OSMANIA UNIVERSITY

Faculty of Pharmacy

SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

(Effective for Batches Admitted from 2016 – 17 Academic Year Onwards)

Program Code: 881 B. Pharmacy (Second Year)

SEMESTER - IV

Course Code	Description	Course Title	Hours/Week			Credits	Marks		Duration of Exam
			L	T	P		Internal	End Exam	
PY.06.881.4.1.T	PS, CORE	Pharmaceutical Chemistry (Chemistry of Natural Products)	4	0	-	4	30	70	3
PY.06.881.4.2.T	PS, CORE	Pharmaceutical Engineering-II	4	0	-	4	30	70	3
PY.06.881.4.3.T	BS, FC	Pharmaceutical Biochemistry	3	0	-	3	30	70	3
PY.06.881.4.4.T	BS, FC	Biostatistics (Pharmacostatistics)	3	0	-	3	30	70	3
PY.06.881.4.5.T	Open Elective	Pathophysiology / Green Chemistry	4	0	-	4	30	70	3
PY.06.881.4.6.P	PS, CORE	Pharmaceutical Chemistry (Chemistry of Natural Products) Ptacticals	0	0	4	2	30	70	4
PY.06.881.4.7.P	PS, CORE	Pharmaceutical Engineering Ptacticals	0	0	4	2	30	70	4
PY.06.881.4.8.P	BS, FC	Pharmaceutical Biochemistry Ptacticals	0	0	4	2	30	70	4
			18	0	12	24	240	560	

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

PATHOPHYSIOLOGY

Scheme of Instruction
Total duration:60 hrs
Periods / Week: 4 credits:4

Instruction Mode : Lecture

Subject Code : PY.06.881.4.5.T

Scheme of Examination
Maximum Marks: 30
Internal Exam : 30
End Semester : 70
Exam Duration : 3 Hrs

Scope: Path physiology is the study of diseases and reactions of the body to such disease producing causes . this course is designed to impart a through knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications and understanding of basic path physiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safety, confidently, rationally and effectively.

Objectives : upon completion of the subject student shall be able to-

1. **Describe the etiology and pathogenesis of the selected disease states:**
2. **Name the signs and symptoms of the disease: and**
3. **Mention the complications of the disease.**

Course Content:

Unit- I

Basic principles of Cell injury and application:

Introduction , definitions , Homeostasis ,components and Types of Feedback systems, causes of cellular injury. Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage , Nuclear damage), Morphology of cell injury – adaptive changes (atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia) , cell swelling , Intra cellular accumulation, calcification , Enzyme leakage and Cell l Death Acidosis & Alkalosis, Electrolyte imbalance.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

- **Basic mechanism involved in the process of inflammation and repair:** Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

Unit II **10Hours**

- **Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure

Unit II **10Hours**

- **Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic id), sickle cell ne i. thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Di etes, th oid diseases, dis rders of sex hormones
- **Nervous system:** Epileps, P rkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzh imer's disease.
- **Gastrointestinal system:** P ptic Ulcer

Unit IV **8 Hours**

- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout
- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy,

Tuberculosis Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeuti s; 3rd edition; London; Churchill Livingstone publication; 2003.

Pharmacy

Recommended Journals

College

1. The Journal of Pathology. ISSN: 1096-9896 (Onlin)
2. The American Journal of Patho gy. ISSN: 0002-9440
3. Pathology. 1465-3931 (Onlin)
4. International Journal of Ph siolog , Pathoph siology and Pharmacology. ISSN: 1944-8171

GREEN CHEMISTRY

Scheme of Instruction

Total Duration	: 45 hrs
Periods / Week	: 4
Credits	: 4
Instruction Mode	: Lecture
Subject Code	: PY 06.881.4.5.T

Scheme of Examination

Maximum Marks	: 100
Internal Exam	: 30
End Semester	: 70
Exam Duration	: 3 Hrs

Course objectives

To familiarize students about environmental benign chemical synthesis. To make students familiarize with principles and importance of various green chemical synthesis. To provide adequate knowledge regarding green reactions, green solvents and other alternative green approaches. To impart adequate information regarding environment pollution, contributing factors and the concerns.

Course outcomes

Upon completion of this course, the students should be able to: Explain the environment pollution factors. Understand the different greener approaches along with their principles.

UNIT – I

Introduction to Green Chemistry

- Inception of green chemistry: history and development
- Principles of green chemistry: description with examples
- Synthetic approaches of green chemistry: In water, solvent less, photochemical, microwave, ultrasonic, catalytic and electrochemical synthesis.

UNIT – II

In water and solvent less organic reactions

- In water reactions: Principle and process involved in the Michael reaction and Wurtz synthesis
- Solvent less organic synthesis:
- Alternative solvents used in green chemistry strategies.

