solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.	-	-
PO8	Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of the engineering practice.		-
PO9	Individual and team work: Function effectively as an individual, and as a member or leader in diverse teams, and in multidisciplinary settings.	-	-
PO10	Communication: Communicate effectively on complex engineering activities with the engineering community and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions.	-	-
PO11	Project management and finance: Demonstrate knowledge and understanding of the engineering and management principles and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments	-	-

SUGGESTED BOOKS:

Text books:

1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.

REFERENCES:

1. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
2. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.

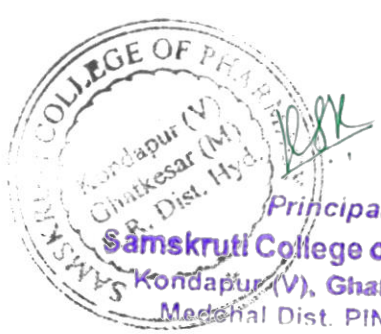
VIII. LESSON PLAN WEEK WISE

Session	Week	Topic	Course learning outc	References
		UNIT-I		
	1	**Introduction to Professional Ethics**	What are Professional ethics	RS and C W
		Basic Concepts Governing Ethics	Concepts	
		Personal & Professional Ethics, Ethical Dilemmas	Clarity of Ethics	
		Life Skills, Emotional Intelligence	skills	
	2	Thoughts of Ethics, Value Education	Ethics, Value Education	
		Dimensions of Ethics,	Ethics	
		, Profession and professionalism, Professional, Associations, Professional Risks		
		Professional Accountabilities, Professional Success, Ethics and Profession.	Accountabilities	
		UNIT-II		
	3	Basic Ethical Principles, Moral Developments	Principles	RS and C W
		Deontology, Utilitarianism	Theories	
		Virtue Theory, Rights Theory, Casuist Theory	Theories	
		Moral Absolution	Morals	
	4	Moral Rationalism	Morals	
		Moral Pluralism,	Morals	
		Ethical Egoism	Overcoming	

SAMSKRUTI COLLEGE OF PHARMACY Kondapur (V) Ghatkesar (M) R. Rural Dist. Hyd.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

	9	Work Place Rights & Responsibilities	Rights & Responsibilities	RS and CW
		Ethics in changing domains of Research, Engineers	Changing Scenario	
		Managers; Organizational Complaint Procedure, difference of Professional Judgment	Different Compliances	
		Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.	Different Compliances	
		Bridge class #5		
	10	within the Ethics in changing domains of research	Ethics and different domains	
		The US government wide definition of research	US scenario	
		misconduct, research misconduct distinguished from mistakes and errors	Enquiry procedure	
		recent history of attention to research misconduct,	Enquiry procedure	
		Bridge class #6		
	11	the emerging emphasis on understanding and fostering	Implementation	
		emphasis on understanding and fostering responsible conduct	Implementation	
		responsible authorship	Setting an Example	
		reviewing & editing	Regular Development	
		Bridge class #7		
		UNIT-V		



Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

			Ego	
		Feminist Consequentialism	values	
		MOCK TEST-1		
	5	Moral Issues	Professional values	
		Moral Dilemmas	Professional values	
		Moral Autonomy	Professional values	
		Revision of Unit-2		
		Bridge class #1		
		UNIT-III		
	6	Professions Kansas City Hyatt Regency Walk away Collapse.	Case Studies	RS and C W
		Professional Conduct,	Professional values	
		Norms of Norms of Professional Conduct	Different norms of Conduct	
		. Profession; Responsibilities,		
		Bridge class #2		
	7	Obligations and Moral Values in Professional Ethics	Obligations and Values	
		Professional codes of ethics, the limits of predictability	Codes and predictability	
		responsibilities of the engineering profession	Role of Engineer	
		Central Responsibilities of Engineers -	Role of Engineer	
		Bridge class #3		
	8	The Centrality of Responsibilities of Professional	Role of Engineer	
		Ethics; lessons from 1979	Case Studies	
		American Airlines DC-10 Crash	Case Studies	
		Kansas City Hyatt Regency Walk away Collapse	Case Studies	
		Bridge class #4		
		MID EXAMS-1		
		UNIT-IV		

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PO12	Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change.	2	Research

SLIGHT (LOW) 2. MODERATE (MEDIUM) 3. SUBSTANTIAL (HIGH)
: NONE

VI. Program Specific Outcomes (PSOs)

Program Specific Outcomes		Level	Proficiency assed by
PSO1	Design and development of high voltages and current equipments to know the performance of electrical equipments by testing.	1	Assignments, seminars
PSO2	Testing techniques for research and advanced studies in Electrical and Electronics engineering	1	Assignments, seminars

1. SLIGHT(LOW) 2. MODERATE (MEDIUM) 3. SUBSTANTIAL (HIGH)
: NONE

VII. SYLLABUS:
COURSE CONTENT:

UNIT – I:

Introduction to Professional Ethics: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

UNIT – II:

Basic Theories: Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

UNIT – III:

Professional Practices in Engineering: Professions and Norms of Professional Conduct, Norms of Professional Conduct vs. Profession; Responsibilities, Obligations and Moral Values in Professional Ethics, Professional codes of ethics, the limits of predictability and responsibilities of the engineering profession, Central Responsibilities of Engineers - The Centrality of Responsibilities of Professional Ethics; lessons from 1979 American Airlines DC-10 Crash and Kansas City Hyatt Regency Walk away Collapse.

UNIT – IV:

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation. Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

UNIT – V: Global issues in Professional Ethics: Introduction, Current Scenario, Technology Globalization of MNCs, International Trade, Cross Cultural Issues, Business Ethics and Corporate Governance, Sustainable Development, Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights

	12	Global issues in Professional Ethics:, , Intellectual Property Rights	Intellectual Property Rights	1
		Introduction – Current Scenario,	Current	
			Scenario,	
		Technology	Technology	RS and C W
		Globalization of MNCs,	MNC Culture	
		International Trade	International Trade	
		Bridge class #8		
	13	World Summits,	World Summits	
		Business Ethics	Business Ethics	
		Corporate Governance	Corporate Governance	
		Sustainable Development Ecosystem	Ecological Awareness	
		MOCK TEST-2		
	14	Energy Concerns	Energy Concerns	
		Ozone	Ecological Awareness	
		Pollution,	Ecological Awareness	
		Ethics in Manufacturing	Balance of life	
		Bridge class #9		
	15	Ethics in Marketing	Ethics in Marketing	
		Media Ethics	Media Ethics	
		War Ethics	War Ethics	
		Bio Ethics	Bio Ethics	
		Bridge class #10		
	16	Intellectual Property	Intellectual Property	
		Intellectual Rights	Intellectual Rights	
		Revision of Unit I, II and III		
		Revision of Unit VI and V		
		Bridge class #11		
		MID EXAMS -2		

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

IX. MAPPING COURSE OUTCOME LEADING TO THE ACHIEVEMENT OF PROGRAMME OUTCOME AND PROGRAMME SPECIFIC OUTCOME.

CO	Programme Outcome											Programme specific outcome	
CO 1	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO10	PO11	PO12	PSO 1	PSO 2
CO 2	-	-	2	-	-	-	-	-	-	-	-	-	1	-
CO 3	2	2	-	-	-	-	-	-	-	-	-	-	1	2
CO 4	2	-	1	-	3	-	-	-	-	-	-	-	2	-
CO 5	1	2	-	-	-	-	-	-	-	-	-	-	1	-
AVG	1.4	1.2	0.6	0.4	0.6	0.2	-	-	-	-	-	-	1	0.4

X. LIST OF TOPICS FOR STUDENT SEMINARS.

1. Understanding of Professional Ethics.
2. Different Theories of Ethics.
3. Professional Responsibilities.
4. National and International scenario of Ethics.
5. Our contribution to the society.

XI. QUESTIONS UNIT WISE

QUESTION BANK: (JNTUH) DESCRIPTIVE QUESTIONS:

UNIT – I

INTRODUCTION TO PROFESSIONAL ETHICS

SHORT ANSWER QUESTIONS

S no	Questions	Blooms Taxonomy Level	Course Outcomes
1	Define professional ethics?	knowledge	1
2	What are called governing ethics?	understand	1
3	What are ethical dilemmas	analyze	1
4	Define value education?	understand	1
5	What are called life skills	knowledge	1

LONG ANSWER QUESTIONS:

S no	Questions	Blooms taxonomy level	Course outcomes
1	Elaborate the concept of value education?	Knowledge	1
2	What are various dimensions of ethics	evaluate	1
3	Explain how professional associations help professionals in organizations	evaluate	1
4	Bring the basic difference between the ethics and profession	analyze	1
5	Explain the basic concepts of professional ethics	analyze	1

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

1. Disclosure of information about unethical acts in an organization to an authority with in or outside the organization which help to prevent such an unethical acts by an motive of an employee is known as_____(whistle blowing)

2. Right to refusal bound to confidentiality ,right to talk freely about professional matters professional judgments are known as_____(rights of professional)

3. Appreciation of professional expertise commitment to profession ,shared vision are said to be_____(collegiality of professions)

4. Reflecting on experience, get more from work life and recreation and matching the ambitions is known as_____(reviewing).

5. _____(editing) process can involve correction, condensation, organization, and many other modifications performed with an intention of producing a correct, consistent, accurate and complete work

6. _____**(Professional judgment)** means the application of relevant training, knowledge and experience, within the context provided by auditing, accounting and ethical standards, in making informed decisions about the courses of action that are appropriate in the circumstances of the audit engagement.

7. a wrong action attributed to bad judgment or ignorance or inattention is_____(mistake)

8. An_____(error) is something you have done which is considered to be incorrect or wrong, or which should not have been done.

9. _____(Ethical standard) in research also garner public support for further funding based on the usefulness quality and integrity of research.

10. The_____(**Nuclear Regulatory Commission (NRC)**)is an independent agency of the United States government tasked with protecting public health and safety related to **nuclear** energy.

UNIT-5

1. Information, entertainment, education, and analysis are part of _____(media ethics).

2. Which can be never justified and can bring term to humanity and completely ravaging the countries which will leave no winner referred to_____(war ethics).

3. _____(bio-ethics) deals with ethics in medicine and biology.

4. _____(intellectual property rights) ensures that others cannot exploit some body's creation without his/her consent or making some financial or other arrangements with use of their invention

5. _____(code of ethics) in a professional societies acts as a guides for an engineer to perform his/her professional duties.

6. The impact of globalization ,privatization and economic interdependence are evident today which we live a life in globalized is_____(global issues).

7. International trade agreements are_____(WTO,GATT,IPR)

8. _____(world summits) many countries to discuss on international issues.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

8. People have rights and these form the basis for deciding the morality of ,actions is_____(right theory).

9. Compare a present ethical problem with a similar problem of the past to find solution is_____(casuist theory).

10. _____(moral absolution) is a kind of dogmatism, which believe in one correct perspective which is the one held by them .

11. Impartial justice can come in to conflict with merry and compassion is _____(moral pluralism|).

12. The theory deals with self interest does not respect the rights of others is _____(ethical egoism).

13. Morally correct actions tend to foster comradeship and harmony Among people is said to be as_____(feminist consequentialism).

14. _____(moral dilemmas) are problems with a moral bearing either of individual or a community.

15. Micro and macro ethical factors generally categorized in _____(moral issues) which faced by individuals and group generally categorized as social issues .

UNIT-3

1. The professionals has to create his/her own norms and standards for professional conduct and follow them scrupulously is known as_____(professional responsibility).

2. As an employee professional gets a lot of information ,some such information may have to be kept confidential which is known as_____(professional confidentiality).

3. An employee needed to bound to obey orders issued to employee and perform the duties assigned by superiors is called_____(respect for authority).

4. One must lead, inspire, influence, encourage the team members to strive better is known as_____(professional accountability).

5. Companies, having good business practices And strong ethical policies do well by gaining investor confidence is_____(corporate governance).

6. One must have right to get a compensation with his/her qualifications is _____(professional rights) .

7. you must feel_____(accountable) for your own actions And the actions of your team.

8. The art of getting the things to be done by others is management. the _____(manager) is one who get the things done by others in time .

9. The practical regime to enforce the right of citizens to information is called _____(right of information)

10. The_____(codes) help in promoting ethical business and also show that ethics in business is not a constraint ,but rather promotes the business.

UNIT-4

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

4	Explain what are the reasons for pollution and ozone deflection?	Understand	5
5	What are the terms business ethics and energy concerns?	Knowledge	5

OBJECTIVE QUESTIONS

UNIT-1

1. Ethics is very important for today's environment of_____(conflicts &stress)in profession.
2. Professional has knowledge and skills that he/she keeps updating with the time through reading and practicing innovating is referred to as _____(professional success)
3. _____(accountability) is a concept used in ethics to denote an organization or individual's ability to shoulder the responsibility of their actions.
4. If the risks arises because of un ethical practices or conduct, the professional is to blamed it is known as_____(professional risks).
5. _____(governing ethics) concerned with a set of moral conduct rules against which behaviors are judged .
6. _____(professional associations) is to promote advance the profession by bringing professionals practicing the profession under one umbrella.
7. Code of conduct, courage, and dependability duty and efficiency, creativity are some _____(ethical skills).
8. Create an awareness and appreciate of the right values to be imbibed for a peaceful and harmonious coexistence is called_____value education)
9. Show concern for the well being of others is_____(personal ethics).
10. _____(ethical dilemma) is a situation where a decision is very difficult to take or a decision taken becomes controversial.

UNIT-2

1. _____(profession) a type of job that requires special training and skill especially one that needs a high level of education such as medical legal, teaching .
2. Ethics is the only means to an end is a thought given by_____(swami Vivekananda).
3. _____is high standard that you expect from a person who is well trained in a particular job.
4. Respect the rights of others is_____(moral autonomy).
5. _____(deontology) defined as duty ethics by CD Board the theory which is created by_____(Immanuel Kant).
6. _____(utilitarianism) which is greatest happiness principle, of that an action is judged by consequences of the action.
7. Good judgment and wisdom are at the core of rational life is called _____(virtue theory).

