B.Pharm SEMESTER – II
ENVIRONMENTAL SCIENCES
Subject code: BP206T
Theory (3 Hours / Week; 3 Credits, 30 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	50	25	35	15

Scope: 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.

Objectives: 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.

Course outcomes: This course provides:

CO1: Tthe knowledge of different environmental problems and its impact on society.

CO2: 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 content:

Unit-I **10hours**

- The Multidisciplinary nature of environmental studies Natural Resources
- Renewable and non-renewable resources:
- Natural resources and associated problems
- 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 **10hours**

- 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 **10 hours**

- Environmental Pollution: Air pollution; Water pollution; Soil pollution

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 Pu blishing Pvt. Ltd.,
4. Ahmedabad – 380 013, India,
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

Paper Code: 0030492001

Paper V: Environmental Studies

Course Outcome:

CO 1: To gain the basic knowledge about environment around us.

CO 2: To understand the effects of water, air and sound pollution on human life.

Unit-I:

Environmental Studies:Multidisciplinary Approach

Definition, Scope & Importance

Public Awareness about environmental studies

Unit II:

Renewable & Nonrenewable resources

Forest Resources, Water Resources, Mineral Resources, Food Resources, Energy Resources and Land Resources

Unit III:

Ecosystems: Concept, Structure and Functions of Ecosystems

Energy flow in ecosystems: Types of Ecosystems: Forest, Grassland, Deserts, Aquatic

Unit IV:

Environmental Pollution:Air Pollution, Water Pollution, Soil Pollution, Marine Pollution, Noise Pollution, Thermal Pollution & Nuclear Hazards

Solid Waste Management

Disaster Management: Floods, Earthquakes, Cyclone and Landslides

Unit V:

Field Work

Visit to Local Areas to document environmental assets – river/ forest/ grasslands/ hill/ mountains
Visit to local polluted site – Urban/rural/industrial/agricultural
Study of Simple ecosystems → Pond, river, hill-slopes etc.

Book: Textbook for Environmental Studies (For Undergraduate Coursesof all Branches of Higher Education) by ErachBharucha, University Grants Commission (2004)

Course Code: 16080202010403 **Course Category: Elective**

Course Title: Gender and Development

Credit: 02 **Contact hour/week=02**

Objectives

To enable students:

- To understand the concept, need, relevance and dimensions of gender empowerment.
- To get sensitised to gender disparities/imbalances and problems of women.
- To understand the efforts at different levels for empowering women.
- To know the support system in the country for women's development.

Contents

1. **Gender and Development:** Concept of gender, gender roles, changing trends, gender analysis matrix. Shift from welfare to development and empowerment, gender in development, gender and development. National and international efforts for gender empowerment.

2. **Status of Women:** Status - meaning, status of women – a situational analysis, demographic, education, employment, political and health (general, occupational, and reproductive). Changing scenario.

3. **Violence Against Women:** Dowry, divorce, female foeticide and infanticide, domestic violence, sexual harassment and exploitation, portrayal of women in mass media. Efforts for elimination of all forms of discrimination.

4. **Policies and Programmes for Women's Development:** National Policy for Empowerment of women, policy perspectives, mainstreaming, a gender perspective in the development process.
   Economic empowerment: Poverty eradication, micro-credit, self-help groups, women and agriculture, women and industry and support services.

Social empowerment: Education, health, nutrition, drinking water and sanitation, housing and shelter, environment.
Legal empowerment: Legal literacy on personal and family laws, role of family court and legal aid centres.
Political empowerment: Role of panchayatiraj in the political empowerment of women.

ORGANIC-PHARMACEUTICAL CHEMISTRY

C(OP)-404:ADVANCED STEREO CHEMISTRY

ELECTIVE-I

4 CREDITS

100 MARKS

Course Outcomes (COs):

- COs1: Student will be able to Generalize the concept of stereo-chemistry and reaction pathway.
- COs2: Describe the stereo chemical and conformational structure of molecules.
- COs3: Chemical reactivity and on the mechanism of organic reaction.
- COs4: Students familiar with the basic concept of stereo chemistry, which will be used for further studies.
- COs5: Providing the knowledge and in depth understanding stereochemistry, it,s effect in synthesis, behaviour of chiral compounds and properties

1. **Isomerism of Organic Compounds**
   General introduction and classification of isomerism, entiomerism, measurement of optical activity, elements of symmetry and chirality of molecule, asymmetric and dissymmetric molecules.
2. **Aliphatic Nucleophilic Substitution**
   Introduction of aliphatic nucleophilic substitution reaction.SN2 reaction mechanism and evidence.SN1 eaction, nucleophilic substitution of allylicsystems.SN1 and SN2 eactions. Rearrangement in allylic systems. Nucleophilic displacements at allylic Halides tosylates. Nucleophilic substitution at the benzylic position. Nucleophilic substitution of vinylic and aryl halides. The SNimechanism,mixed SN1and SN2 reactions. Ambidentnucleophiles, Regioselectivity, set mechanisms, neighboring group participation-Anchimer icassistance and others.
3. **Stereo Chemistry of Fused ring, bridge ring and Spirans**
   Introduction, trans-fused ring system, cis-fused ring system, spirocyclic ring system. Reactions with cyclic transition states.
4. **Stereo Selective and Stereo Regulator Polymerization.**
5. **Stereo Chemistry of N, S, P, As and B compounds.**

Reference Books

1. Organic Chemistry by I.L Finar.
2. Stereochemistry by J.P.Trivedi.
3. Stereochemistry by D.Nasipuri.
4. Stereochemistry of Organic Compounds by P.S.Kalsi (7th edition).
5. Stereochemistry of Organic Compounds byE.L.Elieil and S.H.Wilen(1994).
6. Principle of Asymmetric Synthesis by J.Aube and R.E.Gawely.
7. Stereochemistry by Dacid G. Morris (2001).
8. StereoselectiveSynthesis: A Practical Apporch by M.Nogardi, VCH.
9. Organic Chemistry Clayden, Graves, Warren, Wothers Edition 2001 Oxford University.

PHARMA-ANALYTICAL CHEMISTRY

C(PA)-304: PATENT LAWS ANS CASE STUDIES

ELECTIVE-II

4 CREDITS

100 MARKS

Course Outcomes (COs):

- COs1: Student able to use various parameter of pharma regulatory affairs to make proper documentation as per standard protocol.
- COs2: To learn various topics like SOP, ICH guidelines, GMP, GLP, Calibration and validation used in pharma regulatory affairs.
- COs3: To translate certain theoretical concepts learnt earlier into experimental knowledge by providing hands on experience of basic laboratory techniques followed by ICH guidelines.

1. **Patent Laws:** Indian and international.
2. IPRs and other related laws.
3. Patents search tools and their usages.
4. Selected topics of chemo and bio informatics tools and their applications.
5. Agreements, confidential, nondisclosure agreements.

Reference Book

1. Patents for future by N. B. Zaveri, Vakils, Feffer and Simons Ltd. Mumbai (1st edition 2001)

C-204: ANALYTICAL CHEMISTRY

4 CREDITS

100 MARKS

Course Outcomes (COs):

- COs1: The fundamental knowledge about the innovative approaches for designing of safer chemical products, processes and use of renewable resources for sustainable development.
- COs2: Students should be in a position to used analytical data in chemical sciences.
- COs3: Students understanding the principles of water and air analysis.

1. Environmental Chemistry

Concept and scope of Environmental Chemistry. Terminology and classification of environmental segments, particles, ions and radicals in the atmosphere.

Air pollution: Introduction, major sources of air pollution, air pollutants. Sources of pollutants: gaseous NOx, SOx, CO, hydrocarbons, particulates (Inorganic and Organic particulate matters). Effect of pollutants on humans, animals, materials, and vegetation.

Greenhouse effect and global warming: El Nino and La Nina phenomenon, Asian brown cloud.

Ozone layer: Creation, mechanism of depletion and its effect.

Smog: Sulphurous and photochemical smog, formation mechanism, and its control.

Analysis of air pollutants: Sampling techniques of gases and particulate, analysis of

NOx, SOx, CO, H2S, oxidants and ozone by chromatography and spectrophotometric

methods. Analysis of particulates by HVAS techniques.

Water pollution: Introduction, sources of pollutants, water pollutants, classification

of inorganic, organic, thermal and radioactive pollutants.

Analysis of water pollution: Determination of pH, conductivity, TDS, acidity, alkalinity, chloride, iron, sulphate, sulphide, fluoride, ammonia, nitrate, nitrite, calcium, magnesium, DO,BOD, COD, etc.

Soil pollution: Origin and nature of soil, sources of soil pollution, purpose of analysis. Methods of soil analysis: pH, moisture, total nitrogen, lime potential, total sulphur, manganese, iron, Na, K, Ca, Mg, etc.

2. Green Chemistry

Introduction, importance and twelve principles of Green Chemistry. Designing a green synthesis using these principles. Green Chemistry in day to day life. Green solvents (alternatives of organic solvents).

Ionic liquids, supercritical fluids, CO_2 and H_2O and aqueous phase organic synthesis.

Non-traditional greener alternative approaches: Green reagents, catalysis, biocatalysts.

Applications of non-conventional energy sources: Microwave, ultrasonic assisted synthesis, electro-synthesis and sunlight (UV) radiation assisted synthesis.

3. Analytical Chemometrics

Propagation of measurement of uncertainties, useful statistical tests: Test of significance, F- test, t-test, chisquare-test, correlation coefficient, confidence limits of mean, comparison of mean with true values. Regression analysis (least square method for linear and nonlinear plots). Statistics of sampling and detection limit evaluation. Specific study for analytical method radiation by using validation parameters: (1) accuracy, (2) precision (repeatability and reproducibility), (3) linearity and range, (4) Limit of Detection (LOD) and Limit of quantification (LOQ),(5) selectivity/specificity, and (6) Robustness and Ruggedness.