UNIT – III

Microwave and ultrasonic mediated reactions

- Microwave reactions: Principle and process involved in the [illegible] Diels Alder reaction and Metal halide [illegible]
- Ultrasonic reactions: Principle and process involved in [illegible] reactions.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

UNIT – IV

Catalytic and solid supported reactions

- Catalytic reactions: Principle and process involved in the reactions catalyzed by metal catalysts, phase-transfer catalysts, ionic liquids (Knovenegel condensation) and bio catalysts (Villeger reaction)
- Solid supported reactions: Principle and process
- Alternative reagents used in green chemistry strategies.

UNIT – V

Greener synthesis of pharmaceuticals: Principle and procedure of the following synthesis

OSMANIA UNIVERSITY

Faculty of Pharmacy

SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

(Effective for Batches Admitted from 2016 – 17 Academic Year Onwards)

Program Code: 881 **B. Pharmacy (Fourth year)**

SEMESTER - VIII

Course Code	Description	Course Title	Hours/Week			Credits	Marks		Duration of Exam
			L	T	P		Internal	End Exam	
PY.08.881.8.1.T	PS, CORE	Pharmaceutical Biotechnology	4	0	-	4	30	70	3
PY.08.881.8.2.T	PS, CORE	Pharmacoinformatics	4	0	-	4	30	70	3
PY.08.881.8.3.T	PS, CORE	Cosmetic Technology	4	0	-	4	30	70	3
PY.08.881.8.4.T	PS, FC	Hospital and Clinical Pharmacy	3	0	0	3	30	70	3
PY.08.881.8.5.T	Open elective	cGMP / Pharmaco vigilance	3	0	0	3	30	70	3
PY.08.881.8.6.P	PS, CORE	Pharmaceutical Biotechnology Practical	0	0	4	2	30	70	4
PY.08.881.8.7.P	PS, CORE	Pharmacoinformatics Practical	0	0	4	2	30	70	4
PY.08.881.8.8.P	PS, CORE	Cosmetic Technology Practical	0	0	4	2	30	70	4
			18	0	12	24	240	560	
PY.08.881.8.8.X	Seminar	Curricular/ Co - curricular	-			2	Grade-A/B/C/D/F		Non-CGPA

At the end of theprogram CGPA will be Awarde on 10 Point Scale with the Final Grade on tran

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

CURRENT GOOD MANUFACTURING PRACTICE (cGMP)

Scheme of Instruction

Total Duration	: 45 hrs
Periods / Week	: 3
Credits	: 3
Instruction Mode	: Lecture
Subject Code	: PY.08.881.8.5.1

Scheme of Examination

Maximum Marks	: 100
Internal Exam	: 30
End Semester	: 70
Exam Duration	: 3 Hrs

Course Objectives

To learn the concepts and be able to implement validation processes, standard related to manufacturing, trade and communication as well as environment ; able to impart training in good manufacturing practices; to implement documentation procedures; and to implement validation in APIs and products.

Course Outcomes

The student will be able to know, Concepts of quality, quality management and its implementation. The concept of validation and validation of process, equipments and products. Regulatory guidance's and guidelines like ICH, WHO and other relevant documents. Documentation of BMR, MFR, DMF and relevant process related documents. Environment protection and occupational health safety requirements and requirements.

UNIT - I

cGMP of Pharmaceutical manufacturing: History, evolution and principles of cGMP, schedule-M, USFDA guidelines on pharmaceutical manufacturing, WHO recommendation for pharmaceutical products. Import and Export of pharmaceuticals.

UNIT – II

- **Pharmaceutical Equipments:** Selection, purchase, maintenance and clean in place, maintenance of stores for raw materials.
- **Packaging of Dosage Forms:** cGMP complied packaging and documentation, labelling requirements of various regulated and non-regulated markets for tablets, capsules, liquid orals, parenterals/ injectables, and semisolids.

UNIT – III

Introduction to ISO 9000 and 14000 Series: ISO 9000 & 14000 series, guidence to pharmaceutical manufacturing facilities, cGMP considerations with emphasis on documentation practices. Integration of modern management practices and principles of total quality management (TQM).

UNIT - IV

Calibration and validation: Introduction, definition and general principles of calibration, qualification and validation, Importance and scope of validation , types of validation, validation master plan, Calibration of pHmeter, qualification of UV-visible spectrophotometer, general principles of analytical method validation

Warehousing: Good warehousing practice, material [illegible]

UNIT - V

Validation: General concepts, types and approaches to validation, scope of validation and validation protocol, Relationship between calibration, validation and qualification, Validation master plan, qualifications of utilities - HVAC systems, validation of water

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

systems. Validation of manufacturing process for sterile and non-sterile products (Details protocols and reports). Equipment qualification and cleaning validation.