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

5	What are the central responsibilities of engineering profession ?	Knowledge	3

UNIT-4
WORK PLACE AND RESPONSIBILITIES
SHORT ANSWER QUESTIONS

S no	Question	Blooms Taxonomy Level	Course outcomes
1	What are the changing domains of ethics?	knowledge	4
2	What is professional judgment?	understand	4
3	What is nuclear regulatory commission?	knowledge	4
4	What is research misconduct?	understand	4
5	Define the term errors?	evaluate	4

LONG ANSWER QUESTIONS

S no	Questions	Blooms Taxonomy Level	Course outcomes
1	What are the rights and responsibilities of work place?	understand	4
2	Bring out the basic differences between managers and engineers?	Evaluate	4
3	What is compliant? Explain the organizational complaint?	knowledge	4
4	Explain the US government wide definition of research misconduct?	knowledge	4
5	Bring out the basic difference between errors and mistakes?	Evaluate	4

UNIT-5
GLOBAL ISSUES IN PROFESSIONAL ETHICS
SHORT ANSWER QUESTIONS

S no	Question	Blooms Taxonomy Level	Course Outcome
1	What is globalization	Understand	5
2	What is world summit	knowledge	5
3	What is international trade?	Understand	5
4	Define corporate governance?	Knowledge	5
5	What is ozone deflection?	knowledge	5

LONG ANSWER QUESTIONS

S no	Questions	Blooms Taxonomy Level	Course Outcomes
1	Explain the global issues in professional ethics	Knowledge	5
2	Explain how MNC's came in to existence?	Understand	5
3	What are intellectual property rights? Explain its importance?	Knowledge	5

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

UNIT-2
SHORT ANSWER QUESTIONS

S.No	Question	Blooms Taxonomy Level	Course Outcome
1	What are called ethical principles?	Knowledge	2
2	What are called moral developments	Knowledge	2
3	Define deontology?	Knowledge	2
4	What is casuist theory?	Analyze	2
5	What is moral absolution?	Knowledge	2

UNIT-3
PROFESSIONAL PRACTICES IN ENGINEERING
SHORT ANSWER QUESTIONS

S.no	Question	Blooms Taxonomy Level	Course Outcomes
1	Define basic ethical principles, how principles govern profession?	knowledge	2
2	Explain various theories of professional ethics?	knowledge	2
3	Define feminist consequentialism in detail?	understand	2
4	What are called moral issues and how they influence profession?	create	2
5	Elaborate moral rationalism?	create	2

LONG ANSWER QUESTIONS

S No	Question	Blooms Taxonomy Level	Course Outcomes
1.	Define the norms of professional conduct?	knowledge	3
2	What are professional responsibilities?	knowledge	3
3	What are professional codes of ethics?	evaluate	3
4	What are professional obligations?	knowledge	3
5	What are moral values in professional ethics?	evaluate	3

S No	Question	Blooms Taxonomy Level	course Out come
1	Define various norms of professional ethics?	Understand knowledge	3
2	Bring out the basic differences between responsibilities and obligations?	evaluate	3
3	Explain the differences between the moral and ethical values?	evaluate	3
4	Elaborate the professional codes of ethics?	understand	3

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

9. Technology revolution leads to_____(communication, information, nanotechnology.)

10. Trading with multi nations is referred to as_____(international trade).

WEBSITES:

1. www.universalhumanvalues.info
2. www.uptu.ac.in
3. www.storyofstuff.com

EXPERT DETAILS:

1. Prof. RR Gaur, Professor of Mechanical Engineering (Retd.), PhD, IIT Delhi
2. Prof. Rajeev Sangal, Professor & Director, IIIT Hyderabad
3. Shri Ganesh Prasad Bagaria, Associate Professor, HBTI Kanpur

JOURNALS:

1. The Journal Of Ethics
2. The Journal of Management Development – Emerald
3. International Journal of Human Values

LIST OF TOPICS FOR STUDENT SEMINAR:

1. Ethical Living in a county like India
2. Women professional more ethical than men
3. Ethical values in different cultures
4. Professional values like companies like Infosys, Wipro, GE and Tata

ASSIGNMENT I

1. As a professional Engineer how do you implement ethical values in your organization irrespective of the problems you face from the management and other stake holders.
2. Explore the education, life changing events and human values of a leader you admire.

ASSIGNMENT II

1. Reasons for the unethical behavior in the company and how do you plant to encounter them
2. Three things you learned in HVPE course and how do you apply them in three different situations.

Cases: Relevant CDs, Movies, Documentaries & Other Literature:

1. Al Gore, An Inconvenient Truth, Paramount Classics, USA
2. Charle Chaplin, Modern Times, United Artists, USA
3. IIT Delhi, Modern Technology - the Untold Story

PROJECTS:

1. Ethical practices in IT industries.
2. Ethical Practices in Banks
3. Good governance in government in and Fortune five hundred companies

ake

SAMSKRUTI COLLEGE OF PHARMACY Kondapur (V) Ghatkesar (M) R.R. Dist. Hyd.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

A HAND BOOK

ON

HUMAN VALUES & PROFESSIONAL ETHICS

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

HUMAN VALUES

A human value is defined as 'A principle that promotes well being or prevents harm'. The various factors responsible for evolving human values are our religious Leaders, Gurus and Saviors' teachings and practices, need and judgment of fulfilling individuals need in the society. Human values can be assured of a happy and harmonious human society.

The core human values are:

1. Right conduct
2. Peace
3. Truth
4. Love
5. Co-operation
6. Honesty
7. Trust
8. Non-violence
9. Wisdom

1. Right Conduct:
It encompasses the following values-

a) Self- Help Skills: Care of possessions, diet, hygiene, modesty, posture, self reliance, and tidy appearance.

b) Social Skills: Good behavior, good manners, good relationships, helpfulness, no wastage and good environment.

c) Ethical Skills: Good conduct, courage, dependability, duty,efficiency, ingenuity, initiative, perseverance, punctuality, resourcefulness, respect for all, and sense of responsibility.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

2. Peace:
It encompasses the following values-

Attention, calmness, concentration, contentment, dignity,discipline, equality, equanimity, faithfulness, gratitude, happiness, harmony, humility, inner silence, optimism, patience, reflection, satisfaction, acceptance, control, self-esteem, tolerance, and understanding.

3. Truth:
It encompasses the following values-

Accuracy, curiosity, fairness, fearlessness, honesty, integrity,intuition, justice, optimism, purity, quest for knowledge, reason, self-analysis, sincerity, synthesis, truthfulness, and determination.

4. Love:
It encompasses the following values-

"Love conquers all" says Geoffrey Chaucer. It has immense value. Acceptance, affection, care, compassion, consideration, dedication, devotion, forgiveness, friendship, generosity, gentleness, interdependence, kindness, patience, patriotism, reverence, sacrifice, selflessness, service, sharing, sympathy, tolerance and trust are the segments of love.

5. Co-operation:

Co-operation is the process of working together to the same end. It is undeniably are of the most vital assets one can have when working through a problem. Having the opinion and voice of another person will not only draw out a discussion of the topic, but also lead to a well rounded solution. Co-operation has been in its high importance and held high in regard.

6. Honesty:

Honesty in the realm of human values is extremely important. The idea of staying true to oneself can often feel intimidating and impossible, but what most people felt to realize is that it is not the act of simply telling the truth that makes someone honest rather the quality of person who is being honest. An honest man is often straight forward, upright, sincere and fair.

T rust:

Trust can be interpreted in many ways. But ultimately it comes down to reliability and truth. Without trust, the world simply would not function. We create documents, money and bullet proof glass because we have lost faith which is why the most important human values. Learn to trust and be trusted is not an easy task, butits important is beyond measure. In short, one cannot serve in a world without trust.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

7. Non -Violence
It encompasses the following values-

a) Psychological: Benevolence, compassion, concern for others, consideration, forgiveness, morality, loyalty and happiness.

b)Social: Appreciation of other cultures and religions, brotherhood, care of environment, citizenship, equality, harmlessness, national awareness, perseverance, respect for property, and social justice.

8. Wisdom:

Wisdom is the most important human value in many ways. Its value is very important while living the lives. Wisdom is often confused with the words like knowledge and intelligence. But wisdom is defined as the quality of having experience and good judgment. Wisdom becomes necessary when society gets cramp with knowledge. In the explosion of knowledge based society, wisdom becomes the necessity.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Professional ethics

Personal ethics refers to the ethics that a person identifies with in respect to people and situations that they deal with in everyday life.

Professional ethics refers to the ethics that a person must adhere to in respect of their interactions and business dealings in their professional life.

Personal Ethics:

- These involve your morals and values.
- They are instilled generally, during childhood, by your parents, family, and friends.
- They relate to your deep-rooted principles, and how religiously you follow them determines the kind of person you are.
- The nature of your personal ethics depend on whether your principles have an optimistic effect on the people surrounding you, i.e., your strict adherence to your principles must not spoil someone else's life; a negative impact on society due to your principles violates the very reason you are following them.

Professional Ethics:

- These involve a strict code of conduct laid down at the workplace.
- Your ethics here involve adherence to rules and regulations.
- Non-compliance to such rules may risk your reputation, as your behavior will immediately be reported as brash and unprofessional.
- Your personal views and concerns about any topic will not be of much help in a corporate setting, how well you follow the protocol of the company is what will matter here.

In some cases, personal and professional ethics may clash and cause a moral conflict. For example:

- A police officer may personally believe that a law that he is required to enforce is wrong. However, under the Code of Conduct for the New Zealand Police, he is required to obey all lawful and reasonable instructions to enforce that law unless there is good and sufficient cause to do otherwise.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Life Skills

- The term '*Life Skills*' refers to the skills you need to make the most out of life.
- Life skills are usually associated with managing and living a better quality of life. They help us to accomplish our ambitions and live to our full potential.
- Any skill that is useful in your life can be considered a life skill. Tying your shoe laces, swimming, driving a car and using a computer are, for most people, useful life skills.
- The World Health Organization in 1999 identified the following core cross- cultural areas of life skills:
- Decision-making
- Problem-solving
- Creative thinking
- Critical thinking
- Communication skills
- Interpersonal skills
- Self – awareness
- Empathy
- Assertiveness
- Equantimity
- Resilence and coping with stress

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Dimensions of ethics :

- The different dimensions to study the ethics help in arriving at ethical decisions during complex situation. These varied approaches to ethics look into the question of how ethical action is determined during a particular situation.
- Human beings are confronted with situations wherein their decisions about actions may lead to opposed and perhaps equally unwelcome alternatives.
- There are many dimensions of ethics

I. Utilitarian approach: Utilitarianism was conceived in 19th century by Jeremey Bentham and John Stuart Mill to help legislators determine the law which were morally correct and better. According to them, ethical actions are those that offers the greatest balance good over evil.

II. The right approach: This approach is rooted in the philosophy of Immanuel Kant and others who focused on the individual's right to choose actions based on his or her free will. These philosopher stated that people have dignity based on their capability to choose freely what they will do with their lives and they have fundamental moral right to have these choices respected. The Rights Approach focuses on respect for human dignity.

III. Fairness or justice approach: Aristotle and Greek philosophers have contributed the idea that all equals should be treated equally . In tasic term, The Fairness Approach focuses on the fair and equitable distribution of good and harm, and/or the social benefits and social costs, across the spectrum of society. It starts with the principle that all equals should be treated similarly, and those who are unequal due to relevant differences, should be treated differently in a manner that is fair and proportionate to, or commensurate with, their difference.

IV. Common goods approach: Greek philosophers have contributed the notion life in community is a good in itself and that our actions should contribute to that life. The common good concept was originated in ancient time by many philosophers like Plato, Aristotle, Cicero. More recently, contemporary ethicist, John Rawls defined the common good as certain general conditions those are equally applicable to everyone's advantage. This approach to ethics assumes a

society comprising individuals whose own good is inextricably linked to the good of community.

SAMSKRUTI COLLEGE OF PHARMACY Kondapur (V) Ghatkesar (M) R.R. Dist. Hyd.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Ethical dilemmas and professional risks

- If you have concerns at work-you most probably have a dilemma.the longer you leave resolving it.
- The more chance there is for there to be repercussions for the organization, yourself and the standing of the profession.
- Practices resolving the dilemmas in the five case studies with help from your professional code and the checklist below.
- Decide which principles of the code are affected and the steps you should take to resolve the dilemma.
- CIMA does not supply legal,investment,or career advice.
- If you consult the professional standards and department, whether by telephone or in e mail in writing.
- The information and comments if any made by our staff are given in good faith and for the purpose of general guidance only.
- You are financial director of a large multinational organization and have been privy to information about a takeover bid to acquire a rival firm.
- This situation has a clear impact on your integrity-fair dealing and truthfulness.
- Your obligations in this instance are to confidentiality.

Basic ethical principles

- **General ethical principles**

- There are five general principles that serve as the ideals to which psychologists should aspire within the profession. The principles represent ethical goals but do not explicitly inform or instruct adherence to the goals; instead, the principles aim to influence and to guide professional behavior with respect to the psychologist, research subjects, students, and the individuals who seek psychological services.

Principle A: Beneficence and nonmaleficence

- The beneficence and non maleficence principle of the APA general principles guides psychologists to perform work that is beneficial to others yet does not hurt anyone in the process of carrying out that work. Psychologists are to remain aware of their professional influence and the potential consequences therein on individuals and groups who seek counsel with the psychologist, especially with respect to preventing misuse or abuse, while additionally maintaining awareness of how the psychologist's own physical and mental health may influence their work. Among professional interactions and research, psychologists ought to respect and protect the rights and welfare of patients and participants.

Principle B: Fidelity and responsibility

- The fidelity and responsibility principle of the APA general principles inspires psychologists to cultivate a professional and scientific environment built upon trust, accountability, and ethical considerations. Psychologists are bound to the community by way of their profession and must conduct themselves in a

responsible and ethical manner while also maintaining a similar check on colleagues. Furthermore, psychologists are expected to altruistically devote some of their time to the community.

Principle C: Integrity

- The integrity principle of the APA general principles aims to encourage psychologists to engage in honest, transparent practices within all aspects of the field of psychology.

Principles of deontology.

- In moral philosophy, deontology is the normative ethical theory that the morality of an action should be based on whether that action itself is right or wrong under a series of rules, rather than based on the consequences of the action.
- It is sometimes described as "duty"- or "obligation" or "rule"- based ethics, because rules "bindone to one's duty".
- Deontological ethics is commonly contrasted to consequentialism, virtue ethics, and pragmatic ethics.
- In this terminology, action is more important than the consequences.
- The term deontological was first used to describe the current, specialized definition by C.D. Broad in his book, Five Types of Ethical Theory, which was published in 1930.
- Older usage of the term goes back to Jeremy Bentham , who coined it before 1816 as a synonym of Dicastic or Censorial Ethics.
- The more general sense of the word is retained in French, especially in the term code dedéontologie,in the context of professional ethics.
- Depending on the system of deontological ethics under consideration, a moral obligation may arise from an external or internal source.
- Immanuel kant's theory of ethics is considered deontological for several reasons. First,Kant argues that to act in the morally right way,people must act from duty.

