Shri Guru Ram Rai University

[Estd. by Govt. of Uttarakhand, vide Shri Guru Ram Rai University Act no. 03 of 2017 & recognized by UGC u/s (2f) of UGC Act 1956]

Patel Nagar, Dehradun -248001, Uttarakhand.

Syllabus

Pre Ph.D Course Work

PRE PhD SYLLABUS FOR PHARMACEUTICAL SCIENCES

Paper Code	Subject Title	Credit	Marks
PRMC 101	Research Methodology*	4	80
PRPE 102	Research & Publication Ethics*	2	40
PPCC 103	Advanced Analytical Techniques	4	80
PPCE 104	Pharmaceutical Chemistry	4	80
PPCE 105	Advanced Medicinal Chemistry		
PPCE 106	Pharmaceutical Quality Assurance & Quality Control		
PPCF 107	Field Work (Seminar/ conference presentation, review literature, journal club and other academic activities.)	4	80
PPHC 103	Advanced Analytical Techniques	4	80
PPHE 104	Advanced drug delivery system	4	80
PPHE 105	Pharmaceutical Formulation Development		
PPHE 106	Pharmaceutical production technology		
PPHF 107	Field Work (Seminar/ conference presentation, review literature, journal club and other academic activities.)	4	80
PPLC 103	Advanced Analytical Techniques	4	80
PPLE 104	Pharmacological Screening Methods		
PPLE 105	Recent Advances In Pharmacology And Clinical Research		
PPLE 106	Principles of Drug Discovery & Molecular Pharmacology		
PPLF 107	Field Work (Seminar/ conference presentation, review literature, journal club and other academic activities.)	4	80
PPGC 103	Advanced Analytical Techniques	4	80
PPGE 104	Advanced Pharmacognosy	4	80
PPGE 105	Phytochemistry		
PPGE 106	Indian system of medicine & herbal cosmetics		
PPGF 107	Field Work (Seminar/ conference presentation, review literature, journal club and other academic activities.)	4	80

PPPC 103	**Clinical & Hospital Pharmacy**	**4**	**80**
PPPE 104	**Fundamentals of Clinical Research**	**4**	**80**
PPPE105	**Principles of Quality Use of Medicines**		
PPPE 106	**Pharmacotherapeutics**		
PPPF 107	**Field Work (Seminar/ conference presentation, review literature, journal club and other academic activities.)**	**4**	**80**

***Research Methodology & Research & Publication Ethics subjects are compulsory for all specialization.**

Core Subject

Research Methodology (Compulsory)

Code: PRMC 101

(Credit Score-4)

Unit I-Concept & Types of Research

Meaning and importance of Research – Types of Research – Selection and formulation of Research Problem – Research Design, Classification of Research, Pure and Applied Research, Exploring or Formulative Research, Descriptive Research, Diagnostic Research/Study, Evaluation research/Studies, Action Research, Experimental Research, Analytical Study of Statistical Method, Historical Research.

Unit II –Methods Research

Surveys, Case Study, Field Studies General Survey of various Methods including Survey Method, Interdisciplinary Method, Case Study Method, Sampling Method, Statistical Method, Observation Method, Interview Method, Schedule Method, Questionnaire Method, Documentary Method, Library Method, Historical Method and Scientific Method. Characteristic Features of Scientific Method; Empirical Verifiable, Cumulative, Self - Correcting, Deterministic, Ethical & Ideological neutrality (Value Free), Statistical Generalizability.

Unit III - Data Collection and Data Analysis

Collection, Objectives and Classification of Data, Aims, Methods and Objects of Tabulation of Data, Forms and Processes of Interpretation and Presentation of Data.

Primary, Secondary and Tertiary Data.Construction and adaptation of instruments, administration of questions and tests. Data organization in SPSS & Excel, Graphical representation of data

Definition and Aims of Content Analysis, Problems of Content Analysis, Computer and Content Analysis Discussion and Interpretation of results, Testing of Hypothesis: Logical and Statistical Techniques.