Reference Books:

1. Fundamentals of Mathematical Statistics: by S.C. Chand and V.K. Kapoor: S. Chand and Co.
2. Practical Statistics (Vol 1 and 2) by Singh, Atlantic Publishers.2003.
3. V.K. Ahluwalia, Green Chemistry: Environmentally Benign Reactions. CRC, 2008.
4. Environmental Chemistry by H. Kaur, 3rd edition Pragati Prakashan, Meerut.
5. Environmental Chemistry 7th edition by A.K.De, New Age International Publishers; New Delhi.
6. Spectroscopy 6th edition by H. Kaur, Pragati Prakashan, Meerut.
7. Environmental Chemistry by V.K. Ahluwalia Ane Books India First Edition.

FACULTY OF ARTS	
Syllabus	
Subject: -	**Sociology**
Course (Paper) Name & No. : -	**Gender & Society** **No.-01**

Course (Paper) Unique Code:							
External Exam Time Duration:			For Regular Student:				
			For External Student: 3:00				
Name of Program	**Semester**	**Course Group**	**Credit**	**Internal marks**	**External marks**	**Practical/viva marks**	**Total marks**
PG	01	Elective -1	4	30	70	00	100

Course Outcomes:

CO 1: The course seeks to account students with theoretical understanding of gender sensitization.

CO 2: It is also to get informed about the model of action for improvement of the status of women and to be aware of the diversity in values and problems of women from different part and states of India.

Course Outline:

Unit - 1 Basic concept in Gender studies

- Gender, Equity
- Women in family – socialization, Sexual division of labour
- Patriarchy

Unit - 2 Prevailing Theories

- Liberal
- Radical
- Socialist
- Feminist
- Marxist

Unit - 3 Feminist movements and Contemporary issues

- Origin of feminist movement
- Feminist Movement current trends
- Women leaders in social reform.
- Women's Right
- Violence
- Political Participation

Unit - 4 Gender and media

- Marginalisation of Women
- Print media and women
- Audio visual media and women

Recommended Books:

1. Whelham Imelda: Modern Feminist Thought, Edingurgh University press, Edinburgh 1997.
2. Myers Kristen-Anderson : Feminist Foundations; Towards Transforming Sociology, Sage, New Delhi,1998.
3. V. Geetha and Rajadurai S. V.: Towards a non-Brahmin Millenieum, Samya, Culcutta 1998.
4. Omevedt gail : Phule and the Women's Question in India,Monograph, Whole Book.
5. Clarke Alice : Gender and Political Economy, New Delhi,1995.
6. Sarkar Tanika & Urvashi Butalia : Women and the Hindu Right, Kali for Women, New Delhi, 1995.
7. Vaid Sudesh & Sangari Kumkum: Recasting Women; Essays in Colonial History, Kali for Women, New Delhi, 1989.

8. Chakravati Uma: Rewriting History, Kali for Women, New Delhi, 1998.
9. Kumar Radha: History of Doing, Kali for Women, New Delhi,1993.
10. SatyaMurthy T. V. : Region, Religion, caste, Gender and Culture in Contemporary India, New Delhi, 1996.
11. Tharya Susie & Lalitha K. : Women writing in India, Vol. II, : The feminist press, New York, 1993.
12. Mies Maria & Shiva Vandana : Eco-Feminism, Kali for Women, New Delhi, 1993.
13. Krishnaraj Maitreyi : Concept Series, vol. I, II and III, S.N.D.T., Mumbai, 1989.
14. Gandhi Nandita & Shah Nandita : Issues at Stake, Popular Prakashan, Mumbai, 1992.
15. Sen Illina : Space within the struggle, Kali for Women, New Delhi,1992.
16. Krishnaj Maitreyi: Gender, Population and Development, New Delhi, 1998
17. Patil Sharad : Dasa-Shudra Slavery, Sugawa Prakashan, Pune, 1991.

Course (Paper) Name & No. : -			**Environment & Society** **No.-03**				
Course (Paper) Unique Code:							
External Exam Time Duration:			**For Regular Student: 2:30**				
Name of Program	**Semester**	**Course Group**	**Credit**	**Internal marks**	**External marks**	**Practical/viva marks**	**Total marks**
PG	03	Elective -1	4	30	70	00	100

Course Outcomes:

CO 1: The course plan aims to provide knowledge and scholarship of sociological basis of environment and society interface.
CO 2: It seeks to impart social skills in environmental concerns in order to understand the human suffering.
CO 3: As a prelude to it, the course focuses on "Environment in Sociological Theory", both classical and contemporary.
CO 4: The course also aims at providing knowledge of the debate on environment and development with a focus on environmental justice, policy and action.
CO 5: The study of inter connections between environment and society has gained in enormous significance in recent times on account of the debilitating effects on the environment and society.
CO 6: The course is designed to focus on the environmental issues in the perspective of environmental Sociology.

Course Outline:

Unit – 1

- **Environmental Sociology**

Definition - Nature - scope

Unit – 2

- Environment Movement

Narmada, chipco

- Sustainable development
- Ecological balance
- Costal Management

Unit – 3

- Natural Resource Management in Gujarat
- Water, Sanitation, Pollution, renewable Energy
- Environment Problems
- Environmental justice, policy and action

Unit – 4

- Social impact assessment of environmental issues
- Agenda - 21 -.
- Natural resources - Forest, Water and Land

Recommended Books:

1. Arnold. D. and Guha R.: Nature Culture and Imperialism, Essays on the Environmental History of India, Sage Publications pvt. ltd., New Delhi, 1995.
2. Bandhopadhyay J. (ed.): India's Environment, Crisis and Response
3. Chambers. R. et al. To the hand of the poor, water and trees, Natraj, 1985.
4. Centre for Science and Environment ;85 Second citizens report, CSE, New Delhi, 1984.
5. Centre for Science and Environment: Flood, Flood plains and Environmental Myths, CSE, New Delhi, 1991.
6. Centre for Science and Environment: The fifth Citizens report, CSE, New Delhi, 1997.
7. Centre for Science and Environment; The state of India;s Environment, Dying Wisdom : Rise and Fall and Potential of India's Traditional Water Harvesting Systems, CSE, New Delhi, 1999.
8. Desai Murli, Anhjali Monteiro and Lata Narayan (ed.): Towards a People Centered Development, Part II, TISS, Mumbai, 1998.
9. Fernances W. and Menon G.: Tribal Women and Forest Economy, Deforestation, Exploitation and Social change, Indian Social Institute, Tribes of India, Series 1, New Delhi.
10. Giddens. A. The Consequence of modernity, Polity press, U.K., 1990.
11. Goldblatt. D.: Social Theory and Environment, Polity press, U.K., 1996.
12. Guha Ramchandra, Gadgil Madhav: This Fissured Land, Oxford University Press, Delhi, 1993.
13. Jan Nederveen Pieterse: Development theory, Sage, 2001.
14. Jaffery Roger and Sundaran Nandini (ed.): A new moral economy for India's Forests. Sage Publications Private ltd., Delhi, 1999.
15. Kothari Ashish, Pathak Neema, R. V. Anuradha, Taneja Bansuri (ed.): Communities Conservation - Sage. Delhi, 1998.
16. Singh Satuajit: Taming the Water. Oxford University press, New Delhi, 1997.
17. Maccully Patrick: Silenced Rivers the Ecology and Politics of large Dams. Orient Longman, New Delhi, 1998.
18. Pepper Devid (ed.): The Roots of Modern Environmentalism Routledge, London, 1986.
19. Siva. V.: Ecology and the Politics of Survival, Sage Publication, 1991.

Subject: Economics

Course Name : **Environmental Economics: Theories** No.: **CORE-III_09**

Course Unique Code: 1601250102030900

Semester End Exam Time Duration: Regular 2:15 hrs . External 3.00 hrs.

Name of Program	Semester	Course Group: Foundation / Core/ Elective/ Inter Disciplinary/ Practical / Project	Credit	Internal Marks	External Marks	Practical / Viva Marks	Total Marks
M.A.	III	Core	4	30	70	-	100

Course Objectives:-

C.O._1 This course in meant to acquaint student with the basic Theories of environment economics so that they can develop and use appropriate theoretical frame to analyze and understand important environmental issues.

Course Contents:

Unit-1 : Environmental Economics : Meaning, Nature and Scope: Meaning of environment economic; various definitions; relationship between mainstream economics and environment economics: nature of environmental economics: its positive and normative aspects: interdisciplinary nature of environmental economics: relationship of environmental economics with other disciplines.

Unit-2 : Market Failure Decision making: Market efficiency and Parato-optimality; Market failure possibilities with reference to environmental resources; the reasons for market failure: externalities and problem of cost-internalization; public goods and common-property type nature of environmental resources. Unclear property right, informational asymmetries and possibities of missing markets.

Unit-3 : Environment and Development: Relationship between environment and development: Theory of sustainable development and problems of operational sing this Theory; indict/s and rules of sustainability methods of environmental valuation; integration of national and environmental accounting.

Uniti-4 : Optimal Use of Environmental Resources: Application of Capital Theory for the optimal use of environmental resources, Theories for the use of non-renewable resource; Theories for the use of renewable resources.