Principles of utilitarianism

- Utilitarianism gets its name from the term "utility," which in this context does not mean "useful" but, rather, means pleasure or happiness.
- A world in which this thing exists, or is possessed, or is experienced, is better than a world without it.
- Now Mill admits that we seem to value some things other than pleasure and happiness for their own sake.
- E.g. we value health, beauty, and knowledge in this way
- Actions Are Right Insofar as They Promote Happiness, Wrong Insofar as They Produce Unhappiness
- This principle is controversial. It makes utilitarianism a form of consequentialism since it says that the morality of an action is decided by its consequences.
- That can seem quite sensible. But the principle is controversial because many people would say that what decides the morality of an action is the *motive* behind it.
- So in Bentham's time, this principle of equality was decidedly progressive. It lay behind calls on the government to pass policies that would benefit all equally, not just the ruling elite.
- It is also the reason why utilitarianism is very far removed from any kind of egoism. The doctrine does not say that you should strive to maximize your own happiness.

- Most moral philosophers before him had held that human beings have no particular obligations to animals since animals can't reason or talk, and they lack free will.

Principles of Virtue Theory of Ethics

- **Virtue ethics** are normative ethical theories which emphasize virtues of mind and character. Virtue ethicists discuss the nature and definition of virtues and other related problems. These include how virtues are acquired, how they are applied in various real life contexts, and whether they are rooted in a universal human nature or in a plurality of cultures.
- The western tradition's key concepts derive from ancient Greek philosophy. These theories include arete (excellence or virtue), phronesis (practical or moral wisdom), and eudaimonia (flourishing
- A virtue is generally agreed to be a character trait, such as a habitual action or settled sentiment.Specifically, a virtue is a positive trait that makes its possessor a good human being. A virtue is thus to be distinguished from single actions or feelings. Rosalind Hursthouse says:
- A virtue such as honesty or generosity is not just a tendency to do what is honest or generous, nor is it to be helpfully specified as a "desirable" or "morally valuable" character trait.

  It is, indeed a character trait—that is, a disposition which is well entrenched in its possessor, something that, as we say "goes all the way down", unlike a habit such as being a tea-drinker—but the disposition in question, far from being a single track disposition to do honest actions, or even honest actions for certain reasons, is multi-track.
- It is concerned with many other actions as well, with emotions and emotional reactions, choices, values, desires, perceptions, attitudes, interests, expectations and sensibilities.
- To possess a virtue is to be a certain sort of person with a certain complex mindset. (Hence the extreme recklessness of attributing a virtue on the basis of a single action.)
- Practical wisdom is an acquired trait that enables its possessor to identify the thing to do in any given situation.Unlike theoretical wisdom, practical reason results in action or decision.[4] As John McDowell puts it, practical wisdom involves a "perceptual sensitivity" to what a situation required.

The Salient Features of Theory of Ethics

- In moral philosophy, deontological ethics or deontology (from Greek δέον, *deon*, "obligation, duty" is the normative ethical theory that the morality of an action should be based on whether that action itself is right or wrong under a series of rules, rather than based on the consequences of the action.
- It is sometimes described as "duty-" or "obligation-" or "rule-" based ethics, because rules "bind one to one's duty".Deontological ethics is commonly contrasted to consequentialism, virtue ethics, and pragmatic ethics. In this terminology, action is more important than the consequences.
- The term *deontological* was first used to describe the current specialised definition by C. D. Broad in his book, *Five Types of Ethical Theory*, which was published in 1930. Older usage of the term goes back to Jeremy Bentham, who coined it before 1816 as a synonym of *Dicastic* or *Censorial Ethics* (i.e. ethics based on judgement).

- The more general sense of the word is retained in French, especially in the term *code de déontologie* (ethical code), in the context of professional ethics.
- Depending on the system of deontological ethics under consideration, a moral obligation may arise from an external or internal source, such as a set of rules inherent to the universe (ethical naturalism), religious law, or a set of personal or cultural values (any of which may be in conflict with personal desires).
- Deontological philosophies mmanuel Kant's theory of ethics is considered deontological for several different reasons. First, Kant argues that to act in the morally right way, people must act from duty (*Pflicht*). Second, Kant argued that it was not the consequences of actions that make them right or wrong but the motives of the person who carries out the action. Kant's argument that to act in the morally right way one must act purely from duty begins with an argument that the highest good must be both good in itself and good without qualification.
- Something is "good in itself" when it is intrinsically good, and "good without qualification", when the addition of that thing never makes a situation ethically worse

fundamentals of casuist theory of professional ethics

- Casuistry is a process of reasoning that seek to resolve moral problems by extracting or extending theoretical rules from a particular case, and reapplying those rules to new instances.
- This method occurs in applied ethics and jurisprudence The term is also commonly used as a pejorative to criticize the use of clever but unsound reasoning, especially in relation to moral questions .
- Casuistry describe either a form of reasoning that is presumed to be acceptable, or a form of reasoning that is inherently unsound and of reasoning that is inherently unsound and deceptive.
- The Oxford English Dictionary says that the word "[o]ften (and perhaps originally) applied to a quibbling or evasive way of dealing with difficult cases of duty."

- It's textual references, except for certain technical usages, are consistentl pejorative (e.g.,"Casuistry destroys by distinctions and exceptions,all morality ,and effaces the essential difference better right and wrong").
- The word casuistry derives from the Latin noun casus ("case"or "occurrence ").

Features of moral absolutism and moral rationalism

- Moral absolutism is an ethical view that all actions are intrinsically right or wrong.
- Moral absolutism stands in contrast to other categories of normative ethical theories such as consequentialism, which holds that the morality of an act depends on the consequences or the context of the act.
- Moral absolutism is not the same as moral universalism. Universalism holds merely that what is right or wrong is independent of context or consequences
- Ethical theories which place strong emphasis on rights and duties, such as the deontological ethics of Immanuel Kant, are often forms of moral absolutism, as are many religious moral codes.

- Moral rationalism, also called ethical rationalism, is a view in meta-ethics according which moral principles are knowable a priori, by reason alone.
- Some prominent figures in the history of philosophy who have defended moral rationalism are Plato and Immanuel Kant.
- Perhaps the most prominent figure in the history of philosophy who has rejected moral rationalism is David Hume.
- Recent philosophers who have defended moral rationalism include Richard Hare, Christine Korsgaard,, Alan Gewirtch and Michael Smith.
- Moral rationalism is neutral on whether basic moral beliefs are known via inference or not
- A moral rationalist who believes that some moral beliefs are justified non-inferentially is a rationalist ethical intuitionism.

Principles of Moral Pluralism and Ethical Egoism.

Moral Pluralism

- Moral pluralism is the idea that there can be conflicting moral views that are each worthy of respect.
- Moral pluralists tend to be open-minded when faced with competing viewpoints. They analyze issues from several moral points of view before deciding and taking action.
- Moral pluralists believe that many moral issues are extremely complicated. Thus, no single philosophical approach will always provide all the answers.

Ethical Egoism

- An action is morally right if and only if it is to the advantage of the person doing it.
- **Arguments For Ethical Egoism**

1. An altruistic moral theory that demands total self-sacrifice is degrading to the moral agent.

- Objection: This is a false dilemma: there are many non-egoistic moral theories that do not demand total self-sacrifice.

2. Everyone is better off if each pursues his or her self-interest.

- Objection: (a) This probably is not true in practice; and (b) True egoism isn't concerned with what will make everyone better off.
- **Arguments Against Ethical Egoism**

1. Provides no moral basis for solving conflicts between people.

2. Obligates each person to prevent others from doing the right thing if it is not in accord with the subject's thinking..

3. Has the same logical basis as racism.

4. The egoist cannot advise others to be egoists because it works against the first egoist's interest.

5. No one person can expect the entire world's population to act in such a way as to produce the most benefit (pleasure) for that one person.

Priniciples of Feminist consequentialism?

- Consequentialism is the class of normative ethical theories holding that the consequences of one's conduct are the ultimate basis for any judgment about the rightness or wrongness of that conduct.
- Thus, from a consequentialist standpoint, a morally right act (or omission from acting) is one that will produce a good outcome, or consequence.
- Consequentialism is primarily non-prescriptive, meaning the moral worth of an action is determined by its potential consequence, not by whether it follows a set of written edicts or laws.
- One example would entail lying under the threat of government punishment to save an innocent person's life, even though it is illegal to lie under oath.

- Consequentialism is usually contrasted with deontological ethics (or *deontology*), in that deontology, in which rules and moral duty are central, derives the rightness or wrongness of one's conduct from the character of the behaviour itself rather than the outcomes of the conduct.
- It is also contrasted with virtue ethics, which focuses on the character of the agent rather than on the nature or consequences of the act (or omission) itself, and pragmatic ethics which treats morality like science: advancing.
- socially over the course of many lifetimes, such that any moral criterion is subject to revision
- Consequentialist theories differ in how they define moral goods.

- Some argue that consequentialist and deontological theories are not necessarily mutually exclusive.
- For example, T. M. Scanlon advances the idea that human rights, which are commonly considered a "deontological" concept, can only be justified with reference to the consequences of having those rights.[1] Similarly, Robert Nozick argues for a theory that is mostly consequentialist, but incorporates inviolable "side-constraints" which restrict the sort of actions agents are permitted to do.[1]
- Consequentialism is controversial. Various nonconsequentialist views are that morality is all about doing one's duty, respecting rights, obeying nature, obeying God, obeying one's own heart, actualizing one's own potential, being reasonable, respecting all people, or not interfering with others—no matter the consequences.

Moral autonomy

- Moral Autonomy is the philosophy which is self-governing or self-determining, i.e., acting independently without the influence or distortion of others Ability to relate the problems with the problems of law, economics and religious principles – It is essential to have the ability to analyse a problem and finding the relation with the existing law.
- If the moral issues are not fulfilling and needs to be, then the solutions a Moral autonomy reflects the concept of individuality. This relates to the idea of building one's self with the moral values one has while developing psychologically.re to be suggested according to the moral issues based on the facts and truths of the issue.
- Tolerance while giving moral judgment, which may cause trouble – When the whole analysis is made considering all the viewpoints of the issue, the final output might be or might not be pleasing to the persons involved.
- To have moral autonomy in all the aspects one should have a lot of patience and inter One should adhere to the basic principles of humanity and should be strict with the Don'ts he has in mind and liberal with his Do's.
- A Person must have adequate knowledge and understanding about the use of ethical

language so as to defend or support his views with others. He must have better knowledge in understanding the importance of suggestions and better solutions while resolving moral problems and also about the importance of tolerance on some critical situations.

- The kindness towards his fellow beings is also an important concept to be kept in mind. Inculcation of all these important qualities enhances the skills of Moral autonomy in a person.
- Tolerance while giving moral judgment, which may cause trouble – When the whole analysis is made considering all the viewpoints of the issue, the final output might be or might not be pleasing to the persons involved.
- In the western tradition, the view that individual autonomy is a basic moral and political value is very much a modern development.

Code of ethics of Pharmacists.

Code of ethics for pharmacists :

- Pharmacists are health professionals who assist individuals in making the best use of medicuations with a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- A pharmacist respects the covenantal relationship between the patient and pharmacist.
- Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society.
- In return for this gift ,a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare , and to maintain their trust.
- A pharmacist promotes the good of every patient in a caring compassionate and confidential manner.
- A pharmacist places concern for the well-being of the patient at the center of professional practice.
- In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science.
- A pharmacist is dedicated to protecting the dignity of the patient.
- With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- A pharmacist respects the autonomy and dignity of each patient.
- A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health.
- A pharmacist communicates with patients in terms that are understandable.
- In all cases, a pharmacist respects personal and cultural differences among patients.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Professional objectives of a pharmacist as an employee.

- To craft a winning resume for a job as a pharmacist, you need to show your expertise in dispensing medications and educating patients on proper usage of prescriptions. Examine the employer's job description to identify the exact skills the company needs most. Here are a few qualifications you could mention in your own pharmacist resume objective:

- Skilled in overseeing the work of pharmacy technicians and pharmacist interns
- Well-versed with advising patients about general health topics
- Experience administering flu shots
- Thorough understanding of prescription drug interactions
- Extensive background in running a retail pharmacy
- Working knowledge of compounding a variety of prescriptions
- Conversant with implementing initiatives to increase profitability
- Good communication skills
- Superior clinical judgment
- Strong attention to detail
- Proficient in using Pyxis System
- Ability to read and interpret prescriptions from physicians' orders

Professional objectives of a pharmacist as a business man?

- Integrity of character and ethical behavior are indispensable to the profession of pharmacy.
- It is the general opinion that the primary concern of the business is to serve the society.
- Business must have a social concern and commitment to enjoy social wellbeing.
- A major attribute towards transformation in business aptitude is change.
- The basic purpose of business is optimization of various economic activities which is concerned for evaluation of business techniques
- Economic environment, a complex phenomenon deals the business with government, public, society and community which can influence the structure and system of country.
- Pharmacy has never been a profession for "gold-diggers." It is an occupation for people who have genuine compassion and concern for those who need pharmaceutical care in their quest for good health.
- it is important that this area of activity receive some form of scrutiny or regulation by federal and state departments of health, to prevent the emergence of unscrupulous elements.

Pharmacists can trace their professional heritage to the Apothecaries of middle age who functioned as diagnosticians while they are also mixed and dispensed therapeutic agents.
RESPONSIBILITIES OF A PROFESSIONAL AT THE WORK PLACE?

- **Introduction;**
- Our national library associations have a long history with most close to or having already reached their centenary yet disruptions, from information and communication technologies (ICT) to publishing continue to change the nature of the profession they were established to support.
-
- Librarianship has become more complex through convergence with other disciplines/professions including information and/or communications technology, information systems, content management, web design and development, information architecture, records management and knowledge management.
- . The complexity is further exacerbated by the tension between occupational and organizational professionalism as libraries and information units are subsumed into their parent organizations and commitment to the employing organization overtakes conflicts with, and often overwhelms the commitment to the profession (Noordegraaf, 2011b; Watson, 2002).
- For a profession that has had a longstanding battle with being comfortable in its own skin, these challenges can potentially impact significantly on the professional identity and professionalism of its members.
- **Professional identity and professionalism;**
- As evidenced by the professional literature professional identity and professionalism are inextricably linked. A professional, within a profession. This underpins their professionalism through the behaviours, attitudes and values that underpin their approach to their work. person's professional identity is how they see themselves as a
- **Professional identity;**
- How a person sees themselves as a professional within their profession influences how they view their work and how they behave as they do their job (Hall, 1968). A person's professional identity is one's professional self- concept based on attributes, beliefs, values, motives, and experiences (Ibarra, 1999).
- It is well documented in the sociological studies by Evetts (1995, 2003, 2011, 2013) that professional identity construction begins during the educational process and is consolidated through occupational and professional socialization.
- Professional associations play a key role in professional identity construction and maintenance through their involvement in the formal education processes and continuing professional development (CPD), as well as in the ways they facilitate professional socialization by connecting with their members and enabling members to connect with one another.
    - Occupational socialization occurs both within and external to the workplace as professionals socialize with organizational and industry colleagues rather outside their own profession.