Unit IV: Report Writing

Locating Information on a Topic of Interest, Acquiring Copies of Articles of Interest, The Nature of Scientific Variables, Conceptual Versus Operational Definitions of Variables, Levels of Measurement, Various Paradigms, The Basic Format for a Research Report, Identification of the Parts of a Research Report, Citation and Referencing Styles, Essentials of Report Writing, Aids for Writing Good Research Report.

References:

1. Bagchi, Kanak Kanti (2007) Research Methodology in Social Sciences: A Practical Guide, Delhi, Abijeet Publications.

2. Kothari, C.R (2004) Research Methodology: An Introduction, Delhi, New Age.

3.Cooper, R. Donald and Pamela S. Schindler (2003) Business Research Methods, Delhi, Tata McGraw-Hill.

4. Flyvbjerg, Bent (2001) Making Social Science Matter: Why Social Inquiry Fails and How it can Succeed Again, United Kingdom, Cambridge University Press.

5. Goodde and Hatte (1952) Methods in Social Research, New York, McGraw – Hill.

Research & Publication Ethics (Compulsory)

Code: PRPE 102

(Credit Score-2)

RPE 01 PHILOSOPHY & ETHICS (3 hrs)

1. Introduction to Philosophy: definition, nature & scope, concept, branches
2. Ethics: definition, moral Philosophy, nature of moral judgements and reactions

RPE 02 SCIENTIFIC CONDUCT (5 hrs)

1. Ethics with respect to Science and research
2. Intellectual honesty and research integrity
3. Scientific misconduct: falsification, Fabrication, and Plagiarism (FFP)
4. Reductant Publications: duplicate and over lapping publications, salami slicing
5. Selective reporting and misrepresentation of data

RPE 03 PUBLICATION ETHICS (7 hrs)

1. Publication ethics: definition, introduction & importance
2. Best Practices/ standards setting initiatives & guidelines: COPE, WAME, etc
3. Conflict of interest
4. Publication misconduct: definition, concept, problems that lead to unethical behavior & vice versa, types
5. Violation of publication ethics, authorship & contributorship
6. Identification of publication misconduct, complaints & appeals
7. Predatory publishers & journals

PRACTICE

RPE 04: OPEN ACCESS PUBLISHING (4 hrs)

1. Open access publications & initiatives
2. SHERPA/ RoMEO online resource to check publisher copyright & self- archiving policies
3. Software tool to identify predatory publications developed by SPPU
4. Journal finder/ journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer journal Suggester, etc.

RPE 05: PUBLICATION MISCONDUCT (4hrs)

A. **Group Discussion** (2hrs)

1. Subject specific ethical issues, FFP, authorship
2. Conflict of interest
3. Complaints & appeals: examples & fraud from India & abroad

B. Software (2 hrs)

Use of plagiarism software like Turnitin, Urkund, and other open source software tools

RPE 06 : DATABASES AND RESEARCH METRICS (7 hrs)

A. Databases (4hrs)

1. Indexing databases
2. Citation databases: Web of Science, Scopus etc.

B. Research Metrics (3 hrs)

1. Impact Factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score
2. Metrics: h-index, g index,i10 index, altmetrics

Core Subject

Advanced Analytical Techniques

Paper Code- PPCC 103

(Credit Score-4)

Unit I Spectroscopy

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Woodword'sFieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Applications of UV-Visible spectroscopy.

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra's of compounds and Applications of IR spectroscopy.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quencher Instrumentation and Applications of fluorescence spectrophotometer.

d. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spincoupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra's of compounds to the structure elucidation.

e. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, Applications of mass spectroscopy to structural elucidation of compounds .GC-MS and LC-MS Principle and Application.

Unit II Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g)HPTLC

i) Electrophoresis.