Text and Reference Books:

1. Ayres, R.U. and Leslie Ayres, (1998), Accounting of Resources Vol-1, Edward Elgar,
2. Bhattacharya Ravindra, N. (ed.) (2001), Environment economics, Oxford University Press.
3. Callan, J.S. and Janet M.T. (1996), Environment Economics and Management : Theory, policy and Applications, IRWIN.
4. Field, Barry, C. (1997), Environmental Economics: An Introduction, McGraw-Hill International Edition.
5. Dasgupta, P., (1982), The Control of Resources, Oxford University Press.
6. Kerr, J.M. and Other (1997), Natural Resource Economics, Oxford and IBM publishing Co. Pvt. Ltd, Delhi.
7. Hanley, N. and Other, (1997), Environment Economics in Theory and Practice, Macmillan.
8. Kulastand, C.D. (1999), Environment Economics, Oxford University Press, New Delhi.
9. Parikh, Jyoti and Kirit Parikh, (1997), Accounting and Vitiation of Environment, John Hopkins University, New York.
10. Pears, D.W. and R. Turn/, (1991), Economics of Natural Resource Use and Environment, John Hopkins University, Baitimore.
11. Shankar, U, (Ed.) (2001), Environment Economics, Oxford University Press, New Delhi.
12. Sengupta, R. (2001), Ecology and Economics: An Approach to Sastainable Development, Oxford University Press.
13. Singh, K. (1994), Managing Common Pool Resources: Principles and Practices, Oxford University Press.

Course Name : **Environmental Economics: Issues and Policies** No.: **CORE- IV_12**

Course Unique Code: 1601250102041200

Semester End Exam Time Duration: Regular 2:15 hrs . External 3.00 hrs.

Name of Program	Semester	Course Group Foundation / Core/ Elective/ Inter Disciplinary/ Practical / Project	Credit	Internal Marks	External Marks	Practical / Viva Marks
M.A.	IV	Core	4	30	70	-

Course Objectives:-

C.O._1 The main Objectives of this course is to appraise and sensitive student about major environment issues of India and develop skill to analyze them with the help of appropriate theoretical frames.

Course Contents:

Unit-1 : Environment Issues of Primary sector : Changing land-use and cropping pattern and environmental issues; the problem of grazing-land, pasture and live stock. management; The problem of conservation of forests and bio-diversity; supply and quality of ground-water and its management; the conservation and management of marine fish.

Unit-2 : Industrial Development and Environmental Issues: Change in growth and structure of industries in India; growth of pollutant industries, problem of air and water pollution, management of solid and liquid wasters.

Unit-3 : International Environment Issues: The problem of trans boundary pollution : global warming and acid rain: globalization, international trade and environmental issues : The problem of trade of hazardous waste endangered species and medicinal plants, the problem of patenting, trade and environment in WTO system.

Unit-4 : Environmental Policy in India: Growth of environmental policy in India; Importantenvironmental laws, international environment agreements and India's approach: mechanism of implementation of environment laws in India.

Text and Reference Books:

1. Baumal, W.J. and Oates, 1998, The Theory of Environmental Policy, Cambridge University Press, Cambridge.
2. Chari, S.N. and Vyasalu, Vinod. 2000. Environment mamngement : An Indian Perspective, McMillan India Ltd.
3. Chhatrapati Singh, 1986, Common Property and Common Poverty, India's FORest, FORest Dwellers and the Law, Oxford University Press.
4. Dasgupta, P. and Maller Karl, 1997, The Environment Emerging Developing Issues, Vol.-I and Vol-
   -II, Clareden Press, Oxford.
5. Gadgil, M. and Guha, R., 1993, The Fissured Land : An Ecological Hist/y of India, Oxford University Press.
6. Katar Singh, 1994, Managing Common Pool Resources, Principles and Case Studies, Oxford University Press.
7. Murthy, M.N. James, A.J. and Smita Misra, 1999, Economics of water

pollution, Oxford University Press.
8. Lead India, 2002, Rio, Johniburg and Beyond : India's Progress in Sustainable Development, /ient Longman, New Delhi.
9. Ramprasad Sengupta, 2001, Ecology and Economics, Oxford University Press.
10. Syam Diwam and Arman, R., 2001, Environmental Law and Policy in India, Oxford University Press.

Course Name : **Economics of Gender and Development** No.: **ICT-III_1.4**

Course Unique Code: 1601250502030104

Semester End Exam Time Duration: Regular 2:15 hrs . External 3.00 hrs.

		Course Group				

Name of Program	Semester	Foundation / Core/ Elective/ Inter Disciplinary/ Practical / Project	Credit	Internal Marks	External Marks	Practical / Viva Marks
M.A.	III	Inter disciplinary	4	30	70	-

Course Objectives:-

C.O._1 Gender biases in societal practices and development polices have resulted in persistent gender inequalities.

C.O._2 It is increasingly being realized that mitigating such inequalities and enhancing women's capabilities and entitlements are crucial to the overall development of the country.

C.O._3 This course, **Economics of Gender and Development** will provide students understanding of nature of the economic role f women and their contribution to the national economy and economic development on the basis of scientific and non-sexist analysis.

C.O._4 Specificity of issues pertaining to India be highlighted while teaching.

Course Contents:

Unit-I: Importance and Concepts of Women Studies — Women in Patriarchal and Matriarchal Societies and Structures, Patriarchal and Matrilineal Systems and Relevance to Present Day Society in India; Economic Basis and Functioning of Patriarchy in Developed and LDCs, Particularly India; Gender Bias in the Theories of Value, Distribution, and Population.

Unit-II: Demography of Female Population: Age Structure, Mortality Rates, and Sex Ratio — Causes of Declining Sex Ratios and Fertility Rates in LDCs and particularly in India — Theories and Measurement of Fertility and its Control; Women and their Access to Nutrition, Health, Education, and Social and Community Resources, and their Impact on Female Mortality and Fertility.

Unit-III: Factors Affecting Decision Making by Women; Property Rights, Access to and Control over Economic Resources, Assets; Power of Decision Making at Household, Class, Community Level; Economic Status of Women and its Effect on Work-participation Rate, Income Level, Health, and Education in Developing Countries and India; Role of Kinship in Allocating Domestic and Social Resources. Factors Affecting Female Entry in labour Market; Supply and Demand for Female Labour in Developed and Developing Countries, particularly India; Studies of Female Work Participation in Agriculture, Non- agricultural Rural Activities, Informal sector , Cottage and Small-scale Industries, organized Industry, and Services sector ; Wage Differentials in Female Activities; Determinants of Wage Differentials; Gender, Education, Skill, Productivity, Efficiency, Opportunity; Structures of Wages Across Regions and Economic sector s.

Unit-IV: Concept and Analysis of Women's Work: Valuation of Productive and Unproductive Work; Visible and Invisible Work; Paid and Unpaid Work; Economically Productive and Socially Productive Work — Economic Status, Private Property, and

Participation of women in Pre-industrial and Industrial Societies — Female Contribution to National Income.

Text and Reference Books:

1. Agnihotri, S.B.: Sex ratio in Indian Population: A Fresh Exploration.
2. Boserup E.: Women's Role in Economic Development.
3. Desai, N. and M.K. Raj. (Eds.): Women and Society in India.
4. Government of India: Towards Equality — Rep/t of the Committee on the Status of Women in India, Department of Social Welfare, Ministry of Education and Social Welfare, New Delhi.

Course Name : **Economics of Gender and Development** No.: **ICT-III_1.4**

Course Unique Code: 1601250502030104

Semester End Exam Time Duration: Regular 2:15 hrs . External 3.00 hrs.

Name of Program	Semester	Course Group: Foundation / Core/ Elective/ Inter Disciplinary/ Practical / Project	Credit	Internal Marks	External Marks	Practical / Viva Marks
M.A.	III	Inter disciplinary	4	30	70	-

Course Objectives:-

C.O._1 Gender biases in societal practices and development polices have resulted in persistent gender inequalities.

C.O._2 It is increasingly being realized that mitigating such inequalities and enhancing women's capabilities and entitlements are crucial to the overall development of the country.

C.O._3 This course, **Economics of Gender and Development** will provide students understanding of nature of the economic role f women and their contribution to the national economy and economic development on the basis of scientific and non-sexist analysis.

C.O._4 Specificity of issues pertaining to India be highlighted while teaching.

Course Contents:

Unit-I: Importance and Concepts of Women Studies — Women in Patriarchal and Matriarchal Societies and Structures, Patriarchal and Matrilineal Systems and Relevance to Present Day Society in India; Economic Basis and Functioning of Patriarchy in Developed and LDCs, Particularly India; Gender Bias in the Theories of Value, Distribution, and Population.

Unit-II: Demography of Female Population: Age Structure, Mortality Rates, and Sex Ratio — Causes of Declining Sex Ratios and Fertility Rates in LDCs and particularly in India — Theories and Measurement of Fertility and its Control; Women and their Access to

Nutrition, Health, Education, and Social and Community Resources, and their Impact on Female Mortality and Fertility.

Unit-III: Factors Affecting Decision Making by Women; Property Rights, Access to and Control over Economic Resources, Assets; Power of Decision Making at Household, Class, Community Level; Economic Status of Women and its Effect on Work-participation Rate, Income Level, Health, and Education in Developing Countries and India; Role of Kinship in Allocating Domestic and Social Resources. Factors Affecting Female Entry in labour Market; Supply and Demand for Female Labour in Developed and Developing Countries, particularly India; Studies of Female Work Participation in Agriculture, Non- agricultural Rural Activities, Informal sector , Cottage and Small-scale Industries, organized Industry, and Services sector ; Wage Differentials in Female Activities; Determinants of Wage Differentials; Gender, Education, Skill, Productivity, Efficiency, Opportunity; Structures of Wages Across Regions and Economic sector s.

Unit-IV: Concept and Analysis of Women's Work: Valuation of Productive and Unproductive Work; Visible and Invisible Work; Paid and Unpaid Work; Economically Productive and Socially Productive Work — Economic Status, Private Property, and Participation of women in Pre-industrial and Industrial Societies

— Female Contribution to National Income.

Text and Reference Books:

5. Agnihotri, S.B.: Sex ratio in Indian Population: A Fresh Exploration.
6. Boserup E.: Women's Role in Economic Development.
7. Desai, N. and M.K. Raj. (Eds.): Women and Society in India.
8. Government of India: Towards Equality — Rep/t of the Committee on the Status of Women in India, Department of Social Welfare, Ministry of Education and Social Welfare, New Delhi.