. Studies that have attempted to measure professionalism have found that although both types of socialization influence professional identity, professional socialization influences

Ethics related to Research

- Minimizing the risk of harm.
- Obtaining informed consent.
- Protecting anonymity and confidentiality.
- Avoiding deceptive practices.
- Providing the right to withdraw.
- Disclosure
- Understanding
- Voluntariness
- Competence
- Consent
- Exculpatory language

Ethics of a author of a research article?

- Each person listed as an author on an author should have significantly contributed to both the research and writing.
- In addition all listed authors must be prepared to accept full responsibility for the content of research article.
- The international committee of medical journal editors (ICMJE) is the recognized international expert organization when it comes through guidelines regarding biomedical research authorship.
- There website (www.icmje.org) lists all the requirements for authorship.
- Substantial contributions to conception and design or acquisition of data or analysis and interpretation of data.
- Drafting the article or revising it critically for important intellectual content
- Policies at most scientific journals states that the person should be listed as the author of the paper only if that person made a direct and substantial intellectual contribution to design of the research, the interpretation of the data or drafting of the paper.
- The acknowledgments section can be used to thank those who indirectly contributed to the work
- All the authors are aware of submission and agree with content and support submission.
- Agree that the manuscript can be examined by anonymous reviewers.

Ethics of reviewing and editing a research article ?

- Informed consent is the prime responsibility of the researcher. A standard procedure in professional codes of ethics is 'informed consent' (Resnik 1998: 133). Seek consent for the participation from people. In the case of children and few other exceptional cases, the informed consent of participants as well as their guardians must be obtained.
- The researcher must reveal all the risks associated with the research to the participants. She should highlight all the negative and positive aspects of the research during the consent process. Aim, objectives and nature of the research,

duration of the study, sponsors and other important information must be revealed to the participants.

- The knowledge gap between the researcher and the participants must be considered .
- The privacy, anonymity and confidentiality of the participants and data must be given due consideration (Jensen, 2002). As professional guidelines and some form of a cultural consensus are still being negotiated, research projects need to consider carefully issues of anonymity, confidentiality, and 'informed consent.
- Participants must be given an option of rejecting data-gathering devices like camcorders, audio recorders etc.
- To make them convenient and easily understandable, the questionnaire and other forms of rating scales must be designed in the native language of the participants\
- Participants' safety is the prime concern. They should not be exposed to risks greater than they encounter in their normal lifestyle.
- In case, it's the responsibility of the researcher to protect participants from the risks arising from their research.
- The researcher should protect and promote the rights and interests of the participants.
- To uphold the ethical standards in the research process, the researcher must accept and respect the principles of integrity, honesty, objectivity and openness.

Steps for sustainable development of ecosystem

➢ Sustainable development is the organizing principle for meeting human development goals while at the same time sustaining the ability of natural system to provide the natural resources and ecosystem services up on which the economy and society depend.

➢ The desired result is a state of society where living conditions and resource use continue to meet human needs without undermining the integrity and stability of the natural system.

➢ Sustainable development can be classified as development the needs of the Present with out compromising the ability of future generations.

➢ While the modern concept of sustainable development is derived mostly from the 1987 Brundtland Report,it is also rooted in earlier ideas about sustainable forest management and twentieth century environment concerns.

➢ As the concept developed,it has shifted to focus more on economic development, social development and environmental protection for future generations.

➢ It has been suggested that "the term 'sustainability'should be viewed as humanity Target goal of human-ecosystem equilibrium (homeostasis), while' sustainable development 'refers to the holistic approach and temporal processes that lead us to the end point of sustainability".

➢ The modern economies are endeavoring to reconcile ambitious economic development and obligations of preserving the natural resources and ecosystem, the two are traditionally seen as a of conflicting nature.

➢ Instead of holding climate change commitments and other sustainability measures as a drug to economic development, turning and leveraging them into

market opportunities will do greater good.

➢ The economic development brought by such organized principle and practices in an economy is called managed sustainable development.

➢ The concept of sustainable development has been_and still is subject to ciriticism, inculding the question of what is to be sunstained in sustainable development.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

*MC500: ENVIRONMENTAL SCIENCES

B.Pharm. III Year I Sem. **L T/P/ C**
1 0/0/ 0

Course Objectives: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Course Outcomes: Upon completion of the course the student shall be able to:

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

UNIT – I

The Multidisciplinary nature of environmental studies
Natural Resources
Renewable and non-renewable resources:
Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

UNIT – II

Ecosystems
Concept of an ecosystem.
Structure and function of an ecosystem.
Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

UNIT – III

Biodiversity and Biotic Resources: Introduction, Definition, genetic, species and ecosystem diversity. Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic and optional values. India as a mega diversity nation, Hot spots of biodiversity. Field visit. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts; conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

Unit – IV

Environmental Pollution: Air pollution; Water pollution; Soil pollution, Noise Pollution

UNIT -- V

Environmental Policy, Legislation & EIA: Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wild life Act.

Towards Sustainable Future: Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human Health, Environmental Ethics, Concept of Green Building, Ecological Foot Print, Life Cycle assessment (LCA), Low carbon life style.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Text book of environmental science and technology, Dr. M. Anji Reddy.
5. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
6. Clark R.S., Marine Pollution, Clanderson Press Oxford
7. Cunningham, W.P. Cooper, T. H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
8. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
9. Down of Earth, Centre for Science and Environment

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

SAMSKRUTI COLLEGE OF PHARMACY

COURSE FILE

CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTICS DRUG MONITORING

PREPARED BY

DR.SURYA DEVARAKONDA

DEPARTMENT OF PHARMACY PRACTICE

(2020-2021)

COURSE FILE INDEX

S.NO TITLE

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

CLINICAL PHARMACOKINETICS TO CLINICAL PHARMACOTHERAPEUTIC DRUG MONITORING

UNIT -1:

INTRODUCTION TO CLINICAL PHARMACOKINETICS

UNIT-2:
DEISGN OF DOSAGE REGIMENS

2.1	Monograms and Tabulations in designing dosage regimen
2.2	Conversion from intravenous to oral dosing.
2.3	Determination of dosage and dosing intervals
2.4	Drug dosing in the elderly and pediatrics and obese patients

UNIT-3:
PHARMACOKINETICS OF DRUG INTERACTION

3.1	Pharmacokinetic drug interactions
3.2	Inhibition and Induction of Drug metabolism
3.3	Inhibition of Biliary Excretion

Unit-4:
THERAPEUTIC DRUG MONITORING

4.1	Introduction
4.2	Individualization of drug dosage regimen (Variability- Genetic, Age and Weight, disease, Interacting drugs)
4.3	Indications for TDM, Protocol for TDM
4.4	Pharmacokinetics/Pharmacodynamic Correlation in drug therapy
4.5	TDM of drug used in the following disease conditions: cardiovascular disease, Seizures disorders, Psychiatric conditions ,and Organ transplantations

UNIT-5
DOSAGE ADJUSTMENT IN RENAL AND HEPATIC DISEASE.

2.1	Renal impairment
5.2	Pharmacokinetic considerations
5.3	General approach for dosage adjustment in renal disease
5.4	Measurement of Glomerular Filtration rate and creatinine clearance
5.5	Dosage adjustment for uremic patients
5.6	Extracorporeal removal of drugs
5.7	Effect of Hepatic disease on pharmacokinetics

UNIT-6
POPULATION PHARMACOKINETICS

6.1	Introduction to Bayesian Theory
6.2	Adaptive method or dosing with feed back
6.3	Analysis of Population pharmacokinetic data

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

UNIT-7

PHARMACOGENETICS

7.1	Genetics polymorphism in drug metabolism: Cytochrome P-450 Isoenzymes
7.2	Genetic polymorphism in drug transport and drug targets
7.3	Pharmacogenetics and pharmacokinetics / Pharmacodynamic considerations

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

1.1 VISION OF INSTITUTION

- To become an eminent institute by providing excellent pharmaceutical education and research to improve healthcare needs of community and technological aspects of industries

1.2 MISSION OF INSTITUION

- To set up the institution with academic excellence by imparting education through high quality infrastructure and technologies in pharmaceutical sciences.
- To train pharmacy students through student-centric teaching and learning processes to accomplish industrial research and social needs
- To develop pharmacy professionals as responsible citizens of a society with ethical valves

QUALITY POLICY

Samskruti College of Pharmacy strides towards excellence, by adopting a system of qualitative policies and processes with continue improvements to enhance student's skills and talents for their exemplary contribution to the society, the nation and the world. The college shall strive to become an "Institution of Excellence" in the field of pharmacy studies.

1.3 VISION OF DEPARTMENT

- To be a recognized global leader in developing solutions for evolving healthcare challenges

1.4 MISSION OF DEPARTMENT

- To improve healthcare quality and outcomes through educating the next generation of pharmacists and pharmaceutical scientists in an environment fostering intellectual curiosity, through pursuing impactful basic and applied research, and through developing and evaluating models of clinical practice.

2. PROGRAM OUTCOMES (PO'S)

PO1: Describe the Etiopathogenesis of selected of selected disease states
PO2: Discuss the various methods involved in the diagnosis selected disease statue
PO3: Interpret and analyze the selected laboratory results of specific disease states
PO4: Describe the therapeutic approach to manage the selected diseases
PO5: Discuss the rationale for drug therapy of the selected disease
PO6: Identify the controversies in drug therapy
PO7: Develop the individualized therapeutic plans based on diagnosis
PO8: Identify the patient-specific parameters relevant in initiating the drug therapy
PO9: Describe evidence based medicine

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

3. PROGRAM SPECIFICF OUTCOMES

- To understand therapeutic goals of the drugs used in different diseases.
- To check & analyze drug interactions, adverse drug reactions
- To understand dose and frequency of the medications
- To understand the time-course of clinical and laboratory indices of therapeutic response and adverse effects

5. TIME TABLE FOR PHARMD 5 YEAR 2021-2022

DAY	PRACTICALS (9:30am-12:30pm)		THEORY(1:15PM TO 4:15PM)		
MONDAY			1.	2.	3.
TUESDAY					
WEDNESDAY		L U N C H			
THURSDAY					
FRIDAY					CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING
SATURDAY					CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING

CLINICAL RESEARCH – Dr. SURYA DEVARAKONDA

6. CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING SYLLABUS FOR THE ACADEMIC YEAR 2021-2022

Theory : 2 Hrs./Week

1. **Introduction to clinical Pharmacokinetics.**

2. **Design of dosage regimens:** Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing. Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interactions:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and induction of Drug metabolism

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M)
Medchal Dist. PIN-501301

c. Inhibition of Biliary Excretion

4. **Therapeutic Drug Monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability-Genetic, Age and Weight, disease, Interacting drugs)
   c. Indications for TDM, Protocol for TDM
   d. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Oral transplantations.
5. **Dosage adjustment in renal and hepatic disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in renal disease
   d. Measurement of Glomerular Filtration rate and creatinine clearance
   e. Dosage adjustments for uremic patients
   f. Extracorporeal removal of drugs
   g. Effect of Hepatic disease on pharmacokinetics.
6. **Population Pharmacokinetics**
   a. Introduction to Bayesian Theory
   b. Adaptive method or dosing with feedback.
   c. Analysis of population pharmacokinetic Data
7. **Pharmacogenetics**
   a. Genetic polymorphism in drug metabolism: Cytochrome P-450 Isoenzymes.
   b. Genetic polymorphism in drug transport and drug targets.
   c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamics considerations.

7 GENERAL OBJECTIVES, SPECIFIC OBJECTIVES FOR CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING IN THE ACADEMIC YEAR 2021-2022

YEAR & BRANCH : III-PHARM D
ACADEMIC YEAR : 2020 – 2021
NAME OF THE SUBJECT : CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING
NAME OF THE FACULTY : DR.SURYA DEVARAKONDA
DESIGNATION: PROFESSOR
DEPARTMENT: PHARMACY PRACTICE
COURSE DESCRIPTION: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly Pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the Pathophysiology of common diseases and their management.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

7.1 GENERAL OBJECTIVES:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly Pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management. At completion of this subject it is expected that students will be able to understand -

1. The pathophysiology of selected disease state and the rationale for drug therapy;
2. The therapeutic approach to management of these diseases;
3. The controversies in drug therapy;
4. The importance of preparation of individualized therapeutic plans based on diagnosis;

To study identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternative, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

8. COURSE OUTCOMES

PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (Theory)

CO 1 : To get basic information on clinical pharmacokinetics and design of a dosage regimen and application of concepts of pharmacokinetics to individualize the drug dosage regimen.