Unit III Immunological assays

RIA (Radio immuno assay), ELISA, Bioluminescence assays.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Elective Subject

Pharmaceutical Chemistry

Paper Code- PPCE 104

(Credit Score-4)

Unit I Photochemical Reactions

Basic principles of photochemical reactions.Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions: Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

Unit II Catalysis:

Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

Homogenous catalysis, hydrogenation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs.

Transition-metal and Organo-catalysis in organic synthesis

Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

Phase transfer catalysis - theory and applications.

Unit III Stereochemistry & Asymmetric Synthesis

Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis.

Unit IV Chemistry of peptides

Coupling reactions in peptide synthesis, Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond

formation, deprotection and cleavage from resin, site-specific chemical modifications of peptides

Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

Unit V Interpretation of spectra

Interpretation of spectra from UV, IR, PMR, CMR, 2DNMR and Mass spectrophotometer for structure elucidation of organic compounds.

References:

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.
7. Principles of organic synthesis, ROC Norman and JMCoxan, Nelson thorns
8. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
9. Organic Spectroscopy by Donald L. Paviya, 5th Edition

Elective Subject

Advanced Medicinal Chemistry

Paper Code- PPCE 105

(Credit Score-4)

Unit I Drug discovery and design

Introduction to Computer aided drug design, Molecular modeling methods, molecular mechanics, molecular dynamics, principle of Molecular docking, Rigid docking, flexible docking and extra-precision docking, concept of prodrug design, concept of combinatorial chemistry, high throughput screening, 3D- QSAR based COMFA and COMSIA approaches.

Unit II Molecular Properties and Drug Design

Prediction and analysis of ADMET properties of new molecules and its importance in drug design.De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. Homology modeling and generation of 3D-structure of protein.

Unit III Targets for development of drugs

Systematic study, SAR, Mechanism of action and synthesis of recently developed drugs and molecules in development pipeline for following diseases: cancer, tuberculosis, malaria, epilepsy, and cardiovascular diseases.

Unit IV Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols

Unit V Green Chemistry:

Introduction, principles of green chemistry

Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

Continuous flow reactors: Working principle, advantages and synthetic applications.

References:

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore, RCS Publishers.
5. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
6. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers
7. Principles of Drug Design by Smith.
8. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, II Edition, Elsevier Publishers, New Delhi.
9. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
10. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
11. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
12. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
13. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
14. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
15. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

Elective Subject

Pharmaceutical Quality Assurance & Quality Control

Paper Code- PPCE 106

(Credit Score-4)

Unit I Quality Control and Quality Assurance

a. Concept and evolution and scopes of Quality Control and Quality Assurance, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
b. **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 II Pharmaceutical quality Management

Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO14001:2004, Pharmaceutical Quality Management – ICH Q10, OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO GMP requirements.

Unit III Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC)

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, parenteral, ophthalmic and surgical products.

Unit IV Qualification

User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC,GC, HPLC, HPTLC, LC-MS.

Unit V Validation

Definition of Calibration, Qualification and Validation, Scope, frequency and importance.Difference between calibration and validation.Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

a. **Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.
b. **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

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. 126
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. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
10. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
11. 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 Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001

12. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
13. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
14. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
15. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
16. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider

Core Subject

Advanced Analytical Techniques

Paper Code- PPHC 103

(Credit Score-4)

Unit I Spectroscopy

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV- Visible spectroscopy, Choice of solvents and solvent effect, Woodword'sFieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Applications of UV-Visible spectroscopy.

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra's of compounds and Applications of IR spectroscopy.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quencher Instrumentation and Applications of fluorescence spectrophotometer.

d. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra's of compounds to the structure elucidation.

e. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, Applications of mass spectroscopy to structural elucidation of compounds .GC-MS and LC-MS Principle and Application.

Unit II Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g)HPTLC

i) Electrophoresis.

Unit III Immunological assays

RIA (Radio immuno assay), ELISA, Bioluminescence assays.