Complaints: complaints and evaluation of complaints, handling of return goods recalling and waste disposal.

Documentation in Pharmaceutical Industry: Batch formula record, master formula record, distribution records, Common technical document and drug master files, medical devices, electronic common technical documentation.

RECOMMENDED BOOKS:

1. Good Manufacturing Practice Rationale and compliance by John Sharp
2. Pharmaceutical master validation plan The ultimate guide to FDA GMP GLP and cGMP Compliance by Syed Imtiaz Haider
3. Pharmaceutical dosage forms: Parenterals Vol 2, II Edition, by Kenneth E Avis and Lachman
4. Packaging and Pharmaceuticals and health care products by H. Lockhart, Frank A. Paine
5. The process of new drug discovery and development, I and II Edition by Charles G. Smith, James T and O. Donnell.
6. Establishing a CGMP laboratory audit system- A Practical guide by David M. Bluesner.
7. J.F.Hanlon: Hand book of package engineering :Mac-Grawhill company.
8. Good manufacturing practices: A plan total quality control; S.H.Wilhing, M.M. Tuckerman, S.Hitchings, Marcel Deckker, Inc. Yew york.
9. Cell therapy, CGMP, Facilities and Manufacturing, Springer

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II

Drug and disease classification

- 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 Stardardised MedDRA queries
- WHO drug 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

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
- Communicating with Regulatory Agencies, Business Partners, Sponsors, Public and Media

Unit IV

Safety data generation

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

ICH Guidelines for Pharmacovigilance

- Expedited reporting
- Individual case safety reports

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

PSCP-75
III-1

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

Unit V

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

- Schedule Y of D&C Act
- 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 Waller, 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 Munjal
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
17. Text book of Pharmacovigilance concept and practice by G.P.Mohanta, P.K.Manna

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

PSC 76
7117

SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION
Program Code: 885 M. Pharm. (Pharmaceutical Analysis & Quality Assurance)
2015 – 16

SEMESTER - I

Course Code	Course Title	Hours/Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.884.11.T	Pharmaceutical Analytical Techniques	3	0	-	3	25	75	3
PY.09.886.12.T	Pharmaceutical Product Development	4	0	-	4	25	75	3
PY.09.885.13.T	Quality Controlof Health Related Products	4	0	0	4	25	75	3
PY.09.885.14.T	Instrumental Methods of Analysis	4	0	0	4	25	75	3
PY.09.885.15.T	Quality Assurance	3	0	0	3	25	75	3
PY.09.884.11.P	Pharmaceutical Analytical Techniques	-	0	4	2	25	75	6
PY.09.886.12.P	Pharmaceutical Product Development	-	0	4	2	25	75	6
					22	175	525	
PY.09.885.10.S	SAIL	1	2	0	2	Grade		
PY.09.885.11.S	Seminar	1	0	2	2	Grade		

SEMESTER - II

Course Code	Course Title	Hours/Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.885.21.T	IPR & Regulatory Affairs	3	0	-	3	25	75	3
PY.09.885.22.T	Analytical Method Validation	4	0	-	4	25	75	3
PY.09.885.23.T	Quality Control Methods	4	0	0	4	25	75	3
PY.09.885.24.T	Biological Standardization	4	0	0	4	25	75	3
PY.09.88X.25.T	Elective *	3	0	0	3	25	75	3
PY.09.885.22.P	Analytical Method Validation	-	0	4	2	25	75	6
PY.09.885.23.P	Quality Control Methods	-	0	4	2	25	75	6
					22	175	525	
PY.09.885.20.S	SAIL	1	2	0	2	Grade		
PY.09.885.21.S	Seminar	1	0	2	2	Grade		

* Discipline Centric –Pharmaceutical Packaging Technology / Drug Polymer Technology;
Open – Quality Assurance & Management.

SEMESTER – III

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.885.31.P	Design Seminar	30	6	50	-	6
PY.10.885.32.P	Report on Progressive Seminar	30	10	50	-	10
		480	16	100		

SEMESTER – IV

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.885.41.P	Pre-Submission Seminar	30	10		50	10
PY.10.885.42.T	Submission and Adjudication	30	12		200	6
PY.10.885.43.T	Final Viva-voce	30	2		50	1
		510	24		300	17

Principal
St. Pauls College of Pharmacy

ELECTIVE

PHARMACEUTICAL PACKAGING TECHNOLOGY

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	3 Hrs.
Credits	:	3
Instruction Mode	:	Lecture
Course Code	:	PY.09.885.25.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

To develop understanding and provide scientific basics of the packaging technology

To understands the types of packaging and improve the standards of packaging technology

Course Outcomes:

To appreciate the importance of Pharmaceutical Packaging Technology

Unit - I :

Pharmaceutical Packaging: Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, storage temperature, hazards encountered by the package during storage and distribution.