CO 2 : To asses and manage the drug interactions with clinically significant PK-PD drug interactions

CO 3 : To get knowledge on design and implementation of therapeutic drug monitoring services for various drugs

CO 4 : To attain information on adjustment of the dosage regimen for patients with renal / hepatic impairments

CO 5 : To understand the concept regarding population pharmacokinetics and Pharmacogenetics

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

9. CO AND PO MAPPING FOR THE CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUETIC DRUG MONITORING FOR THE ACADEMIC YEAR 2020-2021

COURSE NAME : CLINICAL PHARAMCOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING FOR THE ACADEMIC YEAR 2020-2021

CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING												
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
C1 PD503	3	3	3	2	3	3	3	3	3	3	3	3
C2 PD503	2	2	3	3	3	2	3	3	3	3	2	2
C3 PD503	3	3	3	3	3	2	2	2	2	3	3	3
C4 PD503	3	2	3	3	3	3	3	3	3	2	3	3
C5 PD503	2	3	3	2	3	3	3	3	2	2	2	2
AVERAGE	2.6	2.6	3	2.6	3	2.6	2.8	2.8	2.6	2.6	2.6	2.6

9.2 RELATIONSHIP OF COURSE OUTCOMES AND PROGRAM OUTCOMES COURSE NAME : CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING FOR THE ACDEMIC YEAR 2020-2021

CO. PD503	PSO1	PSO2
C1. PD503	3	2
C2. PD503	3	2
C3. PD503	3	2
C4. PD503	3	2
C5. PD503	3	2
AVERAGE	3	2

Faculty In-Charge

HOD

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

10. COURS E PLAN FOR ACADEMIC YEAR 2020-2021

YEAR & BRANCH : III- PHARM D
ACADEMIC YEAR : 2020-2021
NAME OF THE SUBJECT : **CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING**
NAME OF THE FACULTY : DR.SURYA DEVARAKONDA
DESIGNATION : PROFESSOR
DEPARTMENET : PHARMACY PRACTICE

TEXT BOOKS:

1. TEXT BOOK OF **CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING** BY Dr. SHIVASHAKTI.
2. **CONCEPTS IN CLINICAL PHARMACOKINETICS** BY ROBIN SOUTHWOOD (AUTHOR), VIRGINIA H. FLEMING (AUTHOR), GARY HUCKABY 9AUTHOR) 1 AUGUST 2018

S.NO	TOPIC TO BE COVERED	T-BOOK R-BOOK	PROPOSED NO OF PERIODS	PROPOSED DATE
1	Introduction to clinical pharmacokinetics	T-1	1	13-8-202
2	Monograms and Tabulations in designation dosage regimen	T-1	1	21-8-2022
3	Conversion from intravenous to oral dosing	T-2	2	27-8-2021 TO 28-8-2021
4	Determination of dose and dosing intervals	T-1	2	3-09-2021 TO 4-09-2021
5	Drug dosing in the elderly and pediatrics and obese patients.	T-1	2	17-9-2021 TO 18-9-2021
6	Pharmacokinetics drug interactions	T-2	2	24-9-2021 TO 25-9-2021
7	Inhibition and Induction of drug metabolism	T-1	1	8-10-2021
8	Therapeutic drug monitoring	T-2	2	22-10-2021 TO 23-10-2021
9	Individualization of drug dosage regimen	T-2	2	29-10-2021 TO 30-10-2021
10	Variability-Genetic, Age and Weight, disease, Interacting drugs	T-1	1	6-11-2021
11	Indications for TDM, Protocol for TDM	T-1	2	19-11-2021 TO 20-11-2021
12	Pharmacokinetic/Pharmacodynamic Correlation in drug therapy	T-2	2	26-11-2021 TO 27-11-2021
13	TDM of drugs used in the following disease conditions: cardiovascular disease,	T-2	1	4-12-2021
14	Seizure disorders	T-2	1	10-12-2021
15	Psychiatric conditions	T-1	2	17-12-2021 TO 18-12-2021
16	Organ transplantations.	T-2	1	24-12-2021
17	Dosage adjustment in Renal and hepatic	T-1	1	31-12-2021

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

	Disease			
18	Renal impairment	T-1	2	7-1-2022 TO 8-1-2022
19	Pharmacokinetic considerations	T-1	2	21-1-2022 TO 22-1-2022
20	General approach for dosage adjustment in Rena disease	T-1	2	28-1-2022 TO 29-1-2022
21	Measurement of Glomerular Filtration rate and creatitine clearance	T-2	2	4-2-2022 TO 5-2-2022
22	Dosage adjustment for uremic patients	T-1	2	11-2-2022 TO 12-2-2022
23	Extracorporeal removal of drugs	T-2	2	25-2-2022 TO 26-2-2022
24	Effect of Hepatic disease on pharmacokinetics	T-1	2	4-3-2022 TO 5-3-2022
25	Introduction to Bayesian Theory	T-1	2	11-3-2022 TO 12-3-2022
26	Adaptive method or dosing with feedback	T-2	1	19-3-2022
27	Adaptive method or dosing with feedback	T-1	2	25-3-2022 TO 26-3-2022
28	Analysis of population pharmacokinetic data	T-2	1	1-4-2022
29	Genetic polymorphism in drug metabolism: Cytochrome P-450 Isoenzymes	T-1	2	8-4-2022 TO 9-4-2022
30	Genetic polymorphism in drug metabolism: Cytochrome P-450 Isoenzymes	T-2	2	15-04-2022 TO 16-04-2022
31	Genetic polymorphism in drug transport and drug targets	T-1	2	22-04-2022 TO 23-04-2022
32	Genetic polymorphism in drug transport and drug targets	T-2	1	29-03-2022 TO 30-3-2022
33	Pharmacogenetics and pharmacokinetics/Pharmacodynamic considerations	T-1	2	6-5-2022 TO 7-5-2022

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Pharmacokinetics — TDM

Therapeutic drug monitoring (TDM) is generally defined as the clinical laboratory measurement of a chemical parameter that, with appropriate medical interpretation, will directly influence drug prescribing procedures. Otherwise, TDM refers to the individualization of drug dosage by maintaining plasma or blood drug concentrations within a targeted therapeutic range or window. By combining knowledge of pharmaceutics, pharmacokinetics and pharmacodynamics.

TDM enables the assessment of the efficacy and safety of a particular medication in a variety of clinical settings. The goal of this process is to individualize therapeutic regimens for optimal patient benefit.

Traditionally, TDM involves measuring drug concentrations in various biological fluids and interpreting these concentrations in terms of relevant clinical parameters. Clinical pharmacists and pharmacologists use pharmacokinetic principles to assess these interpretations.

OBJECTIVES:

→ To attain rapid and safe concentration of drug in plasma within the desired therapeutic range in order to provide the safest approach to optimal drug therapy.

→ To coordinate clinical pharmacology, pathology, chemistry, toxicology, analytical chemistry and medicine.

→ To remove empirical trial and error approach.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

PURPOSE OF THERAPEUTIC DRUG MONITORING:

Performing TDM requires a multidisciplinary approach. Accurate and clinically meaningful drug concentrations are attainable only by complete collaboration by a TDM team, typically comprised of scientists, clinicians, nurses, and pharmacists. Excellent communication among team members is necessary to ensure that best practices in TDM are archieved.

The indications for drug monitoring have widened to include efficacy, compliance, drug-drug interactions, toxicity avoidance, and therapy cessation monitoring.

plasma drug concentration measurements alone may be helpful in several circumstances, although each indication may not apply equally to every drug.

Measuring plasma concentrations may be helpful, however, as a low measurement reflects either poor recent compliance or under treatment. Poor compliance is implicated if the patient is prescribed a dose that is unlikely to be associated with a measured low concentration or if a previous measurement suggested that the plasma concentration should be higher for the given dose.

When initiating drug therapy, the physician may find it useful to measure the plasma drug concentration and tailor the dosage to the individual. This directive applies to all drugs, although it is most important for those with narrow therapeutic ranges such as lithium, cyclosporine, and aminoglycoside antibiotics.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

NECESSITY / INDICATIONS OF TDM:

Which drugs required monitoring and Where it is indicated?

1. Pharmacokinetic variability e.g: aspirin, digoxin.
2. Conc. related therapeutic and adverse effects e.g: phenytoin: ataxia, vertigo, drowsiness.
3. Narrow Therapeutic Index: digoxin.
4. Effect difficult to monitor.
5. Inter Individual variations in metabolism.
6. Saturation kinetics: Omeprazole: P450 2C19.
7. Difficult to recognized toxicity clinically: Cyclosporin, Seizures.
8. Hepatic and renal diseases: aminoglycosside.
9. Multiple drug therapy and drug interaction, probenicid increases level of penicillin.
10. Doubtful patients compliance.

Drug assays are costly, so the reason for monitoring and the additional information to be gained (if any) should be carefully considered. for some drugs, therapeutic drug monitoring helps to increase efficacy (Vancomycin), to decrease toxicity (paracetmol) and to assist diagonsis (salicylates). Routine monitoring is not advocated for most drugs. only clinically meaningful tests should be performed.

The appropriate indications for therapeutic drug monitoring (and examples) include:

Toxicity:

- diagnosing toxicity when the clinical syndrome is undifferentiated (unexplained nausea in a patient taking digoxin).
- Avoiding toxicity (aminoglycosides, cyclosporin).

Dosing:

- After dose adjustment (usually after reaching a steady state).
- Assessment of adequate loading dose (after starting phenytoin treatment).
- Dose forecasting to help predict a patient's dose requirements (aminoglycosides).

Monitoring:

- Assessing compliance (anticonvulsant concentrations in patients having frequent seizures).
- Diagnosing under treatment (particularly important for prophylactic drugs such as anticonvulsants, immunosuppressants).
- Diagnosing failed therapy (therapeutic drug monitoring can help distinguish between ineffective drug treatment, non-compliance and adverse effects that mimic the underlying disease).

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

1. Decision to request.

✓ Any toxicity?

✓ Lack of response.

✓ Assessment of compliance.

✓ Assess therapy after regimen change.

✓ potential drug interactions.

✓ chronic administration needed.

2. Patient demographics.

3. Time of sample withdrawal.

4. Collection of biological sample.

5. Laboratory measurement.

TDM of certain drugs:

Drug	t/2 (h)	Therapeutic range (µg/ml).
Gentamicine	2	6-8
Amikacin	2.3	20-25
Carbamazepin	24-40	4-12
Digoxin	36	0.9-2ng/ml
Cyclosporine	5.6	100-250 ng/ml
Theophylline	4-12	10-15
Lithium	0.8-1.2 mEq/l	0.6-1.2

STUDY PROTOCOL FOR TDM:

1. Tittle of the study/project.
2. Investigators.
    1. Chief investigator.
    2. Joint investigator
    3. co-investigator a) clinical
       b) Research fellow.
3. Place of study.
4. Patient requitment place.
5. Need for TDM study.
6. Objective for study.
7. Criteria for selection of patients
8. Patient history.
9. Withdrawal of blood sample and storage.
10. Instrumental for
    a) Measurement of drug levels
    b) Measurement of clinical parameters
    (ECG, EEG, Respiration etc.)
11. Report preparation.
12. Clinical interpretation.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

INDIVIDUALIZATION OF DOSAGE REGIMEN.

Dosage Regimen – Dosage regimen is defined as the manner in which the drug is taken.

→ For some drugs like analgesics single dose is efficient for optimal therapeutic effect however the duration of most illnesses are longer than the therapeutic effect produced by a single dose, In such cases drugs are required to be taken on a repetitive bases over a period of time depending upon the nature of illness.

→ An optimal multiple dosage regimen is the one in which the drug is administered in suitable doses with sufficient frequency that ensures maintenance of plasma conc. within the therapeutic window for entire duration of therapy.

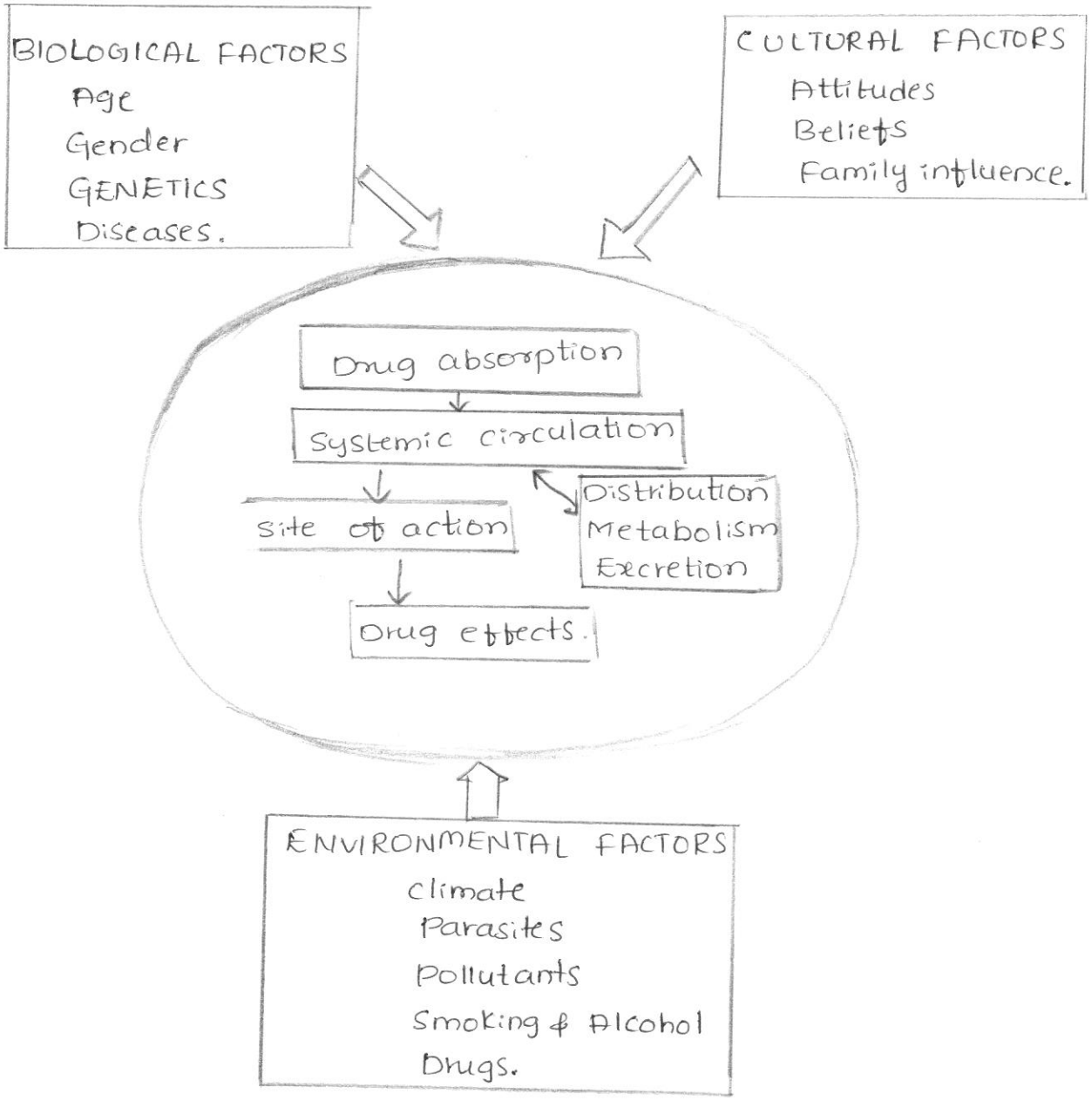
INDIVIDUALIZATON.

→ Rational drug therapy requires Individualization of Dosage regimen to fit a particular patient's needs. The application of pharmacokinetic principles in the dosage regimen design for the safe and effective management of illness in individual patient is called as **Clinical pharmacokinetics**.

→ Same dose of drug may produce large differences in pharmacologic response in different individuals; this is called as **Intersubject variability**. In other words it means that the dose required to produce a certain response varies from individual to individual.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

There are three main sources of variability in pharmacokinetics of drugs and consequently patient's response to drugs.



BIOLOGICAL FACTORS:

1. Age:

→ The factors that affect drug Absorption, including gastric pH, gastric emptying, intestinal motility and blood flow change with age.