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1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Elective Subject

Advanced Drug Delivery System

Paper Code- PPHE 104

(Credit Score-4)

Unit I Rate Controlled Drug Delivery Systems

Principles & Fundamentals, Types, Activation Modulated Drug Delivery Systems; Mechanically activated, pH Activated, Enzyme activated, and Osmotic activated Drug Delivery Systems, Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit II Gastro-Retentive Drug Delivery Systems

Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

Unit III Mucosal Drug Delivery system

Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability andformulation considerations of buccal delivery systems

Unit IV Pulmonary Drug Delivery Systems

Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit V Occular Drug Delivery Systems

Barriers of drug permeation, Methods to overcome barriers. Suitable formulations and evaluation

Unit VI Trans Dermal Drug Delivery Systems

Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems,Formulation and evaluation. concept of implants and osmotic pump.

Unit VII Protein and Peptide Delivery

Barriers for protein delivery.Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Unit VIII Vaccine delivery systems

Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Unit IX Targeted Drug Delivery Systems

Concepts, Events and biological process involved in drug targeting.Tumor targeting and Brain specific delivery.

Unit X Targeting Methods

Introduction preparation and evaluation. Nano Particles &Liposomes: Types, preparation and evaluation

Unit XI Micro Capsules / Micro Spheres

Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes,Aquasomes, Phytosomes, Electrosomes.

Unit XII Nanotechnology and its Concepts

Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

References:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, MarcelnDekker,Inc., New York, 1992.

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002

Elective Subject

Pharmaceutical Formulation Development

Paper Code- PPHE 105

(Credit Score-4)

Unit I Preformulation Studies

Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

Unit IIFormulation Additives

Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science.Design of experiments factorial design for product and process development.

Unit IIISolubility

Importance, experimental determination, phase solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods co-solvency, salt formation, complexation,soliddispersion, micellar solubilization and hydrotropy.

Unit IVDissolution

Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink.Factors influencing dissolution and intrinsic dissolution studies.Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products.Data handling and correction factor.Bio relevant media, in-vitro and in-vivo correlations, levels of correlations.

Unit V Product Stability

Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API &tablets). Solid state stability and shelf life assignment.Stability protocols, reports and ICH guidelines.

References:

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed, B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 nd ed., CBS Publishers & distributors, New Delhi, 2005.
4 Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12.Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rded.,CBS publications, New Delhi, 2008. rd
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rded.,CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 thed.,Inc, New York, 2005.
11. W. Grimm - Stability testing of drug product Marcel Dekker
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II.,4ted.,2004.CBS Publishers & distributors, New Delhi,
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.

18. Wells J. I. Pharmaceutical Preformulation : The physico chemical properties of Drug substances, Ellis Horwood Ltd. England, 1988

Elective Subject

Pharmaceutical Production Technology

Paper Code-PPHE 106

(Credit Score-4)

Unit I Improved Tablet Production

Tablet production process, unit operation improvements, granulation and Pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

Unit II Parenteral Production

Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Unit III Lyophilization & Spray drying Technology

Principles, process, freeze-drying and spray drying equipments.

Unit IV Capsule Production

Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Unit V Disperse Systems Production

Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Unit VI Packaging Technology

Types of packaging materials, machinery, labeling, and package printing for different dosage forms.

Unit VII Air Handling Systems

Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra –filtration, WFI.

References:

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman,Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C.Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker,NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Elli Horwoods, UK.

Core Subject

Advanced Analytical Techniques

Paper Code- PPLC 103

(Credit Score-4)

Unit I Spectroscopy

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV- Visible spectroscopy, Choice of solvents and solvent effect, Woodword's Fieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Applications of UV-Visible spectroscopy.

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra's of compounds and Applications of IR spectroscopy.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quencher Instrumentation and Applications of fluorescence spectrophotometer.

d. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra's of compounds to the structure elucidation.

e. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, Applications of mass spectroscopy to structural elucidation of compounds .GC-MS and LC-MS Principle and Application.