Product-Package Compatibility: Stability of product, packaging selection and development criteria.

Flexible Packaging: Types of films, co-extruded films, foils, coating and laminates, shrink and stretch films.

Corrugated and Solid fiber Boards and Boxes: Type of corrugation methods.

Caps and Closures: Types; caps, closures, liners, child resistant caps. elastomeric closures for parenterals,

Unit - II :

Glass Containers for Pharmaceuticals: Glass types, their chemical performance, testing and quality control.

Plastics Containers for Pharmaceuticals: Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties; Additives and fabrication processes Plastic container for parenterals and transfusion sterile drip kits. Quality control testing and biological toxicity.

Paper and Paper Board: Types ofpaper, folding cartons, quality control testing of paper and paper board.

Metal containers: Aluminum & Tin Plate Drums, Collapsible Tubes & Aerosol Containers, Lacquering, Coating & Lining.

Unit - III :

Sterile product packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile productfilling andsealing machineryi.e. ampoule filling andsealingmachine. Limitations and merits of various packages. Evaluation of the sterile product packages.

Environmental Considerations: Packaging and recycling of packaging materials along with national and international regulations

Unit - IV :

Packaging Machinery: Introduction, strip packaging machinery, form, fill and seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging.

Advances in Packaging Technology: Blister packaging, tamper evident packaging systems, child resistant packaging, aerosol packaging, etc.

Principal
St. Pauls College of Pharmacy

Labels and Labeling: Objectives and contents of a pharmaceutical label. Types of label (including bilingual label, bar code label, radiofrequency(RF) label, structured programlabel, in-mouldlabel and decorative labels), legal requirements of labeling, packaginginserts and outserts. Adhesives and machineryemployed for labeling. Concept of paperless labeling and new developments in labeling technologies.

Books and References:

1. Dean D.A., Evans E.R. Hall I.H. Pharmaceutical Packaging Technology. Taylor & Francis.
2. Jain U.K., Goupale D.C., Nayak S. Pharmaceutical Packaging Technology. Pharma Med Press.
3. Kirwan M.J. Paper and Paper Board Packaging Technology. Blackwell Publishing Ltd.
4. Walter Soroka. Fundamentals of Packaging Technology. Institute of Packaging Professionals.
5. Lockhart H., Paine F.A. Packaging of Pharmaceuticals & Healthcare Products. Blackie Academic & Prof.
6. Hendrickson R. Remington The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 21st Ed.
7. Herrick A.D. Drug Products, Labeling, Packaging, Regulation. General Books, LLC.
8. Yam K.L. The Wiley Encyclopedia of Packaging Technology. John Wiley & Sons.
9. Selke S.E.M. Understanding Plastic Packaging Technology. Karl Hanser Verlag.
10. Hanlon J.F., Kelsey R.J., Forcinio H.E. Handbook of Package Engineering. Technomic Pub. Co.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

DRUG POLYMER TECHNOLOGY

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	3 Hrs.
Credits	:	3
Instruction Mode	:	Lecture
Course Code	:	PY.09.885.25.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

To know and understand the importance of polymers use in drug development

Course Outcomes:

To acquaint with the knowledge of significance of polymers in drug development.

Unit - I :

General Study of Polymer Science: Classification of polymers, Macromolecules: structure and properties (molecular mass, molecular weight distribution, conformation and configuration), Major strategies for synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsions, polymerizations with examples. Methods of polymer modification, Solid state properties of polymers, flow characteristics, crystallinity.

Unit - II :

Evaluation of Polymers in Solution: Polymers in solutions: Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.

Unit - III :

Therapeutic Applications of Polymers: Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.)

Unit - IV :

Bio interactions of Polymers: Interactions of polymers with tissues and cells, Pharmacokinetics of polymer therapeutics, targeted polymer therapeutics, passive targeting of polymeric drugs, enhanced permeation and retention effect (EPR), functional excipients and biological responsemodifiers, polymeric immune-adjuvants and immune-modulators, stimuli responsive systems and intracellular drug delivery.

Unit - V :

Polymer Drugs and Regulatory Issues: Prospects of Polymer Drugs and Regulatory Challenges in Polymer Therapeutics

Books and References:

1. J. Brandrup, E. H. Immergur; Polymer Handbook ;John wiley and Sons
2. L. H. Sperling, Introduction to Polymer Science, Wiley, NY, 1992.
3. H. Morawetz, Macromolecules in Solution (2nd ed.), Wiley-Interscience, NY, 1975
4. C. Tanford, Physical Chemistry of Macromolecules, John Wiley, NY, 1961.