WOMEN WELFARE

Course Outcome :-

CO1.To get knowledge about the status of women in through the ages

CO2.To understand different types of violence emerging against women

CO3.TO understand the problems of rural womwen

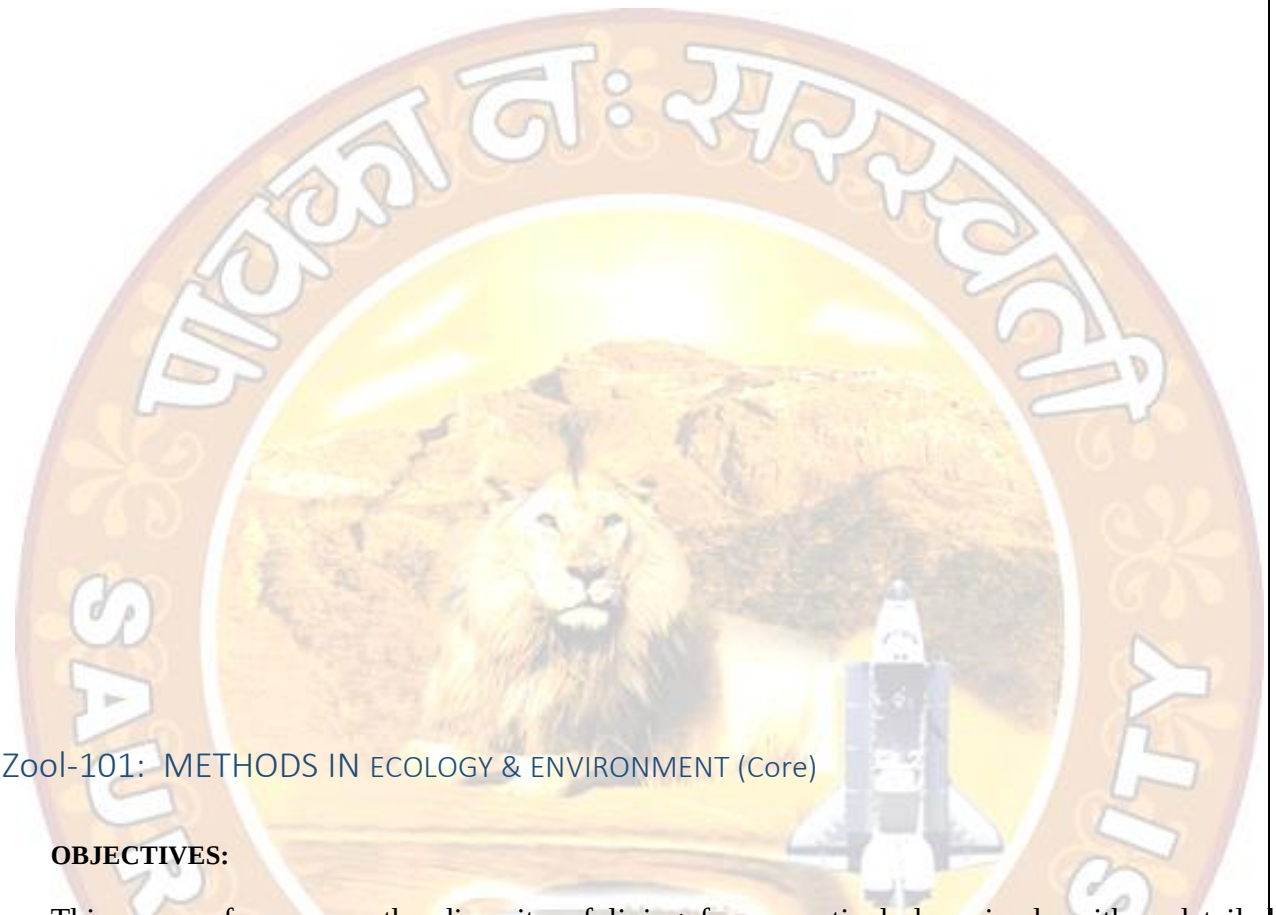
103.3 Rural women

– their problems

Rural women – their problems

– role of education in the development of rural women. Women and health –

health statistics – material health services – nutrition and Sanitation – family welfare.



Zool-101: METHODS IN ECOLOGY & ENVIRONMENT (Core)

OBJECTIVES:

This course focuses on the diversity of living forms particularly animals with a detailed inference on the loss of species due to various reasons and the need of their conservation. It will give a brief introduction to the atmosphere and ocean circulation. Interaction between biomes can be understand by this course content.

COURSE OUTCOME:

CO-1: Develop understanding on the concept and issues of global environmental change.
CO-2: Analyse the causes and effects of depletion of stratospheric ozone layer.
CO-3: Examine the climate change and its effect on living beings.
CO-4: Understand the physical basis of natural green gashouse effect on man and materials.
CO-5: Evaluate human influenced driver of our climate system and its applications.
CO-6: Know the biotic and abiotic components of ecosystem.
CO-7: Food chain & food web in ecosystem.
CO-8: Understand diversity among various groups of animal kingdom.
CO-9: Understand Animal community & ecological adaptation in animals.
CO-10: Scope, importance and management of biodiversity.
CO-11: Engage in field-based research activities to understand well the theoretical aspects taught besides learning techniques for gathering data in the field.

CO-12: Analyse a biological problem, derive testable hypotheses and then design experiments and put the tests into practice.
CO-13: Solve the environmental problems involving interaction of humans and natural systems at local or global level.

Unit-1: Methods in Biodiversity & Biosystematics

1.1 Classical Taxonomy, Molecular Taxonomy
1.2 Sampling and sampling techniques
1.3 Animal diversity, Diversity indices
1.4 Animal distribution

Unit – 2 : Methods in Population Ecology

2.1 Population types
2.2. Population dynamics
2.3 Field Sampling and sampling techniques
2.4 Measurements of population indices.

Unit – 3 : Community Ecology

4.1 Community concept, structure, Keystone species
4.2 Community Indices, Assemblage & Assemblage structure
4.3 Terrestrial communities
4.4 Wetland and Marine communities

Unit - 4. Environmental Pollution & EIA

4.1. Environmental Pollution, EIA: Monitoring Methods & techniques
4.2. Risk assessment selection methods, experimental design.
4.2 Bioassay Methods
4.3 Toxicity assessment methods

EBC 2: PHARMACEUTICAL BIOCHEMISTRY AND REGULATORY AFFAIRS

Objectives:

- To study the drug development process, absorption and metabolism
- To develop a concept of drug action, receptor interaction, roll of enzyme in stimulation or inhibition of drug activity.
- To understand the lethal and effective dose of drug; Mechanism of drug delivery systems.
- To study the different guidelines for manufacturing of drugs.
- In-depth study of intellectual property rights

Course Outcome:

CO 1: Gain detail understanding of how drug act inside the body after absorption from intestine in to blood.

CO 2: Understanding of factors that affect drug absorption, interaction with target receptors and inhibition of enzymes.

CO 3: Understanding of process of product registration and different guidelines which control the manufacturer to follow correct strategy for manufacturing of drug.

CO 4: Learn how to write and file the patent; how to document clinical data of the concern drug research.

UNIT 1: Pharmacokinetics

Introduction to Drug Absorption, Deposition, Drug Metabolism And Elimination, Important Pharmacokinetics Parameters In Defining Drug Disposition and In Therapeutics, Uses of Pharmacokinetics In Drug Development Process, Concept of Prodrug and Soft Drug

UNIT 2: Pharmacodynamics

Introduction, Concept of Receptor Agonists and Antagonists, Drug Receptors Interactions, Theories of Drug Activity Relationship, Treatment of Diseases by Enzyme Stimulation and Enzyme Inhibition, Elementary Treatment of Drug Receptor Interaction, Ld50, Ed50, Mic and Mec etc. (Mathematical Derivations of Equation Excluded), Membrane Active Drugs (Sulphonamides). Mechanisms of Drug effects, Drug Delivery Systems e.g. Liposomes

UNIT 3: **Regulatory Affairs**

Pharmaceutical Products-their Manufacturing, Analytical Aspect, Product Registration and their Requirement looking to WHO-GMP, European DMF, US-FDA Regulations, ICH Guidelines, Pharmacopael and Extra Pharmacopaeal Entry

UNIT 4: Intellectual Property Rights

Documentation Required for Filing Patent, Chemical, Physical and Biological (Clinical) Data Documentation, Patent Writing Art and Introduction of Concept of Non-infringing Patent Ability, Looking to GATT-WTO Scenario, Computer Based Data Mining in Drug Research, Pharmaceutical Product Management Aspect

REFERENCES

1. Pharmacology by Rang and Dele
2. Biochemistry and Molecular Biology of Antimicrobial Drug Action by Franklin, T. J. & Snow, J. A.
3. Pharmacology by S D Seth
4. Pharmacology by Tara V Shahbhag
5. Pathology by Edward
6. Pharmacology by M C Prabhakar
7. Pharmacology by Arvind Arora

BT 314: ENVIRONMENTAL BIOTECHNOLOGY [ELECTIVE I]

Objectives:

To study usefulness of biotechnology in the field of bioremediation and biodegradation.

To study biotechnological and microbial approaches used in environmental sustainability, agriculture, and various other fields.

To understand biodiversity, so as to develop better methodologies and formulations to be used at local level

Course outcomes:

CO1: Students will learn to count on the biological/ renewable resources and sustainable approaches in various fields like agriculture, energy production and recycling of the waste material.

CO2: Approach will be developed to conserve the non-renewable resources and the environment, and to think about more and more use of biological/renewable, non-hazardous resources.

CO3: Students will be exposed to the approaches of the production and post-production processing using the biological material so as to lessen the burden of the pollutants generated by the industrial processes.