→ Thus, in the neonate a condition of achlorhydria persists for the first week of life, and only after 3 years of age gastric acid secretion approaches the adult value.

→ Gastric emptying is also prolonged and peristalsis is irregular during the early months of life.

→ Skeletal muscle mass is also much reduced, and muscle contractions, which tend to promote both blood flow and spreading of an intramuscularly administered drug, are relatively feeble.

→ An elevated gastric pH, a delay in gastric emptying, and both diminished intestinal motility and blood flow are also seen in the elderly.

→ Differences in drug absorption among adults, the very young and the elderly, are therefore expected.

→ Generally, changes in rate rather than in extent of absorption are found.

→ These changes tend to be less apparent in the elderly than in the very young.

→ children often appear to absorb drugs as completely and, if anything, more rapidly than adults.

→ Accordingly, in subsequent calculations of dosage, extent of absorption is assumed not to vary with age.

→ A major exception is for some first-pass drugs given to the elderly, where oral bioavailability increase with age.

Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M).
Medchal Dist. PIN-501301

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

→ The half life is shortest around 1 year of age; it is longest in both newborn and elderly patients.

→ In premature newborns, the urinary excretion is even more depressed per kilogram of body weight than in full-term neonates

→ Metabolic activity may take months to mature, the time required for full maturation varies with the enzyme system.

→ A decrease in unbound metabolic clearance in the elderly patient has been demonstrated for an increasing number of drugs, especially, those principally by oxidation

→ These changes may be associated in part, with the decrease in the size of the liver, as a proportion of body weight, from 2.5% in the young adult to 1.6%, at 90 years of age.

2. Body weight:

→ One aspect of aging is body weight.

→ Weight, 3.5 kg at birth, increases rapidly in childhood and adolescence and then declines slowly in the elderly.

→ As body water spaces, muscle mass, organ blood flow, and organ function are related to body weight, the Volume of distribution, clearance and hence dosage regimens of drugs also depend on body weight.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

→ However, a weight adjustment is generally thought necessary only if the Weight of an individual differs by more than 30% from the average adult weight (70 kg).

→ In practice, then, adjustments for weight are made only for the child and for the adult who is small, thin, big, or obese

→ A dose correction must be considered for thin and Obese patients.

→ The difference in loading dose may not be as great as anticipated from body weight alone.

→ Because, distribution get age-related changes and much depends on the physicochemical properties of the drug.

For example: digoxin and other polar drugs (water soluble) Show better correlation between unbound volume of distribution (V_u) with lean body mass, which is similar in obese and average persons of the same height and frame, than with total body weight.

→ In contrast, total body weight may be more relevant for a drug that is highly lipid Soluble.

→ Though renal and hepatic functions are related to body size, obesity may not produce a corresponding increase in hepatic function.

→ Consequently, the use of total body weight to determine a drug dosage regimen could result in toxic effects if the patient is grossly obese.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

→ Thus, though many drug doses are based on the body weight of the patient (expressed as mg/kg), the influence of obesity or malnourishments is not always considered.

3. Gender:

→ Genetic and physiological differences between men and women can influence both PK and PD.

→ For example, many genes on the Y chromosome, which are expressed only in males, have no counterpart on the X chromosome.

→ The Y chromosome has genes involved in basic cellular function and some genes on the X chromosome are expressed at higher levels in females.

→ Gene expression and regulation are likely to be influenced by hormonal differences between males and females.

→ Genomic imprinting, body size, Organ size, body fat, ADME can also affect pharmacological outcome.

→ other factors such as gastrointestinal transit time, liver enzyme function and urinary creatinine clearance are influenced by both age and sex.

→ Across the path of a woman's life it is necessary to consider the stages of ovarian function to appreciate the potential for drug, sex, and age interactions as they influence rational drug therapy.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Use of oral contraceptives and hormonal changes which occur throughout the menstrual cycle influence pharmacological results.

→ Necessary considerations during pregnancy are alterations in body composition, cardiac output, pulmonary and renal function as well as changes in immune and gastrointestinal systems.

→ In menopause, the ovaries, uterus, urinary tract, hypo-thalamus, cardiovascular systems, and liver are some of the tissues, organs or systems which are altered by the loss of estrogens, androgens, and progestagens.

→ These hormonal changes are also associated with the expression of different diseases after menopause.

Sex differences include the observation that in many developed countries women take more mediations, creating the potential for adverse effects based on drug interactions, they appear more sensitive to adverse events, and may be overdosed more frequently.

Pharmacokinetic Parameter	Physiological Parameter	Sex Difference.
Bioavailability by oral route	Gastrointestinal emptying time	Increased in women, even more prolonged during pregnancy.
	Drug transporters such as P-glycoprotein IP-gp	Sex differences are substrated drug-I specific.
	FDA bioequivalence studies.	In 39% of the data evaluated, there was more than 20% difference in either area under the concentration-time curve or maximum concentration.
Body weight	Male body weight greater than female, FDA bioequivalence stud	Drug dosing without considera-tion of body weight produces [illegible] under the [illegible] curve in women.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

4. Genetics:

→ Genetic polymorphism that lead to the production of isoenzyme with reduced or no activity of to multiple copies of an enzyme with high activity make a major contribution to the variability in the dose requirements of drugs that eliminated by hepatic metabolism.

→ Cytochrome P450 (CYP 450) enzymes, P-glycoproteins are increasingly being recognized for their importance to Pharmacokinetic variability.

→ Most of these genetic differences are complex and are difficult to determine with any degree of certainty; but a few genetic differences are well documented (oxidation, S-methylation, and acetylation).

→ In future genetic screening (phenotyping) may be done to individual patients to design the dose of a drug.

Ethnic group	slow acetylators.
Koreans	10%.
Thai	25%.
Chinese	20%.
Japense	10%.
Indians (India)	60%.
Germans	50%.
Italians and Spanish	55%.
Athabascan Indians	40%.
Yellowknife, Dogrib, and Chippewyan Indians (canada).	10%.

Probe drugs approved by US FDA for genetic phenotyping.

→ Omeprazole / pantoprazole (phenotyping for CYP2C19).

→ Lovastatin (phenotyping for CYP3A4).

→ Dextromethorphan (phenotyping for CYP2D6).

PATIENTS CAN RESPOND DIFFERENTLY TO THE SAME MEDICINE.	
HYPERTENSION DRUGS ACE Inhibition	10-30%.
HEART FAILURE DRUGS Beta Blockers	15-25%.
ANTI-DEPRESSANTS	20-50%.
CHOLESTEROL DRUGS Statins	30-70%.
ASTHMA DRUGS Beta-2-agonists	40-70%.

Percentage of the patient population for which any particular drug is ineffective.

5. Disease conditions:

→ Disease is a major source of variability in drug response.

→ The PK and PD of some drugs have been shown to be influenced by the presence of concurrent diseases other than the one for which a drug is used.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

→ There are also occasions when the pharmacokinetics of a drug is altered in the disease for which it is used.

→ Diseases of the kidney, liver, Cardio vascular system, respiratory system, gastrointestinal system and endocrine System are the major cause that warrant individualized drug therapy.

CONDITION	DRUG	OBSERVATION	VARIATION IN		COMMENTS
			PK	PD	
HEPATIC DISEASES.					
Cirrhosis	Theophylline	Slower fall in plasma concentration	+	−	Clearance reduced. Reduce the dosage to avoid toxicity.
Acute viral hepatitis	Warfarin	Excessive anticoagulant response.	−	+	Reduce dosage to lessen risk of hemorrhage.
RENAL DISEASES.					
Uremia	Gentamycin	Increased toxicity with usual dosage	+	−	Renal clearance diminished, reduce dosage to lessen risk of toxicity.
	Thiopental	Prolonged anesthesia	+/−	+	Reduce dose to avoid excessive sleeping time.

→ The Influence of Hepatic disorder on the drug bioavailability & disposition is unpredictable because of the multiple effects that liver produces.

→ The altered response to drugs in liver disease could be due to decreased metabolizing capacity of the hepatocytes;

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Impaired biliary elimination, due to biliary obstruction (e.g: Rifampicin accumulation in obstruction jaundice).

CONDITION	DRUG	OBSERVATION	VARIATION		COMMENTS.
			PK	PD	
CARDIO VASCULAR DISEASE.					
congestive cardiac failure	lidocaine	Elevated plasma concentration after usual dosage	+	–	Clearance and V_d reduced. Reduce the dosage to lessen toxicity.
GASTROINTESTINAL DISEASES.					
Celiac Disease	Fusidic Acid	Elevated plasma concentration after usual dosage	+	–	BA increased and/clearance diminished
Crohn's Disease	Propranolol	Elevated plasma concentration after an oral dose	+	NS	Increased plasma binding elevated alpha-acid glycoprotein suspected cause; observed only in active phase.

→ In patient with renal failure, the half life of the drug is increase and its clearance drastically decreases if it is predominantly eliminated by way of excretion.

→ Hence, dosage adjustment should take into account the renal function of the patient and fraction of unchanged drug excreted in urine.

→ There are two additional method for dose adjustment in renal insufficiency if the V_d change in assumed to be negligible.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

The adjustment of drug dosage in case of renal disease are carried out by mainly three approaches:

→ Dose adjustment based on Total body clearance.

→ Dose adjustment based on Elimination rate constant or Half life.

→ Dose adjustment in renal failure.

CONDITION	DRUG	OBSERVATION	VARIATION IN		COMMENTS.
			PK	PD	
CARDIOVASCULAR DISEASE.					
Congestive Cardiac Failure	Lidocaine	Elevated plasma Concentration after usual dosage	+	−	Clearance and V_d reduced. Reduce the dosage to lessen toxicity.
GASTROINTESTINAL DISEASES.					
Celiac Disease	Fusidic Acid	Elevated plasma concentration after usual dosage	+	−	BA increased and clearance diminished.
Crohn's Disease	Propranolol	Elevated plasma concentration after an oral dose	+	NS	Increased plasma binding, elevated alpha-1 acid glycoprotein suspected cause; observed only in active phase.

CONDITION	DRUG	OBSERVATION	VARIATION IN		COMMENTS
			PK	PD	
ENDOCRINE DISEASE.					
Thyroid Disease	Digoxin	Diminished response in hyperthyroidism; increased response in myxedema	−	+	Adjust dosage according to thyroid activity.
OTHER.					
Fever	Quinine	Plasma concentration of drug elevated, of metabolite depressed, after usual dosage	+	NS	Impaired metabolism suspected; may need to reduce doses in severe febrile states.

+, Established source of variability.

−, No evidence that variability is increased due to disease.

NS, Not studied.

ENVIRONMENTAL FACTORS

1. Drug interactions:

→ Many of the clinically significant interactions between drugs are pharmacokinetic in origin, often due to induction and inhibition of metabolizing enzymes or transporter proteins.

→ However, interactions can also occur between drugs and food supplements or herbal remedies.

→ Interactions involving competitive inhibition often occur within two to three days whereas induction may take anything form hours to weeks.

→ If the interacting drug has a long elimination half life, the interaction may persist for some time after it has been discontinued.

Absorption:

→ Studies have demonstrated the importance of intestinal CYP3A4 and P-glycoprotein in drug absorption.

→ Induction of these mechanisms by rifampicin and by St. John's wort have been shown to reduce the BA of Digoxin.

→ Absorption can also be altered by drug interactions within the gut that result from binding to other drugs, such as cholestyramine or antacids, or to enteral feeds, as in the case of phenytoin.

Distribution:

→ Drug distribution can be altered by interactions that cause displacement from plasma protein binding.

→ But, these do not normally alter maintenance dose requirements unless there is also a reduction in the clearance of unbound drug.

Metabolism:

→ Metabolism can be altered by enzyme induction or inhibition.

→ Due to wide variability in enzyme activity, the clinical significance of an interaction is often difficult to predict on an individual basis.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

→ These interactions are often dose-dependent and the timescale of the offset and onset of the effect depends not only on the PK of two (or more) drugs concerned, but also the isoenzyme(s) responsible for their metabolism.

Excretion:

→ Probenecid reduces the renal excretion of many antibiotics by competing for anion secretion transport mechanism.

→ Changes in biliary secretion and electro entero-hepatic circulation can also play a role.

→ For example, Pencillins can impair the recirculation of oral contraceptives by altering the bacterial flora of the gut.

OTHER ENVIRONMENTAL FACTORS:

→ Diet, Climate, Smoking, alcohol, drugs, pollutants may cause wide variations in drug response within an individual.

→ Several of these factors can operate simultaneously in the same individual, thus affecting the processes of ADME and receptor interaction in different ways and to different degrees.

→ Studies comparing the metabolism of Antipyrine between Asian Indians in rural Indian villages and Indian Immigrants in England demonstrated that as immigrants adopted the lifestyle and dietary habits of the British, their drug metabolism accelerated.

→ Light-skinned individuals are susceptible to drug induced photoxicity after ingesting certain drugs

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

CONCLUSIONS.

→ Health care providers should give individualised treatment to each patient and resist the temptation to apply "Cookbook" drug therapy that does not take into account variations among individual patients.

→ For the practicing physician, each patient represents a unique and dynamic interaction among determinants that are both genetic and environmental.

→ It is imperative to individualize therapy with respect to the appropriate choice of both drug and dose.

→ A clinical pharmacist with adequate pharmacokinetic background can play a vital role in helping the physician for individualizing drug therapy.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

CI. Pharmacokinetics.

TDM OF DRUGS USED IN THE DISEASE CONDITIONS

TDM OF CARBAMAZEPINE

INTRODUCTION

* Carbamazepine is an iminostibene derivative related to the tricyclic antidepressants.
* It used in the treatment of tonic-clonic [grand mal], partial or secondarily generalized seizures. Carbamazepine is also a useful agent to treat trigeminal neuralgia and bipolar affective disorders.
* Carbamazepine is poorly soluble in water so it lacks as intravenous dosage form.
* Thus the drug is used primarily as a prophylactic agent in the chronic therapy of epilepsy.

Need of TDM:

The accepted therapeutic range for Carbamazepine is 4-12 ug/mL when the drug is used for the treatment of seizures.

1) Carbamazepine plasma protein binding is quite varible among individuals because it is bound to both albumin and α1-acid glycoprotein [AGP].

In patients with normal concentrations of these protins, plasma protein binding is 75-80% resulting in a free fraction of drug of 20-25% AGP secreted in large amount in diseases like. trauma, heart failure, myocardial infarction.

2) Carbamazepine induces it's own hepatic metabolism, ie. Carbama-zepine-10,11-epoxide.