Chairperson, BoS | Head of the Department | Dean of the Faculty

Principal
St. Pauls College of Pharmacy

5. F. W. Billmeyer, Jr. Textbook of Polymer Science, 3rd Ed. John Wiley, New York, 1984.
6. B. D. Ratner, A. S. Hoffman, F. J. Schoen, J. E. Lemons, Biomaterials Science. An Introduction to Materials in Medicine, Academic Press, San Diego, 1996.
7. Biomedical Polymers and Polymer Therapeutics, Eds. E. Chiellini et. al. , KluwerCharles
8. G. Gebelein. T. C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
9. D. S. Soane; Polymer Applications for Biotechnology; Prentice Hall Inc.
10. J. R. Robinson and V. H. Lee: Controlled Drug Delivery – Fundamentals and Application; Marcel Dekker.
11. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications.
12. P. J. Tarcha; Polymers for Controlled Drug Delivery; CRC Press.
13. A. F. Kydonieus; Controlled Release Technologies: Methods, Theoryand Application, Vol-I & II; CRC Press Inc.
14. Academic/Plenum Publishers, NY, 2001.
15. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. A. V. Kabanov,
16. P. L. Felgner, L. W. Seymour, Eds. John Wiley & Sons: New York, 1998.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

QUALITY ASSURANCE AND MANAGEMENT

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	3 Hrs.
Credits	:	3
Instruction Mode	:	Lecture
Course Code	:	PY.09.885.25.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

Acquire knowledge on various quality assurance systems, processes and currentregulatory guidelines related to manufacturing and distribution.

Address quality issues and provide solutions needed to attain Quality leadership in an environmentof continual improvement. Understand the importance of effective management and documentation.

Course Outcomes:

To equip student to be professionally knowledgeable to sustain global quality standards and productive management output in the pharmaceutical industry.

Unit - I :

Basic Concepts of Quality Assurance: Conceptof Quality Control & Quality Assurance, Functions, Sources of Variation, QualityAssurance for Raw Materials, APIs, Packing Materials & Finished Products (Specifications, Receipt, Testing, Sampling and Certificate of Analysis), Production (Change Control, Aseptic Process Control, Temperature, Pressure & Humidity Control Tests, Tests for Air flow Pattern, Microbiological Monitoring) Buildings & Facilities (Designand Construction Features, Construction Materials, Lighting, Air Handling System, Sanitation & Maintenance) Equipment's (Construction, Cleaning and Maintenance, Calibration & Handling)

Unit - II :

Equipment Qualification (EQ): Design Qualification (DQ); Installation Qualification (IQ); Operating Qualification (OQ) and Performance Qualification (PQ)

Standard Operating Procedures (SOP): Operations like Cleaning, Filling, Drying, Compression, Coating, Disinfection, Sterilization, Membrane Filtration etc.

Total Quality Management (TQM): Principles, Elements of TQM, Continuous Improvement and Learning, Management Tools, Tools and Techniques of Quality, New Quality Tools and T echniques

Unit - III :

Inventory Management: Costs, Inventory Categories, Selective Inventory Control, Reorder Quantity Methods and EOQ, Inventory Models, Safety Stock-Stock Out, Lead Time–Reorder Time Methods. Modem Inventory Managements Systems, Inventory Evaluation.

Materials Management: Introduction; Purchasing; Raw Materials; Packaging Materials; Intermediate and Bulk Products; Finished Products; Rejectedand Recovered Materials; Recalled Products; Returned goods; Reagents and Culture Media; Waste Materials; Reference standards; Miscellaneous Materials;

Unit - IV :

Human Resources Management: Introduction; Qualification Experience and Training; Responsibilities and Key Personnel; Personal hygiene and clothing; Legal Aspects; Consultants

Facilities Management: Introduction; Principal Area; Plumbing and Drainage system; Lighting; Ventilation; Heating; Air-Conditioning; Sewage, Refuge and Disposal of Water; Washing and Toilet Facilities; Sanitation; Maintenance; Utilities; Water; Power; Steam; Vacuum; Air; Gases; etc.,

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

Program Code: 886 **M. Pharm. (Pharmaceutics)**

2015 – 16

SEMESTER - I

Course Code	Course Title	Hours /Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.884.11.T	Pharmaceutical Analytical Techniques	3	0	-	3	25	75	3
PY.09.886.12.T	Pharmaceutical Product Development	4	0	-	4	25	75	3
PY.09.886.13.T	Pharmaceutical Production Technology	4	0	0	4	25	75	3
PY.09.886.14.T	Advanced Physical Pharmaceutics	4	0	0	4	25	75	3
PY.09.885.15.T	Quality Assurance	3	0	0	3	25	75	3
PY.09.884.11.P	Pharmaceutical Analytical Techniques	-	0	4	2	25	75	6
PY.09.886.12.P	Pharmaceutical Product Development	-	0	4	2	25	75	6
					22	175	525	
PY.09.886.10.S	SAIL	1	2	0	2	Grade		
PY.09.886.11.S	Seminar	1	0	2	2	Grade		