Unit 1: Environmental impact and Biosensors

- Reducing environmental impact of industrial effluents Toxic site reclamation, removal of spilled oil and grease deposits. Microbial degradation of textile dyes, timber petroleum products, leather plastics and food product
- Biosensors, recent approaches and applications

Unit 2: Bio fertilizers

- Use of mycorrhizae in reforestation and aforestation
- Biofertilizers and biopesticides

- Role of Dienococcus sp. in bioremediation of radioactive waste. Molecular mechanisms of radiation resistant

Unit 3: Environment and energy

- Renewable source of energy: Biomass production and Biogas production. Generation of energy and fuel using microorganisms (Hydrogen production and Methane production)
- Brief account of alternative energy source: Biofuel etc.
- Conservation of energy: Global Warming and carbon credit
- Heavy metals and its effect on microbes and higher organisms

Unit 4: Biodiversity

- Biodiversity & species concept
- Benefits from Biodiversity
- Factors threatening Biodiversity
- Endangered species management & Biodiversity protection

References:

1. Alexander, M. Biodegradation and Bioremediation, Academic Press, 1994.

2. Arceivala, S.J. and Asolekar, S.R., Wastewater treatment for Pollution Control and Reuse, 3rd edition, Tata McGraw Hill, 2007.

3. Atlas, R.M. and Bartha, R. Microbial Ecology, 4th edition, Pearson Education, 2009.

BOT 209: ENVIRONMENTAL SCIENCE

Course Outcome:

CO1: This course creates awareness among students on conservation and judicial use of plant species.

CO2: It helps students to understand the significance of each plant species available in specific geographical region.

CO3: This helps students to get job in plant conservation centers, seed banks, botanical gardens etc.

UNIT 1: Environment

Definition, principles and Scope of Environmental science. Earth, Man and Environment, Ecosystems, Pathways in Ecosystems, Physico-chemical and Biological factors in the Environment, Geographical classification and zones. Structure and composition of atmosphere, hydrosphere, lithosphere and biosphere. Scale of Meteorology, pressure, temperature, precipitation, humidity, radiation and wind. Atmospheric stability, inversions and mixing heights, windroses.

UNIT 2: Ecosystem

Definition, Principles and scope of ecology, Human ecology and human settlement, Ecosystems: Structure and functions, abiotic and Biotic components, food chains, food web, ecological pyramids, population, community ecology and parasitism, prey-predator relationships, Biomes of the world. Overview of Sanctuaries, National park and Botanical garden.

UNIT 3: Pollution

Air: Natural and anthropogenic sources of pollution, primary and secondary pollutants, Transport and diffusion of pollutants. Gas laws governing the behavior of pollutants in the atmosphere. Methods of monitoring and control of air pollution SO2, NOx, CO, SPM. Effects of pollutants on

human beings, plants, animals, materials and on climate, Acid rain, Air Quality Standards. Water: Types, Sources and consequences of water pollution, physic-chemical and bacteriological sampling and analysis of water quality. Standards, sewage and waste water treatment and recycling. Water quality standard. Soil: Physico-chemical as bacteriological sampling as analysis of soil quality, Soil pollution control, Industrial waste effluents and heavy metals, their interactions with soil components. Degradation of different insecticides, fungicides and weedicides in soil. Soil organic and inorganic components. Global Environmental problems: Ozone depletion, global warming and climatic change, clean development mechanism.

UNIT 4: Environmental Impact Assessment

Introduction to environment impact analysis, Environmental impact statement and environmental management plan, Impact Assessment methodologies. Generalized approach to impact analysis. Procedure for reviewing environmental impact analysis and statement. Principles of Remote sensing and its applications of environmental sciences, Application of GIS in Environmental management.

REFERENCES

1. Environmental Science – Y.K. Singh

A textbook on Environmental Science by D. Som and N. Gaurav

M.A. Semester – 4 – ECT - 05 Feminism and Gujarati Literature (OPTIONAL)

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage For Internal Examination	Weightage For Semester End Examination
Provide Sub. Code	Prog. In C & Numerical Methods	4	4	30	70
ECT-05 - 1601010202040401	Feminism and Gujarati Literature (OPTIONAL)	4	4	30	70

Course Outcomes

ECT - 05 Feminism and Gujarati Literature: (Optional)

CO1 An introduction to Feminist Gujarati literature.

CO2 Some feminist Gujarati literary texts can be studied.

Course Content

ECT – 05 Feminism and Gujarati Literature (OPTIONAL)

UNIT – 1 : Feminism : Nouns, Concept and Symptoms

UNIT – 2 : Feminist Gujarati Literature

UNIT – 3 : Narichetnani Navlikao (Raghuvir Chaudhari)

UNIT – 4 : Fargati (Paresh Nayak)

PHILOSOPHY COURSE : IX – ECT – 03

ETHICS (WESTERN)

Objectives:

The course is aimed as to be covered as a one semester course with 60 hours classroom work. The purpose is to give a comprehensive understanding of classical Western Ethics with some implications of contemporary ethics. The requirement is the familiarity with classical texts and some articles in Ethics.

Course	Unit	Sub – Unit	Credit
9 Ethics (Western)	9.1 Ethics nature scope and Hedonistic theories.	9.1.1 Nature and scope of Ethics. 9.1.2 Statement of fact and statement of Values. 9.1.3 Psychological and Ethical Hedonism. 9.1.4 Utilitarianism of Mill.	4
	9.2 Rationalistic Ethics.	9.2.1 Ethics and rationality. 9.2.3 Kant's moral theory. 9.2.3.1 Categorical imperative. 9.2.3.2 Duty for duty's sake.	
	9.3 Intuitionalist Ethics	9.3.1 Ethics and perfectionastic view. 9.3.2 Bradley's metaphysical Ethics.. 10.3.2.1 My station and its duties.	
	9.4 Contemporary Ethics.	9.4.1 Moore's undefiniability of Good. 9.4.2 Emotivism in Ethics. 9.4.2.1 Ayer's emotive theory. 9.4.2.2 Stevenson's Emotive meaning of Ethics terms. 9.4.3 Sartra's concept of Human freedom and bad faith.	

Subject: LIBRARY & INFORMATION SCIENCE

Course Name & No.: INFORMATION SOURCES, SERVICES AND

SYSTEMS IN

HUMANITIES & SOCIAL SCIENCES

Course Unique Code: 1901340302010101

External Exam Time Duration: 2.5 Hours

Name of the Program	Semester	Course Group	Credit	Internal Marks	External Marks	Practical/ Viva Marks	Total Marks
M.Lib.I.Sc	1	Elective-1	4	30	70	00	100

[Structure of Semester-end Examination: Total 5 Questions with internal options. Q 1 to 3 Descriptive [Essay, Analytical and Definitional type] Q 4 & 5: Short and One to two line answers] Total Marks: **70.** Time **2.5 Hours.]**

[Structure for Internal Evaluation: A report on Information Sources of any one selected Discipline**]**

Objectives of the Course :

- To understand the structure and development of the specific subject / discipline in Humanities & Social Sciences.
- To prepare specialised professional manpower in the specific subject / discipline in Humanities & Social Sciences

Course Outcomes :

After studying this course, students shall be able to:

CO: 01. Comprehend structure and development of Humanities and Social Sciences.

CO: 02. Explore various disciplines in the field of Humanities and Social Sciences.

CO: 03. Understand information sources, services and systems of Humanities and Social Sciences

CO: 04. Highlight the role of available databases in these fields.

CO: 05. Plan and design databases in Humanities and Social Sciences when required

CO: 06. Carry out professional services in the libraries of Humanities and Social Science institutions

Course Contents :

Unit-1 Study of the specialized subject / discipline

- Structure and development of the subject/ discipline

- Definition, Terminology,
- Branches and Landmarks in the subject / discipline

Unit-2 Information Systems

- Planning, Design and Evaluation of Information Systems

Unit-3 Database Design

- Database Design, Creation and Development in the area pertaining to information components of the subject, study of data structure
- Selection of DBMS and Retrieval aspects
- Content creation and development

Unit-4 Information systems and networks in the subject / discipline

- Study of information sources services
- Internet – based sources & services

COURSE OUTCOMES

- To create understanding about need for the business ethics in recent time for the sustainability of business in long run and developing a mindset of students for the ethical decision making.
- It also enables students to understand the importance of transparent business practices through corporate governance.

COURSE CONTENT

Unit - 1	Introduction to Ethics
	Meaning and concept of Ethics, Types of Ethics, Advantages of Ethical Practice, Ethical Behaviour, Ethical Issues, Ethical Dilemma, Whistle Blowing, Theories of Ethic, Ethics from Ramcharit manas and mahabharat, manusmruti and shukraniti, business ethics from mahabharat, manusmruti and shukraniti
Unit – 2	Ethics in Business and Management
	• Business Ethics, Scope of Business Ethics, Elements of Business Ethics, importance of ethics in business, Ethical Organisation • Ethics in different managerial functions: ethics in Finance, ethics in Marketing, Ethics in Human Resource management and ethics in information Technology
Unit - 3	Corporate Social Responsibility
	Meaning of CSR, Need for CSR, Current state of CSR in India, four faces of Social Responsibility, Types of Social Responsibility, Changing expectations of social responsibility, arguments for and against CSR, Gender sensitivity as ethical issue, Framework of Social Orientations, CSR Principles and Strategies, legal aspect of CSR in India
Unit – 4	Business Ethics in Global Economy
	Ethical perceptions and international Business, Global Values, Various Ethical Issues around the Globe, Cross Cultural Issues, Cross religion and Cross Racial Issues, indian values for globalization.
Unit – 5	Corporate Governance
	• Concept, need and importance of Corporate Governance, corporate governance and Agency theory, models of Corporate Governance, various committees and their recommendations of Corporate Governance, ancient indian concept of governance • Corporate Governance in India, Board of Directors, Appointment, Duties/role & Responsibilities of Directors, current Scenario of Corporate Governance in India