Unit II Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g)HPTLC

i) Electrophoresis.

Unit III Immunological assays

RIA (Radio immuno assay), ELISA, Bioluminescence assays.

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Elective Subject

Pharmacological Screening Methods

Paper Code- PPLE 104

(Credit Score-4)

Unit 1

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 2

Dose selection in Animal Experimentation, 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.

Unit 3

Preclinical screening models for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

Unit 4

Preclinical screening models for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants

Preclinical screening models for antiulcer, antidiabetic, anticancer and antiasthmatics.

Unit 5

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

References:

1. Fundamentals of Experimental Pharmacology 7th/2019 Author: M. N. Ghosh, ISBN: 9788190296507, Publisher : Hilton & Company, Edition : 7th

2. Kulkarni, S. K. Handbook of experimental pharmacology 3rd edition vallabh publication New Delhi

3. CPCSEA guidelines for laboratory animal facility.

4. Drug Discovery and Evaluation: Pharmacological Assays, 2007 by Hans VogelPublisher: Springer; 3rd completely rev., updated and enlarged ed. edition (November 20, 2007) Language: English, ISBN-10: 3540714200

5. Drug Screening Methods by S. K. Gupta Publisher: Jaypee Brothers Medical Publishers (P) Ltd. (December 1, 2004), Language: English,ISBN-10: 8180613976, ISBN-13: 978-8180613975

Elective Subject

Recent Advances In Pharmacology And Clinical Research

Paper Code- PPLE 105

(Credit Score-4)

Unit-1: Molecular Pharmacology

Receptor occupancy and cellular signaling systems including G- proteins,cyclic nucleotides, calcium and calcium binding proteins, phospholipases.

***Pharmacology of receptors*:** Classification, cellular signaling systems, and pharmacology of agonists and antagonists of Excitatory Amino Acid receptors, Purinoreceptors, GABA and Benzodiazepine receptors

***Ion Channels and Their Modulators*:** Classification and biology of potassium ionic channels, and pharmacology of their modulators

***Novel Target Sites*:** Physiological functions, pharmacological implications, and Therapeutic potential of Akt (Protein kinase B),(b) Caspases, AMP activated protein kinases, Protein kinases and Phosphodiesterases

Unit-II: Neuropeptides

Biological functions, pharmacological implications, their agonists and antagonists,and therapeutic potentials of Neuropeptide Y,Substance P and Cholecystokinin

Transporter Proteins: Classification and biology of ATP binding cassette (ABC) transporter superfamily, Multidrug resistance (MDR) proteins and Cystic fibrosis transmembrane regulator (CFTR)

Unit-III: Programmed Cell Death (Apoptosis)

Molecular biology, physiological and pharmacological implications and therapeutic potentials of apoptosis.

Cytokines and Chemokines: Classification, physiology, pharmacology, pathological, and therapeutic implications of various cytokines and chemokines.

Growth Factors: Biology and therapeutic potentials of various growth factors. .

Biology of Vascular Endothelium: Biology of EDRF, EDCF, and EDHF.

Unit-1V: Drug development process

Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research –

Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

Unit-V Types and Designs used in Clinical Research

Planning and execution of clinical trials, Clinical Trial Study team, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques, Types of research designs based on Controlling Method Time Sequences, Sampling methods, Health outcome measures.

References:

1. Rang & Dale's pharmacology by H P Rang; James Ritter; R J Flower; G Henderson, Publisher: [Edinburgh] : Elsevier/Churchill Livingstone, [2016] Edition/Format: eBook : Document : English : Eighth edition

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone

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

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

5.International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

6.Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.

Elective Subject

Principles of Drug Discovery & Molecular Pharmacology

Paper Code- PPLE 106

(Credit Score-4)

Unit 1

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins.Role of transgenic animals in target validation.