SEMESTER - II

Course Code	Course Title	Hours /Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.885.21.T	Int. Property Rights & Regulatory Affairs	3	0	-	3	25	75	3
PY.09.886.22.T	Biopharmaceutics and Pharmacokinetics	4	0	-	4	25	75	3
PY.09.886.23.T	Advances in Drug Delivery System	4	0	0	4	25	75	3
PY.09.886.24.T	Process Scale Up and Validation	4	0	0	4	25	75	3
PY.09.88X.25.T	Elective *	3	0	0	3	25	75	3
PY.09.886.22.P	Biopharmaceutics and Pharmacokinetics	-	0	4	2	25	75	6
PY.09.886.23.P	Advances in Drug Delivery System	-	0	4	2	25	75	6
					22	175	525	
PY.09.886.20.S	SAIL	1	2	0	2	Grade		
PY.09.886.21.S	Seminar	1	0	2	2	Grade		

* Discipline Centric – Cosmetic Technology/Drug Polymer Technology;
Open – Pharmaceutical Biotechnology

SEMESTER – III

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.886.31.P	Design Seminar	30	6	50	-	6
PY.10.886.32.P	Progressive Seminar	30	10	50	-	10
		480	16	100		

SEMESTER – IV

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.886.41.P	Pre-Submission Seminar	30	10		50	10
PY.10.886.42.P	Submission and Adjudication	30	12		200	6
PY.10.886.43.P	Final Viva-voce	30	2		50	1
		510	24		300	17

Chairperson, BoS Head of the Department Dean of the Faculty

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

ELECTIVE

COSMETIC TECHNOLOGY

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	3 Hrs.
Credits	:	3
Instruction Mode	:	Lecture
Course Code	:	PY.09.886.25.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

To provide the concepts of various parameters involved in the formulation and development of Cosmetics

Course Outcomes:

Understand the formulation concepts and factors influencing the developmentofvarious Cosmetics

Unit – I :

General Raw Materials in CosmeticFormulations: Overview of raw materials-Water, natural & synthetic oils, fats& waxes, inorganic solids, emulsifiers, thickeners, hydrocolloids, polymers, surfactants, antioxidants, humectants, poly-siloxanes, preservatives; Coloring agents used in cosmetics. Quality evaluation of colors, safety, toxicity and regulatory aspects of colors w.r.t. cosmetic products;

Perfumes in cosmetics: Raw materials in perfumery, developing a perfume composition, current trends including emulsified and solid perfumery, analytical and separation techniques of perfumes, sensory analysis, safety and toxicological evaluation of perfumes, manufacturing and packaging of perfumes, legislation and regulations for perfumes in cosmetics.

Unit – II :

Novel Approaches in Cosmetic Formulations: Concepts of micro-emulsions, liposomes, niosomes, nanoparticles, iontophoresis, to enhance functional attributes & delivery of cosmeceuticals.

Therapeutic Ingredients in various Cosmetics: Skin Products, Dentifrices, Hair care and Nail preparations, and performance evaluation of these activities.

Herbal Cosmetics: Current trends in use of herbal materials in cosmetics such as *aloe Vera, henna, tea tree oil, neem in various cosmetic products*

Unit – III :

Physiological Consideration: Skin, Hair, Nail and Eye- in relation to Cosmetic Application.

Rheology of Cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions.

Manufacturing Techniques: Cosmetic creams, powders, compacts, sticks, liquids, foam and aerosols.

Packaging: Package development and design for cosmetics including aerosol packs.

Unit – IV :

Quality Standards of Cosmetic Products: QualityControl, BIS guidelines for quality of finished products for cosmetics, Microbiological Quality of Cosmetic Products

Evaluation of Cosmetics: Textural Analysis, Performance, Physicochemical, Microbiological and Psychometric evaluation of various cosmetic products such as creams, gels, powders, lipstick, nail lacquer, shampoo, sunscreen products, dentifrices. Design and Assessment of preservative systems for cosmetics, evaluation of preservatives in cosmetic products and factors affecting activity of preservatives.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

Unit – V :

Clinical Safety Testing: ; Safety and toxicity evaluation of cosmetic products; Irritation, sensitization, photoirritation, photoallergy, ocular irritation and protocols for the same. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products.

Regulatory Requirements: Manufacturing and Sale of Cosmetics.

Books and References:

1. Hilda Butler, Klewer, Poucher's Perfumes, Cosmetics & Soaps, 10th Ed, Academic Publishers, NL, 2000
2. S. Nanda, A. Nanda and R. Khar, Cosmetic Technology, Ed. Birla Publications Pvt. Ltd., New Delhi, 2007
3. M. Paye, A.O. Barel, H. I. Maibach, Handbook of Cosmetic Science and Technology, Informa Healthcare USA, Inc. 2007.
4. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Vol. 6, Marcel Dekker Inc., 1992
5. J. Knowlton and S. Rearce; Handbook of Cosmetic Sciences and TechnologyElsevier SciencePublisher.
6. J. B. Wilkinson and R. J. Moore; Harry's Cosmetology; Longman science and Technical.
7. S. N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
8. E. G. Thomssen; Modern Cosmetics; Universal Publishing Corporation.
9. M.S. Balsam, E. Sagarin, S.D. Gerhon, S.J.Strianse and M.M.Rieger, Cosmetics Science and Technology, Edited Volumes 1,2 and 3.Wiley-Interscience, Wiley India Pvt. Ltd.,2008
10. R. L. Elder; Cosmetic Ingredients, their Safety Assessment; Pathotox.
11. H. R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
12. W. C. Waggoner; Clinical Safety and Efficacy Testing of Cosmetics; Marcel Dekker.
13. C. G. Gebelein, T. C. Cheng and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum.
14. L. Appell; The Formulation and Preparation of Cosmetics, Fragrances and Flavors; Micelle Press.
15. W. A. Poucher; Poucher's Perfumes, Cosmetics and Soaps; vol. 3 Chapman and Hall
16. Dr. Laba; 'Rheological Properties of Cosmetics and Toiletries; Marcel Dekker
17. Drugs & Cosmetics Act & Rules, 1940 (with latest amendments)..

St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

PHARMACEUTICAL BIOTECHNOLOGY

Scheme of Instruction

Total Duration	:	60 Hrs.
Hours/Week	:	3 Hrs.
Credits	:	3
Instruction Mode	:	Lecture
Course Code	:	PY.09.886.25.T

Scheme of Examination

Max. Marks	:	100
Mid Semester	:	20
Quiz	:	05
End Semester	:	75
Exam Duration	:	3 Hrs.

Course Objectives:

To understand the basics of biotechnology in production ofdrugs and pharmaceuticals

Course Outcomes:

To apply the knowledge of biotechnology in development of Biopharmaceuticals

Unit - I :

Status and Scope of Biotechnology in Pharmacy Enzyme immobilization- Principles and Pharmaceutical applications. Immobilization of enzymes, proteins and their applications – biosensors, enzyme electrodes, immune-sensors, optical sensors

Biotransformation principles and industrial applications in the production ofchemicals and drugs;

Unit - II :

Biotechnology based pharmaceutical using recombinant DNA Technology, interferons and reverse transcriptase.

Production and Control of Biotech derived products: Recombinant DNAproducts – insulin, growth hormone, erythropoietin, cytokines; Vaccines – attenuated virus, genetic alterations of live virus as a vector of other pathogens (recombinant virus or recombinant vaccinia virus); Diagnostic proteins – protein A, protein G,

antibodies; Quality control testing of biotech products – determining impurities, contamination -viral, bacterial endotoxin, rabbit pyrogen test, sterility, protein identification, finger prints by electrophoresis, isoelectric focusing, immunogenicity, partial sequence analysis

Unit - III :

Optimization of fermentation processes-Ethyl Alcohol, Antibiotics, Vitamins, Amino-acids and Pharmaceutical solvents-raw materials, process and process validation.

Biotech products through fermentation: Fermentation – batch, continuous fermentation. Role of bioengineering in fermentation – geometry of fermentation tanks, design of impellers, agitation systems and environmental conditions of fermentation; Fermentative production of important secondary metabolites – penicillins, amino glycosides polyene macrolides, macrolides, anthracyclines; Principles of downstream processing of fermentation products; Unit operations and techniques employed inn downstream processing of fermentation; products, microbial strain selection and preservation methods; Genotype and phenotype variation of characters of microbes;

Unit - IV :

Plant biotech products: Substances produced by plant cell culture; Transgenic plants and their application; Biotransformations with plant cell culture;

Bio-technology & GMP- Formulation approaches to protein stabilization. Regulatory aspects of Biotechnology based pharmaceuticals.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

Chairperson, BoS | Head of the Department | Dean of the Faculty

Introduction to Bio-informatics. Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons. Applications of predictive pharmaceutics, chemico-pharmaceutics, cheminformatics, bioinformatics and data mining.