TEXT BOOKS

- Dr. N.m.Khandelwal,: Ethics and Indian Ethos for management, Pacific university, Udaipur.
- K. Nirmala, B.A. Karunakara Reddy and N. Aruna Rani, Business Ethics and Corporate Governance, Himalaya Publishing House, 1st Edition, 2015
- C.S.V. Murthy, Business Ethics and Corporate Governance, Himalaya Publishing House, 1st edition, 2014
- S. K. Mandal, Ethics in Business and Corporate Governance, Tata McGraw-Hill Education Pvt. Ltd, 2nd edition, 2012

REFERENCE BOOKS

- C.S.V. Murthy, Business Ethics Text & Cases, Himalaya Publishing House, 2nd edition, 2015
- Riya Rupani, Business Ethics and Corporate Governance, Himalaya Publishing House, 4th revised edition, 2015
- Dr.S.S.Khanka, Business Ethics and Corporate Governance, S.Chand, 2013.
- A.C.Fernando: Corporate Governance, Principles, Policies and Practices, Pearson, 2012.
- N.Bala subramanian : Corporate Governance and Stewardship, Tata McGraw-Hill Education Pvt. Ltd ,2012.
- D. Geeta Rani and R. K. Mishra, Corporate Governance Theory and Practice, Excel Books, 1st edition, 2008
- Hitesh J. Shukla, Corporate Governance in India, Saurashtra University, 2007

Subject :	**Master of Social Work**		
Course (Paper) No.	**25**	**Name:**	**Environment And Population**
Course (Paper) Unique Code		**Core**	1601510102041100
External Exam Time Duration		**02:30 Hours**	

Name of Program	**Semester**	**Course Group** **Foundation/ Core/ Elective-1/ Elective-2/ Practical/ Project**	**Credit**	**Internal Mark**	**External Mark**	**Practical Viva mark**	**Total marks**
Master of Social Work	04	Core	4	30	70	-	100

Course Outcomes:

CO1-Understand characteristics, determinants of population growth.

CO2-Examine population policy, plan and initiatives.

CO3-Understand inter-relatedness of human life, living organisms and environment.

CO4-Examine utilization and management of resources.

CO5-Develop skills to participate in activities related to the two areas.

Course Contents:

UNIT	**UNIT TITLE**	**DESCRIPTION**	**TEACHING METHOD**	**WEIGHTAGE OF PAPER**
1	Characteristics of population:	➢ Population, determinants of growth. Global concerns - Characteristics of Indian Population – Distribution by age, sex, literacy and occupation – Fertility trends - Birth and death ratio. ➢ Population Policy, World Action Plan, population Policy of India- Implementation	Lecture Assignment and discussion	20%
		➢ Initiatives – Government and NGO.		

2	Family Planning:	➢ Objectives, scope, methods, Implementation, mechanisms and progress. ➢ Concept and Scope of Population education, family life education, sex education, and family planning education. ➢ Population and Environment: ➢ Interrelatedness of human life, living organisms ➢ Environment and natural resource – Environment, lifestyle, degradation. ➢ Environment management, maintaining, improving, enhancing – Current issues of Environment.	Lecture Assignment and Group work	20%
3	Environmental Ethics: Issues And Possible Solutions	➢ Resource consumption patterns and the need for their equitable utilization ➢ Equity – Disparity in the Northern and Southern countries ➢ Urban – rural equity issues ➢ The need for Gender Equity ➢ Preserving resources for future generations ➢ The ethical basis of environment education and awareness ➢ The conservation ethic and traditional value systems of India	Lecture Assignment Group Work and Self Study	20%
4	Natural Resources and Diversity:	➢ Utilization and management – Forest, land, water, air, energy sources - Pollution - Sources, treatment, prevention - Soil, water, air, noise - Waste matter - disposal, recycling, renewal, problems, issues – programs for forest, land and water management.	Lecture Assignment Group Work and Self Study	20%
5	Environment Protection Laws and Role of Social Worker:	➢ Acts related to environmental protection – Forest conservation-Water pollution – Standards and tolerance levels – Unplanned urbanization-Environmental movements in India - Role of NGOs in Environmental issues – Government agencies in environmental protection – Social work initiatives at different levels.	Lecture Assignment and Group Work	20%

Methods of Assessments: Examination &Assignments

Reference Books:

Cassen, R.H 1978 :India Population, Economy and Society,London: Macmillan.

Family planning Association Family planning Counseling Guide, of India Population Reports Service Series J.N 35 and 36

Fisher, W.F 1997 :Towards Sustainable Development (Struggling over India's Narmada River), New Delhi: Rawat Publications.

Gadgil, and Guha. 1997 :This Fissured Land – An Ecological History of India: :Delhi: Oxford University Press.

Klieinman.R (Ed.) 1998 :Family Planning Handbook for octors, :Hertford: IPPF

Krishna. M. 1995 :Air Pollution and Control,:Kakinada: Kaushal and Co.

Miller, Jr. Tyler, :G and Living in the Environment, California: Armstrong. 1982 Wordsworth International Group.

Mohan, R. 1985 :"Urbanization in India's Future", Population and Development Review, Vol.11(4)

Oxford, 1987 :Our Common Future, Delhi: Oxford University Press.

Prasad, R.K :Population Planning, Policy and Programs,:New Delhi: Deep and Deep Publications.

Reddy, Laxmi, M.V.1994 :Population Education,:New Delhi: Asish Publication.

Ryding, S.O. 1992 :Environmental Management Handbook,:Ahmedabad: IOS Press.

Sapru, R.K (Ed.) 1987 :Environment Management in India, Vol. II, New Delhi: :Ashish Publishing House

Satapathy, N. 1998 :Sustainable Development (An Alternative Paradigm),:Ahmedabad: Karnavati Publications.

Seshadri and Pandey, :J (Eds.) Population Education, A Natural Source:1991 Book, New Delhi: NCERT.

Erach Bharucha :Text book for environmental studies:U.G.C. New Delhi

Subject :	**Master of Social Work**		
Course (Paper) No.	**18**	**Name:**	**Industrial Relation & Labour Welfare**
Course (Paper) Unique Code		**Core**	1601510102030900
External Exam Time Duration		**02:30 Hours**	

Name of Program	**Semester**	**Course Group** **Foundation/ Core/ Elective-1/ Elective-2/Practical/ Project**	**Credit**	**Internal Mark**	**External Mark**	**Practical Viva mark**	**Total marks**
Master of Social Work	03	Core	4	30	70	-	100

Course Outcomes:

CO1-The Legal system pertaining to labour – management relations require careful study by students of labour welfare.

CO2-To make students understand the importance of industrial relation.

CO3-To familiar the students about the role in IR System.

Course Contents:

UNIT	**UNIT TITLE**	**DESCRIPTION**	**TEACHING METHOD**	**WEIGHTAGE OF PAPER**
1	**Industrial Relation-1**	➢ Introduction of Industrial Relation ➢ Definition of Industrial Relation, ➢ Content of Industrial Relation ➢ Objectives of Industrial Relation ➢ Participants/Variables in Industrial Relation ➢ Aspects of Industrial Relation ➢ Industrial Relation Strategy	Lecture Observation Discussion	20%
2	**Industrial Relation-2**	➢ Industrial Relation Program ➢ Scope of Industrial Relation Work ➢ Importance of Peaceful IR ➢ Collective Bargaining - Role of Collective Bargaining - Workers' Participation in Collective Bargaining	Lecture, Discussion	20%
3	**Trade Union-1**	➢ Definition and Characteristics of Trade Union ➢ Principles of Trade Unionism ➢ Objectives & Functions of a Trade Union ➢ Trade Union Movement in India ➢ Growth of Trade Union Movement ➢ Federations of Trade Unions ➢ Features and Weakness of Trade Unionism ➢ Recommendations of the National Commission on Labour	Lecture Discussion	20%

4	**Labour Welfare**	➢ Definition & Concept of Labour Welfare ➢ Aims, Objectives, Value & Motivation of Labour Welfare ➢ Principles, Theories of Labour Welfare ➢ Statuary & Non-Statuary Measure in India ➢ Function & Role of Labour Welfare Officer	Lecture Discussion	20%
5	**Industrial Dispute**	➢ Definition of Industrial Dispute ➢ Types of Industrial Dispute ➢ Effect of Industrial Dispute ➢ Internal & External Industrial Dispute Procedure ➢ Authority under act 1947	Lecture Discussion	20%

Methods of Assessments: Examination &Assignments

Reference Books:

Punekar S.D.(1978) :Labour Welfare, Trade Unionism and Industrial Relation, :Himalaya Publication House, Bombay

VenkatRatnam, C.S. (2001), : Globalisation and Labour-management Relation :Sage Publication response books,New Delhi.

Mathur, D.C. (1993), : Personnel Problems and Labour Welfare, :Mittal Publications, New Delhi Sinha, (2004), : Industrial Relation, Trade Unions, and Labour Legislation.

Sivarethinamohma, (2010), :Industrial Relations &Labour Welfare : Text and Cases Singh P.N., : Employee Relations Management

Paul Edwards (2003), : Industrial Relations: Theory & Practice, Vol.1:By John Wiley & Sons

PAPER V: LABOUR LAW

Course Outcomes:

CO1: Students will know the development and the judicial setup of Labour Laws.

CO2: Concepts of various laws concerning with Hospital problem

COURSE CONTENTS:

Labour law:

1. Health insurance
2. Industrial relation
3. Labour law
4. Legal aspect of hospital administration
5. Organ transplant act

REFERENCE BOOK(S):

1. Parikh C. K. Text book of Medical Jurisprudence and Toxicology, Bombay Medical Publications, 1981.

PGDI-202

IPR, PATENT, DOCUMENTATION, STATUTORY AND REGULATORY AFFAIRS

Course outcomes (COS)

CO1: Learner should be able to use various parameter of pharma regulatory affairs.

CO2: Understanding ICH, SOP, GMP, GLP used in pharma and applied industries.

CO3: Case studies of related topics.