Epoxide concentrations tend to be higher in patients taking enzyme inducers and lower in patients taking enzyme inhibitors. The ADR [nausea, vomiting, lethargy, dizziness

drowsiness, headache, blurred vision, diplopia, unsteadiness, ataxia, incoordination] can also be seen early during dosage titration periods soon after dosage increases are made.

Clinical monitoring parameters:

1) Carbamazepine has antidiuretic effects associated with reduced levels of antidiuretic hormone, some patients may develop hyponatremia during chronic therapy.

2) Hematologic adverse effects: Thrombocytopenia, leukopenia [trend downward in white blood cell count with < 2500 cells/mm2 or absolute neutrophil count < 1000 cells/MM2], or anemia are common while patients is on carbamazepine treatment.

3) Drug induced hepatitis ~~during~~ due to carbamazepine therapy has also been reported.

The severe hematologic and hepatic adverse effects tend to occur early in treatment because of this, many clinicians measure a complete blood cell count and liver functions tests monthly for the first 3-6 months after a patient first begins carbamazepine treatment, and repeat these tests every 3-6 mothiths for the first year.

Clinical pharmacokinetics:

Absorption of carbamazepine from regular tablets is generally slow and irregular. Time to peak concentration vary from four to eight hours or longer because to very low water solubility of this drug. It is dissolution rate limited absorption.

Carbamazepine has relatively large volume of distribution. It is found in Cerebo Spinal fluid, other body fluid and breast milk. Salivary concentration reflect unbound plasma

Concentration and measurement of carbamazepine in saliva can become a useful tool in therapeutic monitoring. The distribution characteristics of the 10,11- epoxide metabolite of carbamazepine is important because of it's anticonvulsant properties [therapeutic and toxic]. The epoxide metabolite is less bound than carbamazepine, and it's free fraction in plasma is twice that of parent drug.

plasma clearance of carbamazepine is greater than that of other antiepileptic drugs, it's extraction ratio is still less than 0.2 Clearance of carbamazepine depends on age and polytherapy. The concentration dose ratio of carbama-zepine increases linearly with age within each age group, the concentration dose ratio decreases by 30% to 50% whenever one or two other antiepileptic drugs.

Effects of Disease states and conditions on pharmacokinetics and Dosing.

After single doses of carbamazepine, the oral Clearance (Cl/F) is 11-26 mL/h/kg and half life is 35 hours for adults. During multiple dosing after maximal auto induction has taken place, oral clearance equals 50-100 mg/h/kg and half life equals 5-27 hours.

DISEASE CONDITION	PARAMETER	REASON
patient receving hepatic drug metabolising enzyme [rifampin, phenytoin]	Clearance increased and half life decreased	Induction.
Cirrhosis and acute hepatitis with hypoalbu-minemia	Clearance decreased and vd increased	Lack of CYP3A4 Decrease protein
Elderly 3rd trimester	Clearance decreased.	

DRUG INTERACTION

DRUG	SUBSTRATE	INTERACTION
phenytoin phenobarbital	Carbamazepine	Increased clearance Decreased serum concentration.
Cimiticline macrolide antibiotic Azol antifungal Diltiazam verapamil fluvoxamide	Carbamazepine	Decreased clearance increased serum concentration
Grape fruit juice	Carbam azepine	increased clearance
Carbamazepine	OC Calcium channel blockers Theophyline	increased clearance Decreased serum Concentration.

TDM OF CYCLOSPORINE

Introduction.

Cyclosporine is a cyclic polypeptide with immuno-suppressant properties that is used for the prevention of graft-versus-host disease in hematopoietic stem cell transplantation patients, for the prevention of graft rejection in solid organ transplant patients, and for the treatment of psoriasis, rheumatoid arthritis and a variety of other autoimmune disease.

The drug discovered in Norway, two new strains of fungi were isolated from soil samples.

studies in renal transplant patients show that cyclosporine is as effective as or superior to conventional immunosuppressive therapy. The impact of cyclosporine is more dramatic in hepatic cardiac and heart-lung transplant patients.

preliminary studies show that cyclosporine is beneficial in some patients with refractory uveitis and newly diagnosed insulin dependent diabetes mellitus, however the delayed toxic effects of continuous cyclosporine use are not yet known.

The major adverse effects of cyclosporine is dose related nephrotoxicity, the greatest concern associated with long-term use of cyclosporine is the development of lymphoproliferative disorders.

Therapeutic range depends on type of organ transplant the desirable range of AUC in the first three (3) months for kidney transplants is 4400-5500 ng.h/L.

The therapeutic range of cyclosporine used by clinicians varies greatly according to the type of assay used to measure cyclosporine and whether blood or serum concentrations are determined by the clinical laboratory, because cyclosporine is bound to red blood cells, blood concentrations are higher than simultaneously measured serum or plasma concentrations.

Often, desired cyclosporine concentrations differ between the various types of organ transplants, change with time during the posttransplantation phase, and are determined by protocols specific to the transplantation service and institution. Thus, it is especially important for clinicians to be aware of these various factors, as acceptable cyclosporine concentrations under these different circumstances may differ from those listed by their clinical laboratory or those given in this text.

Why cyclosporine needs to be monitored?

There are several criteria that a drug must meet to be a suitable candidate for therapeutic drug monitoring (TDM) and cyclosporine fulfills these criteria. cyclosporine has a narrow therapeutic index, it exhibits the desirable pharmacological effect only within narrow ranges of concentration in the blood, too much drug leads to nephrotoxicity and too little to graft rejection the dose response relationship is poor as cyclosporine absorption is highly variable both between and within patients.

The clinical effect of cyclosporine is difficult to measure and the major adverse effect of the drug is hard to distinguish clinically from a lack of therapeutic effect; the drug is given prophylactically. and graft rejection may be the first indication of therapeutic ineffectiveness.

Basic clinical pharmacokinetic parameters.

Cyclosporine follows linear pharmacokinetics.

* Cyclosporine is almost completely eliminated by hepatic metabolism [>99%]
* Cyclosporine is a low-to-moderate hepatic extraction ratio drug with an average liver extraction ratio of ~30%

Effects of Disease states and conditions on cyclosporine pharmacokinetics and Dosing.

Transplantation type does not appear to have a substantial effect on cyclosporine pharmacokinetics

The overall mean for all trasplant groups is a clearance of 6 mL/min/kg, a volume of distribution equal to 5L/kg, and a half-life of 10 hours for adults. Average clearance is higher [10 mL/min/kg] and mean half-life is shorter (6 hours) in children (≤ 16 years old).

Because the drug is primarily eliminated by hepatic metabolism, clearance is lower [3mL/min/kg] and half-life prolonged [20 hours] in patients with liver failure. Immediate-ly after liver transplantation, cyclosporine metabolism is depressed until the graft begins functioning in a stable manner.

Additionally, patients with transient liver dysfunction, regardless of trasplantation type, will have decreased cyclospori-ne clearance and increased half-life values. Immediately after transplantation and surgery, oral absorption of cyclosporine, especially in liver transplant patients with T-tubes, is highly variable. obesity does not influence cyclosporine pharmacokinetics, so doses should be based on ideal body weight for these individuals.

Renal failure does not change cyclosporine pharmacokinetics, and the drug is not significantly removed by hemodialysis or peritoneal dialysis 40-42 the hemofiltration sieving coefficient for cyclosporine is 0.58, which indicates significant removal. Replacement doses during hemoperfusion should be determined using cyclosporine concentrations.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Initial Dosage Determination methods

Several methods to initiate cyclosporine therapy are available. The pharmacokinetic dosingmethod is the most flexible of the ~~the~~ techniques. It allows individualized target serum concentrations of be chosen for apatient, and each pharmacokinetic parameter can be customized to reflect specific disease states and conditions present in the patient. Literature-based recommended dosing is a very commonly used method to prescribe initialdoses of cyclosporine. Doses are based on those that commonly produce steady-state concentrations in the lower end of the therapeutic range although there is a wide variation in the actual concentrations for a specific patient.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

pharmacokinetic Dosing Method

CLEARANCE ESTIMATE

cyclosporine is almost completely metabolized by the liver. Unfortunately, there is no good way to estimate the elimination characteristics of liver metabolized drugs using an endogenous marker of liver function in the same fashion that serum creatinine and estimated creatinine clearance are used to estimate the elimination of agents that are renally eliminated. Because of this, a patient is categorized according to the disease states and conditions that are known to change cyclosporine clearance, and the clearance previously measured in these studies is used as an estimate of the current patient's clearance rate. For example, an adult transplant patient with normal liver function would be assigned a cyclosporine clearance rate equal to 6mL/min/kg, while a pediatric transplant patient with the same profile would be assumed to have a cyclosporine clearance of 10mL/min/kg.

Selection of Appropriate pharmacokinetic model and Equations.

When given by intravenous infusion or orally, cyclosporine follows a two-compartment model. When oral therapy is chosen, the drug is often erratically absorbed with variable absorption rates, and some patients may have a "double-peak" phenomenon occur where a maximum concentration is achieved 2-3 hours after dosage administration with a second maximum concentration 2-4 hours after that because of the complex absorption profile and the fact that the drug is usually administered twice daily, level simple

pharmacokinetic equation that calculates the average cyclosporine steady-state serum concentration [Css in ng/mL = µg/L] is widely used and allows maintenance dose computation.

$$Css = [F(D/T)] / Cl \text{ or } D = [Css \cdot Cl \cdot T] / F$$

F is the bioavailability fraction for the oral dosage form [F averages 0.3 or 30% for most patient populations and oral dosage forms],

D is the dose of cyclosporine in milligrams,

Cl is cyclosporine clearance in liters per hour.

T is the dosage interval in hours.

If the drug is to be given intravenously as intermittent infusions, the equivalent equation for that route of administration is

$$Css = [D/T] / Cl \text{ or } D = Css \cdot Cl \cdot T.$$

If the drug is to be given as a continuous intravenous infusion, the equation for that method of administration is

$$Css = Ko/Cl, \text{ or } Ko = Css \cdot Cl,$$

where Ko is the infusion rate.

STEADY-STATE CONCENTRATION SELECTION.

Clinicians should become familiar with the cyclosporine protocols used at the various institutions at which they practice. Although it is unlikely that steady state has been achieved, cyclosporine concentrations are usually obtained on a daily basis, even when dosage changes were made the previous day, owing to the critical nature of the

therapeutic effect provided by the drug.

Literature - Based Recommended Dosing.

Because of the large amount of variability in cyclosporine pharmacokinetics, even

When concurrent disease states and conditions are identified, many clinicians believe that the use of standard cyclosporine doses for various situations is warranted. Indeed, most transplant centers uses doses that are determined using a cyclosporine dosage protocol. The original computations of these doses were based on the pharmacokinetic dosing method described in the previous section, and subsequently modified based on clinical experience. In general, the expected cyclosporine steady-state concentrations used to compute these doses is dependent upon the type of transplanted tissue and the post transplantation time line. Generally speaking, initial oral doses of 8-18 mg/kg/d or intravenous doses of 3-6 mg/kg/d [1/3 the oral dose to account for ~30% oral bioavailability] are used and vary greatly from institution to institution. 1-5 for obese individuals [>30% over ideal body weight], ideal body weight should be used to compute initial doses.

TDM OF PHENOBARBITAL

INTRODUCTION :

phenobarbital is a barbiturate. The mechanism action of phenobarbital is elevation of seizure threshold by interacting with γ-aminobutyric acid A [GABAA] postsynaptic receptors which potentiates synaptic inhibition

Clinical pharmacokinetics :

Absorption :

* The rate and extent of absorption of phenobarbital indicated the potential for dissolution-rate-limited absorption.
* phenobarbital is absorbed rapidly and completely
* The absolute bioavailability of phenobarbital was measured relative to intramuscular and intravenous administration and found to be close to unity.
* The Absolute bioavailability of oral phenobarbital in humans approaches 100%.

Distribution :

* The steady-state volume of distribution is 21.7 +- 1.2L/m2.
* phenobarbital distributes into cerebrospinal fluid and saliva.
* The cerebrospinal fluid : plasma concentration ratio [0.47] is close to free fraction of phenobarbital in plasma [0.40]
* The drug is bound to mainly to plasma albumin, and its free fraction increases in Hypoalbuminemia.

Metabolism :

* Metabolism represents an important route of elimination [45% - 65% of the dose]
* The total body clearance of phenobarbital is 2.5 +- 0.5ml/min/m2.
* The renal clearance is 1 ml/min/m2 is urine-flow-as well as ph dependent.
* phenobarbital exhibits the longest elimination half-life.

* The half life in adults [75-126 hours] is shorter than in neonates and longer than in children.
* The typical maintenance dose for phenobarbital is 2.5-5mg/kg/d for neonates, 3-4.5 mg/kg/d for pediatric patients [<10 years old], and 1.5-2 mg/kg/d for older patients. For the acute treatment of status epilepticus, intravenous phenobarbital doses of 15-20 mg/kg are used.

Therapeutic and toxic concentrations:

* The Therapeutic range of phenobarbital 15-40 g/mL.
* In children with febrile convulsions, phenobarbital concentrations of 16mcg/ml.
* The most common concentration-related adverse effects of phenobarbital involve the central nervous system: ataxia, headache, unsteadiness, sedation, confusion and lethargy. other concentration-related side effects are nausea, and in children, irritability and hyperactivity.
* At phenobarbital concentrations >60 µg/mL, stupor and coma have been reported.
* slowness and ataxia occur in chronically treated patient at phenobaibitol serum concentration of 35-80mcg/ml.

Effects of disease states and conditions on pharmacokinetics and dosing:

Normal: phenobarbital clearance rate [cl] for older children [>12 years old] and adults is 4mL/h/kg. and for younger children is 8mL/h/kg. phenobarbital volume of distribution [v] equals 0.7 L/kg, and its half life averages 120 hours in neonates [0-4 weeks old], 60 hours in children [<2 months old] and 100 hours in adults.

* In patients with hepatic disease a 50% increase in half life is seen in adults with liver cirrhosis or acute viral hepatitis.
This loss of functional hepatic cells reduces the amount of enzymes available to metabolize the drug and decreases clearance.
* phenobarbital is also eliminated by the kidney, patients with renal dysfunction [creatinine clearance < 30mL/min].
* An Index of liver dysfunction can be gained by applying the child-pugh clinical classification system to the patient.
* A child-pugh score greater than 8 is grounds for a decrease of 25-50% in the initial daily drug dose for phenobarbital.