Books and References:

1. Wiseman A.,ed, Principles of Bio-technology", Chapman & Hall.
2. Antebi E, Fishlock D., "Biotechnology- Strategies for life", Cambridge.
3. Higgins 1.1., Best, DJ & Jones "Biotechnology, Principles & Applications" Blackwell Scientific Pub., Oxford.
4. Stanbary P.F. and Whitaker, "Principles of Fermentation Technology" Pergamon Press, Oxford.
5. Golub E "The Limits of Medicine: How Science Shapes our Hope for the Cure Time Books, New York.
6. Bickerstaff GF. "Enzymes in Industry and Medicine, New Studies in Biology" Edwin Arnold, London.
7. Glick. BR, Pasternak J.I., "Molecular Biotechnology-Principles and Applications of Recombinant DNA" ASM Press Washington.
8. H. J. Rechm, G. Reed, Biotechnology. Vols 1 – 12, A. Pulher, P. Stadler Eds, Weinhelm, New York
9. H. D. Kumar, A text book of Biotechnology, Affiliated, East – West Press Pvt. Ltd.
10. C. Clark, Genetic Engineering Fundamentals, Karl Kammer, Meyer Virginia,.
11. Benjamin Lewin, Genes V, Oxford University Press.
12. Bernard R Glick, John E Thompson, Methods in Plant Molecular Biologyand Biotechnology, CRC Press.
13. Leo C Vining, Colin, Stuttard Butterworth, Genetic and Biochemistryof Antibiotics Production, Heinemann.
14. Paul N Chermisinoff, Robert P Ouellett, Biotechnology-Applications and Research, Technomic Pub. Co. Inc.
15. Meran R. L. Owen, Jan Pen, Transgenic Plants: A production systems for industrial and pharmaceutical proteins, John Wiley and Sons.
16. William R Strohl, Biotechnologyof antibiotics, Marcel Dekker.
17. Sunil Maulik and Salil D Patel, Molecular Biochemistry– Therapeutic Applications and Strategies, John Wiley and Sons,

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27/29$/30#
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**209/211$/212#**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

Principal
St. Pauls College of Pharmacy

Pharmacy Council of India

New Delhi

Rules & Syllabus for the Bachelor of Pharmacy (B. Pharm) Course

---

[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B. Pharm) course regulations 2014]

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:
The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I **10 Hours**

Marketing:
Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:
Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **10 Hours**

Product decision:
Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III **10 Hours**

Promotion:
Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

Unit IV **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V **10 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international 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 **10Hours**

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 **10Hours**

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 By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

Principal
St. Pauls College of Pharmacy,
Turkayamjal, R.R. Dist-501 510

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. 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

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

- Terminologies of adverse medication related events
- Regulatory terminologies

10 hours

Unit II

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

10 Hours

Unit III

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

8 Hours

Unit IV

Safety data generation

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

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

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

7 hours

Unit V

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 Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

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

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

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;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

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.

Principal
St. Pauls College of Pharmacy

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 principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. 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.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

UNIT-IV **08 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I 10Hours

a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

a) DNA and the Flow of Molecular Information
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III **10 Hours**

a) Proteins: Defined **and** Amino Acids
b) Protein Structure

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

c) Regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

BP809ET. COSMETICSCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT IV **08 Hours.**

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps,and syndet bars. Evolution and skin benfits.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

Principal
St. Pauls College of Pharmacy
Turkapally, R.R. Dist-501 510.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. **b. Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's,antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

Principal
St. Pauls College of Pharmacy

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I — 10 Hours

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II — 10 Hours

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III — 10 Hours

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer.

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

Hyphenated techniques- LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.

   (2) They shall come into force from the date of their publication in the official Gazette.

2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

2. **Upon completion of the course the student shall be able to :** –
   a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   b. solve the problems of different types by applying theory; and
   c. appreciate the important applications of mathematics in pharmacy.

3. **Course materials:**

   Text books
   a. Differential calculus By Shantinarayan
   b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

   Reference books
   a. Integral calculus By Shanthinarayan
   b. Engineering mathematics By B.S.Grewal
   c. Trigonometry Part-I By S.L.Loney

4. **Lecture wise programme :**

   Topics

   1 **Algebra :** Determinants, Matrices
   2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
   3 **Analytical Geometry :**Points, Straight line, circle, parabola
   4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
   5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
   6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
   7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

BIOLOGY :

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

a. Text book of Biology by S.B.Gokhale
b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

01 Introduction
02 General organization of plants and its inclusions
03 Plant tissues
04 Plant kingdom and its classification
05 Morphology of plants
06 Root, Stem, Leaf and Its modifications
07 Inflorescence and Pollination of flowers
08 Morphology of fruits and seeds
09 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

01 Study of Animal cell
02 Study animal tissues
03 Detailed study of frog
04 Study of Pisces, Raptiles, Aves
05 Genearal organization of mammals
06 Study of poisonous animals

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Principal
St. Pauls College of Pharmacy
Turkayamjal, R.R. Dist-501 510.