Unit 2

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening

Unit 3

a. Cell culture techniques Basic equipment's used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium in flux assays Principles and applications of flow cytometry

b. Biosimilars

Unit 4

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Unit 5

Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors.Applications of recombinant DNA technology.

References:

1. Pharmacogenomics: TheSearch forIndividualized Therapies. Edited byJ. Licinioand M-L.Wong
2. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
3. Basic Cell CultureprotocolsbyCheril D.HelgasonandCindyL.Miller
4. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
5. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 HumanaPressInc.
6. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identificationand Validation.2006byTaylor and FrancisGroup, LLC.
7. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols.SpringerNew YorkDordrechtHeidelbergLondon.
8. Abby L .Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American ChemicalSociety:Washington,DC,1999.
9. J. Rick Turner. New drug development design, methodology and analysis. John Wiley & Sons,Inc., New Jersey.

Core Subject

Advanced Analytical Techniques

Paper Code- PPGC 103

(Credit Score-4)

Unit I Spectroscopy

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV- Visible spectroscopy, Choice of solvents and solvent effect, Woodword's Fieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Applications of UV-Visible spectroscopy.

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra's of compounds and Applications of IR spectroscopy.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quencher Instrumentation and Applications of fluorescence spectrophotometer.

d. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra's of compounds to the structure elucidation.

e. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, Applications of mass spectroscopy to structural elucidation of compounds .GC-MS and LC-MS Principle and Application.

Unit II Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g)HPTLC

i) Electrophoresis.

Unit III Immunological assays

RIA (Radio immuno assay), ELISA, Bioluminescence assays.

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Elective Subject

Advanced Pharmacognosy

Paper Code- PPGE 104

(Credit Score-4)

Unit I Plant drug cultivation

General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants.

Unit II Marine natural products

General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

Unit III Nutraceuticals

Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

Unit IV Phytopharmaceuticals

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β-Carotene ii) Xanthophyll (Lutein)

b) Limonoids – i) d-Limoneneii) α– Terpineol

c) Saponins – i) Shatavarins

d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin

e) Phenolic acids – Ellagic acid

f) Vitamins

g) Tocotrienols and Tocopherols

h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol

i) Miscellaneous

j) Analytical Profiles of: *Andrographispaniculata*, *Boswelliaserata, Coleus forskholii*, *Curcuma longa*, *Embelica officinalis*, *Psoraleacorylifolia*.

Unit V Ethnobotany and Ethnopharmacology

Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, new development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

References:

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modern Methods of Plant Analysis-Peach & M.V. Tracey, Vol. I &II
4. Textbook of Pharmacognosy by T.E.Wallis
5. Marine Natural Products-Vol. I to IV.
6. Natural products: A lab guide by Raphael Ikan, AcademicPress1991.
7. Glimpses of Indian Ethanopharmacology, P. Pushpanga dam. Ulf Nyman. V. George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products-Paul J.Schewer1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal &B.M.Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K.Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.

14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press,New York,1998
15. Recent Advances in Phytochemistry-Vol.1&4: Scikel Runeckles-Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutosh kar, New Age Publications, New Delhi.

Elective Subject

Phytochemistry

Paper Code- PPGE 105

(Credit Score-4)

Unit I Biosynthetic pathways and Radio tracing techniques

Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following Phyto-pharmaceuticals containing drugs: a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids. b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin. c) Steroids: Hecogenin, guggulosterone and withanolides d) Coumarin: Umbelliferone. e) Terpenoids: Cucurbitacins.

Unit II Drug discovery and development

History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : Artemesin, Andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.

Unit III Extraction and Phytochemical studies

Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

Unit IV Phytochemical finger printing

HPTLC and LCMS/GCMS applications in the characterization of herbal extracts.Structure elucidation of phytoconstituents. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C)

a. Carvone, Citral, Menthol

b. Luteolin, Kaempferol

c. Nicotine, Caffeine

d. Glycyrrhizin.