- Introduction to statutory and regulatory requirement for the industries overviews of Laws related to environmental protection and international standard certification awareness.(ISO, OHSAS, NABL)
- Regulatory requirements for Pharmaceutical products (API and Formulations) FDA, DCGI, WHO, Schedule-M, GMP, GLP, ICH Guidelines.
- Documentation in Pharmaceutical organizations, SOP's, Validations, Calibrations, Qualifications, Standardizations and preparation of various dossiers.
- Patent, IPR and related topics. IPR, Patent, Indian Patent Act , International pantentization related to generics.
- Recent updates.

PGDI-203

PROJECT WORK/DISSERTATION

Course Outcomes (COs):

- Selected analytical problem solving by Specific Sophisticated instrumental technique
- Exposure to the Scientific Database
- Statistical Analysis of the data
- Result, Data compilation and Thesis writing
- Publication

B.Pharm SEMESTER – II
ENVIRONMENTAL SCIENCES
Subject code: BP206T
Theory (3 Hours / Week; 3 Credits, 30 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	50	25	35	15

Scope: 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.

Objectives: 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.

Course outcomes: This course provides:

CO1: Tthe knowledge of different environmental problems and its impact on society.

CO2: 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 content:

Unit-I **10hours**

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

- 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 **10hours**

- 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 **10 hours**

- Environmental Pollution: Air pollution; Water pollution; Soil pollution

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 Pu blishing Pvt. Ltd.,
4. Ahmedabad – 380 013, India,
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

B.Pharm SEMESTER – V
PHARMACEUTICAL JURISPRUDENCE
Subject code: BP505T
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	8	75	25	35	15

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

Course outcomes: Upon completion of the subject should have:

CO1: How to become a responsible person while discharging duty as a pharmacist in different facets of pharmacy profession.

CO2: To acquire certain knowledge related to laws that help in becoming a pharma entrepreneur.

CO3: The code of ethics during the pharmaceutical practice

Course Content:

Unit-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

- Objectives, Definitions, Legal definitions of schedules to the Act and Rules
- Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties**.**
- Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,
- Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

Unit-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

- Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties
- Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.
- Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

Unit-III **10 Hours**

- **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

Unit-IV **08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

Unit-V **07 Hours**

- **Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

B.Pharm SEMESTER – VI
HERBAL DRUG TECHNOLOGY
Subject code: BP603T
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	8	75	25	35	15

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

- understand raw material as source of herbal drugs from cultivation to herbal drug product
- know the WHO and ICH guidelines for evaluation of herbal drugs
- know the herbal cosmetics, natural sweeteners, nutraceuticals
- appreciate patenting of herbal drugs, GMP .

Course outcomes: The students are expected to Learn:

CO1: The pharmacognostic aspects of Alkaloids, Enzyme marines, plant sweetener, pestisides and herbisides specifically, the sources, the preparation methods and utilization of containing drugs.

CO2: Understand basic idea of extraction, isolation and separation of active phytoconstituents from medicinal plants.

CO3: Understand concept of phytochemical screening of the phytoconstituents obtained from the natural sources.

Course content:

Unit-I **11 Hours**

Herbs as raw materials

- Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs
- Selection, identification and authentication of herbal materials

- Processing of herbal raw material

Biodynamic Agriculture

- Good agricultural practices in cultivation of medicinal plants including Organic farming.
- Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

- Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

Unit-II **7 Hours**

Nutraceuticals

- General aspects, Market, growth, scope and types of products available in the market. Health
- benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
- Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic,
- Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions:

- General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

Unit-III **10 Hours**

Herbal Cosmetics

- Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

- Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

- Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

Unit- IV **10 Hours**

Evaluation of Drugs

- WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues

- Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

Unit-V **07 Hours**

General Introduction to Herbal Industry

- Herbal drugs industry: Present scope and future prospects.
- A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

- Components of GMP (Schedule – T) and its objectives
- Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

B.Pharm SEMESTER – VII
INDUSTRIAL PHARMACY II
Subject code: BP702T
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	75	25	0	0

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

- Know the process of pilot plant and scale up of pharmaceutical dosage forms
- Understand the process of technology transfer from lab scale to commercial batch
- the approval process and regulatory requirements for drug products

Course outcomes:

CO1: To demonstrate an understanding of the QA and QC, quality, good pharmacy practices, regulatory guidelines, and patent issues related with different drugs and pharmaceuticals.

CO2: Know different Laws and Acts that regulate pharmaceutical industry

Course Content:

Unit-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

Unit-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality

agreement, licensing, MoUs, legal issues

Unit-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

Unit-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

Unit-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

B.Pharm SEMESTER – VIII
PHARMACEUTICAL REGULATORY SCIENCE
Subject code: BP804ET
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	75	25	0	0

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

- Know about the process of drug discovery and development
- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

Course outcomes: The students will get the knowledge on:

CO1: The process of drug discovery, development and generic product development

CO2: Describe the regulatory approval process and registration procedures for API and drug products in various countries

CO3: Learn the basic understanding of regulations of India with other global regulated markets

Course content:

Unit I **10Hours**

New Drug Discovery and development

- Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10 Hours**

Regulatory Approval Process

- Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

- Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10 Hours**

Registration of Indian drug product in overseas market

- Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials

- Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

- Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance
8. By Fay A. Rozovsky and Rodney K. Adams
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene

10. Drugs: From Discovery to Approval, Second Edition By Rick Ng

B.Pharm SEMESTER – VIII
PHARMACOVIGILANCE
Subject code: BP805ET
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	75	25	0	0

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives: At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle

Course outcomes: This course will provide the knowledge about:

CO1: Development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization

CO2: Various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

CO3: Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India

CO4: ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning, CIOMS requirements for ADR reporting, writing case narratives of adverse events and their quality.

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports

- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.
- Drug safety evaluation in special population
- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal MunjalText book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

11. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
12. http://www.ich.org/
13. http://www.cioms.ch/
14. http://cdsco.nic.in/
15. http://www.who.int/vaccine_safety/en/
16. http://www.ipc.gov.in/PvPI/pv_home.html

B.Pharm SEMESTER – VIII
QUALITY CONTROL AND STANDARDIZATION OF HERBALS
Subject code: BP806ET
Theory (3 Hours / Week; 4 Credits, 45 Hours)

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	75	25	0	0

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

- Know WHO guidelines for quality control of herbal drugs
- Know Quality assurance in herbal drug industry

Course outcomes: This subject will help the student

CO1: Know the details of various methods and guidelines for the evaluation and standardization of herbs and herb drugs.

CO2: Know the regulatory approval process and their registration in Indian and international markets

CO3: Appreciate EU and ICH guidelines for quality control of herbal drugs

Course content:

Unit I **10 hours**

- Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms
- WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

- **Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine.
- WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

- EU and ICH guidelines for quality control of herbal drugs.
- Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

- Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.
- Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

- Regulatory requirements for herbal medicines.
- WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.
- Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control
8. principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
9. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
10. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn.
11. World Health Organization, Geneva, 1981.
12. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
13. WHO. WHO Global Atlas of Traditional, Complementary and Alternative
14. Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.

15. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

M.PHARM SEMESTER I
REGULATORY AFFAIRS MPH 104T)
Theory: 4 Hrs. /Week

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents filing process of IND, NDA and ANDA

- To know the approval process
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements

Objectives

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

Course Outcomes

CO1 At the end of the course, the student will be having a good understanding of the drug development process as a whole and the practical concepts, regulatory aspects related to Research & Development as well as manufacturing and marketing of Pharmaceutical Products.

CO2 The students will become familiar to various guidelines and regulatory requirements of various countries

CO3 The students will acquire knowledge regarding the protocols in developing clinical trials and various procedures regarding the same.

CO4 Information regarding the important pharmacokinetic parameters and various tests will be achieved

Course content

Unit 1 **24 Hrs**

a) **Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

b) **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Unit 2 **12 Hrs**

CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit 3 **12 Hrs**

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit 4 **12 Hrs**

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/

9. europa.eu/index_en.htm

10. https://www.tga.gov.au/tga-basics

M.PHARM PHARMACOLOGY SEMESTER II
Pharmacological and Toxicological Screening Methods – II
(MPL 202T)
Theory: 4 Hrs. /Week

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

Course Outcome

CO.1: Exhibit awareness and responsiveness to the system of health care including preclinical evaluation of drugs, ethical requirement for the usage of animal experiments, and regulations of the experiments.

CO.2: Graduates are able to understand the process of drug discovery, in-vivo, in-vitro experiments, and newer screening methods.

Course content

Unit 1 **12 Hrs.**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

Unit 2 **12 Hrs.**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies

Unit 3 **12 Hrs.**

- Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II)
- Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

Unit 4 **12 Hrs.**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit 5 **12 Hrs.**

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

REFERENCES

14. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).

15. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,

16. 2005, ministry of health and family welfare (department of health) New Delhi

17. Drugs from discovery to approval by Rick NG.

18. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

19. OECD test guidelines.

20. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

21. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

M.PHARM PHARMACOLOGY SEMESTER II

Clinical Research and Pharmacovigilance (MPL 204T)

Theory: 4 Hrs. /Week

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

Course Outcome

CO.1: Graduates are able to demonstrate different phases of clinical trial, able to understand regulatory requirements for clinical trial.

CO.2: Students are able to design, conduct and manage the clinical trial. They can detect new adverse drug reactions.

CO.3: They are able to understand the principles of Pharmacovigilance.

Course content

Unit 1 **12 Hrs**

Regulatory Perspectives of Clinical Trials:

- Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR
- Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

Unit 2 **12 Hrs**

Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case control, Cross sectional, Clinical Trial Study Team, Roles and

responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

Unit 3 **12 Hrs**

- Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT
- Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

Unit 4 **12 Hrs**

- Basic aspects, terminologies and establishment of pharmacovigilance
- History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety,
- Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Unit 5 **12 Hrs**

Methods, ADR reporting and tools used in Pharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data

Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

M. PHARM (QA) SEMESTER I
QUALITY MANAGEMENT SYSTEMS (MQA 102T)
Theory: 4 Hrs. /Week

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

Course Outcome

CO1: Got fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry.

CO2: Understand the importance of quality, tools for quality improvement, quality evaluation of pharmaceuticals.

CO3: Familiarized with statistical approaches for quality.

CO4: Understand the concept of stability testing of drug products and drug substances.

Course content

Unit 1. **12 Hrs**

a) Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality

b) Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

c) Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies.

d) Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, optimising costs, Preventing cost of quality.

Unit 2. **12 Hrs**

Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

Unit 3. **12 Hrs**

Six System Inspection model: Quality Management system Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection.

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

Unit 4. **12 Hrs**

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

Unit 5. **8 Hrs**

Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

Unit 6. **4 Hrs**

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

10. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
11. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
12. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
13. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001

14. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997

15. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

16. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications

17. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

M. PHARM (QA) SEMESTER I
QUALITY CONTROL AND QUALITY ASSURANCE
(MQA 103T)
Theory: 4 Hrs. /Week

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

Course Outcome

CO1: Understand Various aspects of quality control and quality assurance in pharmaceutical industries.

CO2: Familiarised with important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

CO3: Understand the importance of documentation and responsibilities of QA & QC departments.

CO:4 Understand the scope of quality certifications applicable to pharmaceutical industries.

Course content

Unit 1. **12 Hrs**

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation.

CPCSEA guidelines.

Unit 2. **12 Hrs**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control,

utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

Unit 3. **12 Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

Unit 4. **12 Hrs**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

Unit 5. **12 Hrs**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley& Sons; 2008.

14. Packaging of Pharmaceuticals.

15. Schedule M and Schedule N.

M. PHARM SEMESTER I (RA)
Clinical Research Regulations (MRA 103T)
Theory: 4 Hrs. /Week

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives:

Upon completion of the course, the student shall be able to (know, do and appreciate).

- History, origin and ethics of clinical and biomedical research and evaluation.
- Clinical drug, medical device development process and different types and phases of clinical trials.
- Regulatory requirements and guidance for conduct of clinical trials and research.

Course Outcome:

CO1: Awareness regarding different types and phases of clinical trials.

CO2: Understanding regulations history, origin & concept of different ethical guidelines related to clinical trials.

CO3: Gives idea regarding requirements of conduct of clinical trial in India, US and Europe.

Course content

Unit 1 **12 Hrs.**

Clinical Drug Development Process

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation

Unit 2 **12 Hrs.**

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
    - Ethical principles governing informed consent process
    - Patient Information Sheet and Informed Consent Form
    - The informed consent process and documentation

Unit 3 **12 Hrs.**

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

Unit 4 **12 Hrs.**

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E11 – Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatics principle applied in clinical research

Unit 5 **12 Hrs.**

- USA & EU Guidance
  - USA: FDA Guidance
  - CFR 21Part 50: Protection of Human Subjects
  - CFR 21Part 54: Financial Disclosure by Clinical Investigators
  - CFR 21Part 312: IND Application
  - CFR 21Part 314: Application for FDA Approval to Market a New Drug
  - CFR 21Part 320: Bioavailability and bioequivalence requirements
  - CFR 21Part 812: Investigational Device Exemptions
  - CFR 21Part 822: Post-market surveillance
  - FDA Safety Reporting Requirements for INDs and BA/BE Studies
  - FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
- European Union: EMA Guidance
  - EU Directives 2001
  - EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use
  - EU Annual Safety Report (ASR)
  - Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
  - EU MDD with respect to clinical research
- ISO 14155

References:

14. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams.

15. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD.

16. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene.
17. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
18. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
19. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
20. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA.
21. Country Specific Guidelines from official websites.
22. Drugs & Cosmetics Act & Rules and Amendments

Recommended Websites:

23. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
24. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
25. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
26. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
27. FDA New Drug Application:
28. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
29. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
30. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
31. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

M.PHARM SEMESTER II (RA)
Regulatory Aspects of Drugs & Cosmetics (MRA 201T)
Theory: 4 Hrs./Week

Scope:

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

Course Outcome:

CO1: Acquired the knowledge of regulatory approval process and registration procedures for drug products in USA, Canada, EU, Australia, Japan and Brazil

CO2: Understand the role of various committees across the globe like APEC, EAC, GCC, PANDRH, SADC, etc.

CO3: Learnt the requirements for registration of drugs and post approval requirements in ASEAN countries

CO4: Learned the regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries

CO5: Understand the concept of Certificate of Pharmaceutical Product (CoPP) in General and Country Specific

Course content

Unit 1 **12 Hrs**

USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada

Unit 2 **12 Hrs**

European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

Unit 3 **12 Hrs**

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

Unit 4 **12 Hrs**

Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

Unit 5 **12 Hrs**

Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand CIS (Commonwealth Independent States): Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions/ Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, SpringerTrade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

POST GRADUATE DIPLOMA IN CLINICAL RESEARCH (PGDCR)
SEMESTER-I
Clinical trials: Design and regulations Theory
(PGDCR-103)

Course Outcome: At the end of each unit of learning students will be able to:

CO1: Discuss about various types and design of clinical trials.

CO2: Acquired knowledge about Schedule Y and ICMR guideline.

CO3: Discuss the role of Indian GCP guideline.

CO4: Acquired knowledge about how to apply for clinical trial in India.

CO5: Discuss Investigator Brochure and Informed Consent Form as essential document in clinical trial.

Unit 1:

- Types of clinical trials

Unit 2:

- Design and organization of phase-I, phase-II, phase-III, phase-IV trials

Unit 3:

Various regulatory requirements in clinical trials:

- Schedule Y, ICMR guidelines.

Documents in clinical study:

- Investigator Brochure (IB), Protocol & Amendment in Protocol, Case Report Form (CRF), Informed Consent Form (ICF), Content of Clinical Trial Report Essential Documents in Clinical Trial

Good Clinical Practice:

- ICH guidelines
- Indian GCP guidelines (CDCSO guidelines)
- ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects

Schedule Y

- Roles & Responsibility of various clinical trial personnel like Sponsor, Investigator, Monitor, Auditors as per ICH GCP and ICMR guidelines

Unit 4:

- Study of various clinical trials (completed or ongoing), Clinical Trial Application in India, Import & Export of Drug in India, Investigational New Drug application (IND), Abbreviated New Drug Application (ANDA), New Drug Application (NDA).

REFERENCES:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
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4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh
7. Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
8. Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.
9. Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.
10. Comprehensive Pharmacy Review- Shargel Leon
11. Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers
12. A textbook of Clinical pharmacy practice- Parthasarthi G.
13. Rick NG. Drugs from Discovery to Approval. John Wiley & Sons, Inc 2004
14. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
15. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
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18. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication **7.** Bert Spilker. Guide to Clinical Trials. **8.** Sandy Weinberg. Guidebook for Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009

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22. Schedule Y, Drug and Cosmetic act 1940 and rules 1945,

PD – 307: PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

Scope:

This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments is the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

Course outcome (COs):-

CO1: practice the Professional ethics;

CO2: understand the various concepts of the pharmaceutical legislation in India;

CO3: know the various parameters in the Drug and Cosmetic Act and rules;

CO4: Know the Drug policy, DPCO, Patent and design act;

CO5: understand the labeling requirements and packaging guidelines for drugs and cosmetics;

CO6: be able to understand and the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and

CO7: other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

1. Mithal, B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

1. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
2. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
3. Reports of the Pharmaceutical enquiry Committee
4. I.D.M.A., Mumbai. DPCO1995
5. Various reports of Amendments.
6. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
7. Eastern Book Company, The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

Course content

Unit 1

Pharmaceutical Legislations – A brief review.

Unit 2

Principle and Significance of professional ethics. Critical study of the code of Pharmaceutical ethics drafted by PCI.

Unit 3

- Drugs and Cosmetics Act, 1940, and its rules 1945.
- Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
- Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.
- Constitution and Functions of DTAB, DCC, CDL.
- Qualification and duties –Govt. analyst and Drugs Inspector.

Unit 4

Pharmacy Act –1948.

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

Unit 5

Medicinal and Toilet Preparation Act –1955.

Objectives, Legal Definitions, Licensing, Bonded and Non-Bonded Laboratory,

Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

Unit 6

Narcotic Drugs and Psychotropic substances Act-1985 and Rules. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.

Unit 7

Study of Salient Features of Drugs and magic remedies Act and its rules.

Unit 8

Study of essential Commodities Act Relevant to drugs price control Order.

Unit 9

Drug Price control Order & National Drug Policy (Current).

Unit 10

Prevention of Cruelty to animals Act-1960.

Unit 11

Patents & design Act-1970.

Unit 12

Brief study of prescription and Non-prescription Products.

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

Fifth year

PD – 501: CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

Course outcomes (COs) :-

CO1: Demonstrate competency in biopharmaceutical clinical trial research designs and regulatory affairs management to meet the health and medical needs of current and future biopharmaceutical product consumers

CO2: Evaluate critical domestic and global regulatory and health care issues that challenge and influence biopharmaceutical product development

CO3: Effectively assess and manage ethical clinical trial programs and biopharmaceutical development projects

CO4: Forecast the resources necessary for developing and managing biopharmaceutical clinical research grants and trials as required and regulated by global regulatory agencies

Course content

Unit 1 Drug development process:

Introduction Various Approaches to drug discovery

a. Pharmacological
b. Toxicological
c. IND Application
d. Drug characterization
e. Dosage form

Unit 2 Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO)guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB/IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICHGCP

a. Sponsor
b. Investigators

c. Clinical research associate

d. Auditors

e. Contract research coordinators

f. Regulatory authority

11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)

12. Informed consent Process

13. Data management and its components

14. Safety monitoring in clinical trials.

References:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects2000. Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan2000, Wiley Publications.

7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. Mc Graw Hill Publications,2001