Drug interactions:

* phenobarbital is a potent inducer of hepatic drug metabolism for the CYP1AR, CYP2C9, and CYP3A4 enzyme systems
* The compounds whose metabolism and clearance are increased by concurrent phenobarbital treatment includes carbamazepine, lamotrigine, valproic acid, cyclosporin, nifedipine, diltiazem, verapamil, oral contraceptives, tricyclic antidepressants, quinidine, theophylline, and warfarin.
* The decrease the metabolism and clearance of phenobarbital felbamate and valproic acid.

phenytoin may also exhibit an interaction with phenobarbital where both agents change the metabolism and clearance of each other.

INITIAL DOSAGE DETERMINATION METHODS:

1. pharmacokinetic Dosing Method
2. Literature-Based Recommended Dosing

pharmacokinetic Dosing method.

In order to do this, pharmacokinetic parameters for the patient will be estimated using average parameters measured in other patients with similar disease state and condition profiles.

Clearance estimate:

patient is categorized according to the disease states and conditions that are known to change drug clearance, and the clearance previously measured in these studies is used as an estimate of the current patient's clearance.

Volume of distribution estimate:

The volume of distribution of drug is assumed to equal ~~0.7 L/kg~~ for adults and children.

Half-life and elimination rate constant estimate:

Once the correct clearance and volume of distribution estimates are identified for the patient, they can be converted into the half-life [t1/2] and elimination rate constant [K] estimates using the following equations:

$$t1/2 = [0.693 \cdot V] / Cl,$$

$$K = 0.693 / t1/2 = Cl/V.$$

Selection of appropriate pharmacokinetic model and equations.

phenobarbital follow a one-compartment pharmacokinetic model.

pharmacokinetic equation that computes the average phenobarbital steady-state serum concentration [Css in µg/mL = mg/L] is widely used and maintainance dosage calculation

$$Css = [F(D/T)] / Cl \text{ or}$$

$$D = [Css \cdot Cl \cdot T] / F$$

Where F is the bioavailability fraction for the oral dosage form [F=1]

D is the dose of the anticonvulsant in mg,

Cl is anticonvulsant clearance in L/h, and

T is the dosage interval in hours.

When intravenous therapy with phenobarbital

$$Css = [D/T] / Cl \text{ or}$$

$$D = Css . Cl_T$$

Literature-Based Recommended Dosing:

In general, the expected steady-state serum concentrations used to compute these doses was in the lower end of the therapeutic range for each drug. if the patient has significant hepatic dysfunction [child-pugh score ≥ 8] or Renal disease [creatinine clearance < 30 mL/min], maintance doses prescribed using this method should be decreased by 25-50% depending on how aggressive therapy is required to be for the individual.

Use of phenobarbital serum concentrations to alter:

* Because of pharmacokinetic variability, the narrow therapeutic index of phenobarbital and the desire to avoid adverse side effects, measurements of serum concentrations for these anticonvulsants is conducted for most patients to ensure that therapeutic, nontoxic levels are present.
* In addition to phenobarbital serum concentrations, important patient parameters [seizure frequency, potential side effects, etc..] should be followed to confirm that the patient is responding to treatment and not developing adverse drug reactions.

* When phenobarbital serum concentrations are measured in patients and a dosage change is necessary, clinicians should seek to use the simplest, most straight-forward method available to determine a dose that will provide safe and effective treatment.

* In most cases, a simple dosage ratio can be used to change doses since phenobarbital follow linear pharmacokinetics. Sometimes, it is not possible to simply change the dose because of the limited number of oral dosage strengths, and the dosage interval must be changed. In some situations, it may be necessary or desirable to compute the phenobarbital pharmacokinetic parameters for the patient and utilize these to calculate the best drug dose.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

* An additional benefit of this dosing method is that a complete pharmacokinetic workup (determination of clearance, volume of distribution, and half-line) can be done with one or more measured concentrations that do not have to be at steady state.

Linear pharmacokinetics Method:

Phenobarbital follow linear, dose-proportional pharmacokinetics, steady state serum concentrations changes in proportion to dose according to the following equation:

$D_{new} / C_{ss,new} = D_{old} / C_{ss,old}$ or

$D_{new} = (C_{ss,new} / C_{ss,old}) D_{old}$,

where D is the dose,

Css is the steady state concentration, Dold indicates the dose that produced the steady-concentration that the patient is currently achieving and Dnew denotes the dose necessary to produce the desired steady state concentration.

Pharmacokinetic parameter method:

- This is the first techniques available to change doses using serum concentrations.
- It allows the computation of an individuals own, unique pharmacokinetic constants and uses these to calculate a dose that achieves desired phenobarbital concentrations. This method requires that steady state has been achieved aphieved and uses only a steady state phenobarbital concentration (Css).

Phenobarbital clearance (Cl) can be calculated using the following formula:

$$Cl = [F(D/T)] / Css$$

Where F is the bioavailability fraction for the oral dosage form (F = 1 for oral phenobarbital products),

D is the dose of phenobarbital in milligrams,

C_{ss} is the steady-state phenobarbital concentration in milligrams per liter, and

T is the dosage interval in hours.

Similarly, phenobarbital clearence during intravenous theraphy can be computed using the equivalent formula: $Cl = (D/T)$

TDM OF VALPROIC ACID

INTRODUCTION:

Valproic acid is an agent that is chemically related to free fatty acids and is used in the treatment of generalised, partial, and absence (petit mal) seizures.

Valproic acid is also a useful agent for the treatment of bipolar affective disorders and the prevention of migraine headaches

Its antiepileptic effect is thought to result from its ability to increase concentrations of the neuroinhibitor 'γ-aminobuty-ric acid (GABA), to potentiate the postsynaptic response to GABA or to exert a direct effect on cellular membranes.

Therapeutic Ranges

Therapeutic Range: 50-100 µg/mL (or) 347 - 693 µmol/L

Possible toxic levels: >100 µg/mL (or) >693 µmol/L

Generalised Seizure: 30 - 60 µg/mL

Partial Seizure: 55-100 µg/mL

In the upper end of the therapeutic range (>75 Mcg/mL) some patients will begin to experience the concentration dependent adverse effects of valproic acid therapy: ataxia, sedation, lethargy, and tiredness.

Basic Clinical pharmacokinetic Parameters

1. Absorption and Bioavailability
   a. Rapidly and completely absorbed (f = 1)
   b. Oral (fasting) → peak: 1-3 hours
   c. Meal (food) → peak late 6-8 hours
   d. Enteric coated → absorbed delayed 3-5 hrs (lag time 2-4 hrs)

2. Distribution and protein binding
   a. Vd = 0.15 L/kg (0.1 - 0.5 L/kg)
   b. Protein (Albumin) binding get saturated at a concentration >50 µg/mL

3. Metabolism and elimination
   a. >95% hepatic metabolism
   b. 1-3% renal excretion
   c. Oral clearance (Cl/F) is 7-12 mL/h/kg for adults
   d. In children 6-12 years old, oral clearance is 10-20 mL/h/kg.

4. Half-Life (t1/2)
   a. Half-line is 12-18 hours in adults
   b. Half-line for children 6-12 year old is 6-8 hours

Time to sample

Sampling after reaching steady state is recommended if it requires 5-7 half lives. Trough sample is taken but sometimes both trough and peek samples are withdrawn.

Clinical Monitoring Parameters.

The goal of theraphy with anticonvulsants is to reduce seizure frequency and maximize quality of life with a minimum of adverse drug effects. Patients should be monito-red for concentration related side effects (ataxia, sedation, lethargy, tiredness, tremor, stupor, coma, and thrombocy-topenia) as well as gastrointestinal upset associated with local irritation of gastric mucosa (nausea, vomiting and anorexia).

Elevated liver function tests, increased serum amm-onia, alopecia, and weight gain have been reported during chronic valproic acid treatment. Serious, but rare, idiosyncratic side effects include hepatotoxicity, pancreatitis, pitting edema, systemic lupus-like reactions, and leucopenia with bone marrow changes.

Effects of Disease States and Conditions on Pharma-cokinetics and Dosing.

Patients with liver cirrhosis or acute hepatitis have reduced valproic acid clearance because of destruction of liver parenchyma. This loss of functional hapatic cells reduces the amount of enzymes available to metabolize the drug and decreases clearance.

INSUFFICIENT ALBUMIN CONCENTRATION	DISPLACEMENT BY ENDOGENOUS COMP - OUNDS	DISPLACEMENT BY EXOGENOUS COM - POUNDS
Liver disease Nephrotic syndrome Pregnancy Cystic fibrosis Trauma Burns Malnourishment Elderly	Hyperbilirubinemia Jaundice Liver disease Renal dysfunction	Drug interactions Warfarian phenytoin Aspirin (>2 g/d) NSAIDs with high albumin binding.

Drug Interactions:

- Phenytoin, lamotrigine, rifampin, and carbamazepine can increase valproic acid clearance and decrease valproic acid steady-state serum concentrations.
- Cimetidine, Chloropromazine, and felbamate are examples of drugs that decrease valproic acid clearance and increase valproic acid steady-state concentrations.
- Aspirin, coarfarin, and phenytoin all have plasma protein binding drug interactions with valproic acid, and these drugs have higher unbound fractions when given concurrently with valproic acid. The drug interaction between valproic acid and phenytoin deserves special examination because of its complexity and because these two agents are regularly used together for the treatment of seizures.

The volume of distribution may be larger because of reduced plasma protein binding (free fraction ≈ 29%). Protein binding may be reduced and unbound fraction may be increased owing to hypoalbuminemia and/or hyperbilirubinemia (especially albumin content is ≤ 3 g/dL and/or total bilirubin ≥ 2 mg/dL). Average half-life for valproic acid in patients with liver disease is 25 hours. An index of liver dysfunction can be gained by applying the child-Pugh clinical classification system to the patient.

A child-Pugh score greater than 8 grounds for a decrease of 25-50% in the initial daily drug dose for Valproic acid. As in any patient with or without liver dysfunction, initial doses are meant as starting points for dosage titration based on patient response and avoidance of adverse effects.

Doses of valproic acid do not require adjustment for patients with renal failure, and the drug is not removed by dialysis.

During the third trimester of pregnancy, oral clearance of valproic acid may decrease and require dosage adjustment. Clearance rates can be higher and half-lives shorter in patients receiving other hepatic drug-metabolizing enzyme inducers.

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Initial Dosage Determination Methods.

Several methods to initiate valproic acid therapy are available

The pharmacokinetic dosing method is the most flexible of the techniques. It allows individualized target serum concentra-tions to be chosen for a patient, and each pharmacokinetic parameter can be customized to reflect specific disease states and conditions present in the patient.

Literature-based recommended dosing is a very commonly used method to prescribe initial doses of valproic acid. Doses are based on those that commonly produce steady-state concentrations in the lower end of the therapeutic range, although there is a wide variation in the actual concentrations for specific patients.

Pharmacokinetic Dosing Method

In order to select initial dosage with this method, Pharmacokinetic parameters for the patients will be estimated using average parameters measured in other patients with similar disease state and condition profiles.

Clearance estimate: Valproic acid is predominately metabolized by liver. Unfortunately, there is no good way to estimate the elimination characteristics of liver. Because of this, a patient is categorised according to the disease states and conditions that are known to change valproic acid clearance, and the clearance previously measured in these studies is used as an estimate of the current patient's clearance. This approach will avoid accendental over dosage as much as possible.

Volume of Distribution Estimate: Valproic acid volume of distribution is assumed to equal 0.15 L/kg for 0.2 L/kg for children under 12 years of age. Patients with cirrhosis or renal failure may have larger volumes of distribution as a result of decreased plasma protein binding.

Half-Life and Elimination Rate Constant Estimate: Once the correct clearance and volume of Distribution estimates are identified for the patient, they can be converted into the valproic acid half-life ($t_{1/2}$) and elimination rate constant (k) estimates using the following equations: $t_{1/2} = (0.693 V) / Cl$, $k = 0.693 / t_{1/2} = Cl/V$

Selection of Appropriate pharmacokinetic model and Equations

Maintenance dosage calculation: $Css = [F(D/T)] / Cl$ or $D = (Css \cdot Cl \cdot T) / F_T$ where F is the bioavailability fraction for the oral dosage form (F = 1 for oral rapid-release products, F = 0.9 for oral sustained-release tablets), D is the dose of valproic acid in milligrams, and T is the dosage interval in hours. Cl is valproic acid clearance in litres per hour. When intravenous therapy is required, the same pharmacokinetic equation is widely used: $Css = (D/T) / Cl$ or $D = Css \cdot Cl \cdot T$, where D is the dose of valproic acid in hours. Cl as valproic acid clearance in litres per hours.

The equation used to calculate an intravenous loading dose (LD in milligrams) based on a simple one-compartment model: $LD = Css$

Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301

Literature - Based Recommended Dosing.

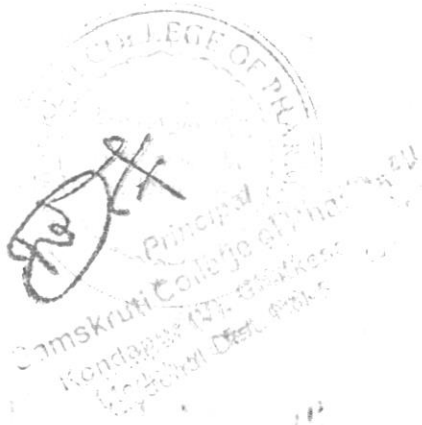
Based of the large amount of variability in valproic acid pharmacokinetics, even when concurrent disease states and conditions are identified, most clinicians believe that the use of standard valproic acid doses for various situations is warranted or necessary. The original computation of these doses were based on the pharmacokinetic dosing methods, and subsequently modified based on clinical experience with the patient

In general, the expected valproic acid steady-state serum concentrations used to compute these intial doses was 50 ug/mL. Usual initial maintanence doses for pediatric patients are 10 mg/kg/d if the child is not taking a hepatic enzyme inducer (phenytoin, phenobarbital, carbamazepine and rifampin) or 20 mg/kg/d if the child is taking a hepatic enzyme induces. For adults, initial maintenance doses are 7.5 mg/kg if the patient is not taking hepatic enzyme inducers or 15 mg/kg/d if a hepatic enzyme induces is concurrently administered.

Two or more divided daily doses are initially used for these total doses. To avoid gastrointestinal side effects, doses over 1500 mg given at one time should be avoided. Dosage increases of 5-10 mg/kg/d are made every 1-2 weeks depending on response and adverse effects. Most adults will require 1500 - 3000 mg/d of valproic acid.

If the patient has significant hepatic dysfunction

(Child - Pugh score ≥ 8), maintenance doses prescribed using this method should be decreased by 25 - 50 % depending on how aggresive the therapy is required to be for the individual.



Principal
Samskruti College of Pharmacy
Kondapur (V), Ghatkesar (M),
Medchal Dist. PIN-501301