Unit V Monographs of herbal drugs

General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols.

Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.

References:

1. Organic chemistry by I. L.Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C.Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn.1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and Seemi Siddiqui
10. Organic Chemistry of Natural Products, Vol.1& 2.Gurdeep R Chatwal.
11. Chemistry of Natural Products-Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis-Peach & M.V. Tracey, Vol. I & II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.

15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

Elective Subject

Indian System of Medicine & Herbal Cosmetics

Paper Code- PPGE 106

(Credit Score-4)

Unit I **Indian System of Medicine & Herbal Cosmetics**

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM. Ayurveda Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

Unit II 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. Quality assurance in ISM formulation industry - GAP, GMP and GLP.Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.

Unit III Formulation development of various systems of medicine.

Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM.

Unit IV Herbal/natural cosmetics

Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

References:

1. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
2. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
3. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
4. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
6. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt.ofIndia,New Delhi.
7. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
8. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
9. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
10. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
11. Homeopathic Pharmacy: An introduction & Handbook, Steven B. Kayne, Churchill Livingstone, New York.
12. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
13. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.

14. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
15. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
16. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
17. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
18. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.
19. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
20. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
21. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, NewDelhi.
22. Supriya KB. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
23. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
24. KathiKeville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
25. Chattopadhyay PK. Herbal Cosmetics &Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
26. Balsam MS &Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, NewYork.

Core Subject

Clinical & Hospital Pharmacy

Paper code- PPPC 103

Credit Score- 4

Unit I Introduction to Clinical Pharmacy

Definitions, development and scope of clinical pharmacy.

Unit II Introductiontodailyactivitiesofaclinicalpharmacist

a. Drugtherapymonitoring (medication chartreview,clinicalreview,pharmacist interventions)
b. Wardroundparticipation
c. Adversedrugreactionmanagement
d. Druginformationandpoisonsinformation
e. Medicationhistory
f. Patientcounselling
g. Drug utilistion evaluation (DUE)and review (DUR)
h. Qualityassuranceofclinicalpharmacyservices

Unit III Patient data analysis

The patient's case history, its structure and use in evaluation of drug therapy &Understanding common medical abbreviations and terminologies used in clinical practices.

Unit IV Drug &Poison information

a. Introductiontodruginformationresourcesavailable
b. SystematicapproachinansweringDIqueries
c. Criticalevaluationofdruginformationandliterature
d. Preparationofwrittenandverbalreports
e. EstablishingaDrugInformationCentre
f. Poisonsinformation-organization&informationresources

Unit V Pharmacovigilance

a. Scope,definition and aims of pharmcovigilance.
b. Adverse drug reactions - Classification, mechanism, predisposing factors, causalityassessment[differentscalesused]

c. Reporting,evaluation, monitoring, preventing & management of ADRs

d. Role of pharmacist in managementofADR.

Unit VI Patient counselling Techniques

Communication skills, including patient counseling techniques, medication history interview, presentation of cases. Pharmaceutical care concepts

Unit VII Hospital pharmacy-Organisation and management

a. Organizational structure-Staff, Infrastructure & workload statistics

b. Managementofmaterialsandfinance

c. Roles& responsibilitiesofhospitalpharmacist

Unit VIII Hospitaldrugpolicy

a. Pharmacyand Therapeuticcommittee(PTC)

b. Hospitalformulary

c. Hospitalcommittees

- Infectioncommittee
- Researchandethicalcommittee

Unit IX Hospitalpharmacyservices

a) Procurement & warehousing of drugs and Pharmaceuticals

b) Inventorycontrol-

Definition,various methods of Inventory Control- ABC,VED,EOQ, Leadtime, safetystock

c) Drug distribution in the hospital

i) Individual prescription method

ii) Floorstockmethod

iii) Unit dose drug distribution method

References:

a) Practice Standards and Definitions- The Society of Hospital Pharmacists of Australia.

b) A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi etal, Orient Orient Langram Pvt. Ltd. -ISSBN8125026.

c) Australian drug information-Procedure manual. The Society of Hospital Pharmacists

of Australia.

d) HospitalpharmacybyWilliam.E.Hassan

e) Atext bookofHospital Pharmacy by S.H.Merchant & Dr. J.S.Qadry. Revised by R. K.Goyal & R.K .Parikh.

Elective Subject

Fundamentals of Clinical Research

Paper code- PPPE 104

Credit Score- 4

Unit -1 Drug development process:

Introduction, VariousApproachestodrugdiscovery

1. Pharmacological
2. Toxicological
3. INDApplication
4. Drugcharacterization
5. Dosageform

Unit II 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 Applicationsubmission.
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.Clinicalresearchassociate
    d.Auditors
    e.Contractresearchcoordinators
    f.Regulatoryauthority

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

12. Informed consent n Process

13. Data management and its components

14.Safety monitoring in clinical trials

References:

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

b) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005,JohnWileyandSons.

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

Elective Subject

Principles of Quality Use of Medicines

Paper code- PPPE 105

Credit Score- 4

Unit –I Introduction to Quality use of medicines (QUM):

Definition and Principles of QUM, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

Unit-II Concept of QUM:

Evidence based medicine:Definition, concept of evidence based medicine, approach and practice of evidence based medicine in clinical settings.

Essential drugs: Definition, need, concept of essential drug, National essential drug policy & list.

Rational drug use:Definition, concept & need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

Unit-III QUM in special population:

Paediatric prescribing, Geriatric prescribing, prescribing in pregnancy & lactation, prescribing in immune-compromised and organ failure patients.

Unit IV- Medication Errors:

Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors.

Unit-V Pharmacoepidemiology:

Definition, scope, need, aim & applications;

Outcome Measurement: Outcome measures, Drug use measures- defined daily doses, prescribed daily doses, medication adherence measurement.

Concept of risk: Measurement of risk, attributable risk and relative risk.

Pharmacoepidemiological methods: Qualitative models & Quantitative models.

Unit- VI Pharmacoeconomics:

Definition, history of Pharmacoeconomics, need of Pharmacoeconomic studies.

Cost categorization: Direct costs, Indirect costs, Intangible costs.

Outcomes and measurements of Pharmacoeconomics.

Pharmacoeconomics evaluations: Definition, steps involved, applications, cost minimization analysis, cost benefit analysis, cost effective analysis, cost utility analysis, cost of illness, cost consequences analysis.

References:

a) Text book of Clinical Pharmacy **P**ractice– **E**ssential concepts and skills– **P**arthasarathi G, Karin Nyfort-Hansen and MilapNahata.

b) AndrewsEB,MooreN.Mann's**P**harmacovigilance

c) Dipiro **J**T, Talbert RL, Yee GC. **P**harmacotherapy: A**P**athophysiologic Approach.

Elective Subject

Pharmacotherapeutics

Paper code- PPPE 106

Credit Score- 4

Unit I Cardiovascular system:

Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias.

Unit II Gastrointestinal system:

Peptic ulcer disease, Gastro Oesophageal Reflux Disease, Inflammatory bowel disease.

Unit III Respiratory system:

Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonarydiseases.

Unit IV Endocrinesystem:

Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

Unit V Renal system:

Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders.

Unit VI Musculoskeletal disorders:

Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematous.

Unit VII Oncology:

Basic principles of Cancertherapy, General introduction to cancer chemotherapeuticagents, Chemotherapyof breast cancer, leukaemia. Management of chemotherapy nausea and emesis.

References:

a) Pharmacotherapy: A Pathophysiologicapproach - Joseph T. Dipiroetal. Appleton & Lange.

b) Clinical Pharmacy and Therapeutics- EricT.Herfindal, Williams and Wilkins Publication.

c) Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble