HNB Garhwal University (A Central University), Srinagar Garhwal, Uttarakhand

SCHOOL OF SCIENCES

DEPARTMENT OF PHARMACEUTICAL SCIENCES

SYLLABI

FOR

Pre Ph.D Course
(Under Credit Based Continuous Evaluation Grading System)
(Academic Session 2020-2021)

SYLLABUS FOR PRE Ph.D. COURSE (Pharmaceutical Sciences)

PRE PH.D. PROGRAM/COURSE CREDIT STRUCTURE

SEMESTER I

Course	Course Code	Subject Title	L	T	P	Credits	Max. Marks
I	SOS/DPH/LC-101	Research Methodology	4	-	-	4	100
II	SOS/DPH/LC-102	Research and Publication Ethics (RPE) (Part A) Paper I (Theory): Philosophy and Ethics Scientific Conduct Publication Ethics	1	-	-	2	100
		Research and Publication Ethics (RPE) (Part A) Paper II (Practice): Open Access Publishing Publication Misconduct Databases and Research Metrics	-	-	1		
		Research and Publication Ethics (RPE) (Part B) Computer Applications in Drug Development	1	-	-	1	100
III	SOS/DPH/LE-10X	Elective I	4	-	-	4	100
IV	SOS/DPH/LE-10Y	Elective II	4	-	-	4	100
		Total	14	-	1	15	500

Total hours: 15; Total Credits 15

List of Electives

Elective Course	Course Code	Subject Title	L	T	P	Credits	Max. Marks
I	SOS/DPH/LE-103	Advanced Pharmaceutical Techniques	4	-	-	4	100
II	SOS/DPH/LE-104	Advanced Drug Delivery System	4	-	-	4	100
III	SOS/DPH/LE-105	Advanced Pharmaceutical Technology	4	-	-	4	100
IV	SOS/DPH/LE-106	Advanced Medicinal Chemistry	4	-	-	4	100
V	SOS/DPH/LE-107	Advanced Industrial Pharmacy	4	-	-	4	100

Note: Student has to choose any two electives from above list

Course I Course Code: SOS/DPH/LC-101
Subject Title: Research Methodology (Theory)

4 Credits (4-0-0)

Unit 1

Research Methodology: An Introduction: Meaning of Research, Objectives of Research, Motivation in Research, Types of Research, Research Approaches, Significance of Research, and Research Methods versus Methodology, Research and Scientific Method, Importance of Knowing How Research is Done, Research Process, Criteria of Good Research, Problems Encountered by Researchers in India.

Defining the Research Problem: Selecting the Problem, Necessity of Defining the Problem Technique Involved in Defining a Problem, an illustration.

Unit 2

Research Design: Meaning of Research Design, Need for Research Design Features of a Good Design, Important Concepts Relating to Research Design, Different Research Designs, Basic Principles of Experimental Designs, Developing a Research Plan.

Sampling Design: Census and Sample Survey, Implications of a Sample Design, Steps in Sampling Design, Criteria of Selecting a Sampling Procedure, Characteristics of a Good Sample Design, Different Types of Sample Designs, Random Sample from an Infinite Universe, Complex Random Sampling Designs.

Unit 3

Statistical Analysis: Introduction, significance of statistical methods. Normal distribution. Probability. Degrees of freedom. Measures of variation - standard deviation, Non linear regression, iteration methods. Analysis of variance. Standard error. Test forstatistical two ways ANOVA and multiple comparison procedures. Significance - students Test, chi-square test. Fishers exact test. Wilcoxon rank test. Two-tailed student's t-test. Mann-Whitney test. Dunnet's two-tailed test, Kruskell - Wallis nonparametric test.

Unit 4

Literature review: Need, Procedure- Search for existing literature, Review the literature selected, Develop a theoretical and conceptual framework, writing up the review.

Unit 5

Computer: Introduction to the creation and advancement of databases, algorithms, computational and statistical techniques for data analysis, Important Characteristics, The Binary Number System, Applications of Microsoft excel for quantitative and in statistical data analysis.

Recommended books:

1. Kothari, C.R. (2004). Research Methodology: Methods and Techniques, New Age International Publishers, New Delhi
2. Arya., P.P. and Pal, Y. (2001), Research Methodology in Management: Theory and Case Studies, Deep and Deep Publishers Pvt. Ltd., New Delhi
3. Robert A. Day (1998), How To Write & Publish a Scientific Paper. Oryx Press; 5 edition

4. Frank D. Bell (1995), Basic Biostatistics: Concepts for the Health Sciences. William C. Brown
5. Suresh C. Sinha and Anil K. Dhiman, (2002), Research Methodology (2 Vols-Set) Vedams Books (P) Ltd.
6. Krishnaswamy, K. N., Sivakumar, Appa Iyer and Mathirajan, M. (2006), Management Research Methodology: Integration of Principles, Methods and Techniques (Pearson Education, New Delhi).
7. Ranjit Kumar, (2006), Research Methodology- Step-By-Step Guide for Beginners, (Pearson Education, Delhi) ISBN: 81-317-0496-3.
8. Trochim, William M. K., (2003), 2/e, Research Methods, (Biztantra, Dreamtech Press, New Delhi), ISBN: 81-7722-372-0.
9. Central Drugs Standard Control Organization http://cdsco.nic.in/

Course II Course Code: SOS/DPH/LC-102 (Part A) Paper-I
Subject Title: Research and Publication Ethics (RPE) (Part A) Paper-I

PAPER-I Theory: **Philosophy and Ethics, Scientific Conduct, Publication Ethics**

1Credits (1-0-0)

RPE 01: PHILOSOPHY AND ETHICS (3 hrs.)

1. Introduction to philosophy: definition, nature and scope, concept, branches
2. Ethics: definition, moral philosophy, nature of moral judgments and reactions

RPE 02: SCIENTIFICCONDUCT (5hrs.)

1. Ethics with respect to science and research
2. Intellectuals honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP)
4. Redundant publication: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data

RPE 03: PUBLICATION ETHICS (7 hrs.)

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

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Course II Course Code: SOS/DPH/LC-102 (Part A) Paper-II
Subject Title: Research and Publication Ethics (RPE) (Part A) Paper-II

Paper II (Practice): Open Access Publishing, Publication Misconduct Databases and Research Metrics

1Credits (0-0-1)

RPE 04: OPEN ACCESS PUBLISHING (4 hrs.)

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

RPE 05: PUBLICATION MISCONDUCT (4 hrs.)

A. Group Discussions (2 hrs.)
   1. Subject specific ethical issues, FFP, authorship
   2. Conflicts of interest
   3. Complaints and appeals: examples and fraud from India and aborad

B. Software tools (2hrs.)
   Use of plagiarism software like Turnitin, Urkund and other open source software tools

RPE 06: DATABASES AND RESEARCH METRICS (7 hrs.)

A. Databases (4 hrs.)
   1. Indexing databases
   2. Citation databases: Web of Science, Scopus, etc.

B. Research Metrics (3 hrs.)
   1. Impact Factors of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score
   2. Metrics: h-index, g index, i10 index, altmetrics

References

1. Bird, A. (2006). Philosophy Of Science, Routledge
2. MacIntyre, Alasdair (1967) A short history of ethics. London
3. Praveen Chaddah, (2018)Ethics in Competitive Research: Do not get scooped; do not get plagiarized, ISBN: 9789387480865
4. National Academy of Sciences; National Academy of Engineering and Institute of Medicine. (2009) *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*. Washington, DC: The National Academies Press.
5. Resnik, D.B. (2011). What is ethics in research &why is it important. National Institute of Environmental Health Sciences,1-10. Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
6. Beall, J. (2012) Predatory publishers are corrupting open access. Nature, 489(7415), 179-179.
7. https://doi.org/10.1038/489179a

8. Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance (2019), ISBN: 978-81-939482-1-7.
9. http://www.insaindia.res.in/pdf/Ethics_Book.pdf

Course II Course Code: SOS/DPH/LC-102 (Part B)
Subject Title: Research and Publication Ethics (RPE) (Part B)

Paper: Computer Applications in Drug Development

1Credits (1-0-0)

1 Computers in Pharmaceutical Research and Development: A General Overview, History of Computers in Pharmaceutical Research and Development.

2 Computational Modeling: Introduction, Modeling Techniques

3 Computer-aided formulation development: Uses of Computers in R&D, Computers in Market analysis

4 Computer Simulations in Pharmacokinetics and Pharmacodynamics, Computers in Clinical Development.

5 Artificial Intelligence (AI), Robotics, Pharmaceutical Automation, Pharmaceutical applications, Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technol ogy, 1 Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Elective Course I
Course Code: SOS/DPH/LE-103
Subject Title: Advanced Pharmaceutical Techniques (Theory)
4 Credits (4-0-0)

Unit 1

Spectroscopic methods: Theory, Instrumentations, chemical applications and structural elucidation by UV, IR, ^{1}H NMR, ^{13}C NMR including DEPT, Mass Spectrometry, ESR and Emission spectroscopy.

Unit 2

Separation Techniques: Fundamental principles, theory, instrumentation and application of Gas-liquid Chromatography, HPLC, Size Exclusion chromatography, GC-

MS, LC-MS, UPLC, HPTLC, Ion Pair & Ion Exchange Chromatography and Supercritical Fluid Chromatography.

Unit 3

Thermal Analysis: Theory, Instrumentation & application of Thermogravimetric analysis (TGA) and Differential Thermal Analysis (DTA).

Calorimetric Analysis: Theory, Instrumentations, chemical applications and structural elucidation, Differential Scanning Calorimetry (DSC), Isotherm titration Calorimetry (ITC).

Unit 4

Modern Pharmacognostic Techniques: Extraction, isolation, identification and characterization of bioactive phytoconstituents of following groups: Alkaloids, Flavonoids, Glycosides, Steroids, Triterpenoids

Unit 5

Immunochemical Techniques: Immunoelectrophores, Immunoprecipitation, ELISA, Radio-immuno assays. Southern blot and northern blot assays.

Bioassays: in-vitro and in-vivo techniques

Bioavailability and bioequivalence testing: Definitions, in-vitro and in-vivo bioavailability testing.

Lyophilization: Principles and Practice of freeze-drying. Freeze drying equipment

Recommended Books:

1. Skoog: Principles of Instrumental Analysis (Saunders College Publishing Philadelphia).
2. M. Orchin and H.H. Jaffe – Theory and Applications of Ultra Violet Spectroscopy (John Wiley and Sons, N.Y).
3. Silverstein. Basseler, Moiril-Spectrometeric Identification of Organic Compounds (John Wiley and Sons, N.Y).
4. Willard, Merritt, Dean-Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi).
5. Pharmaceutical Dosage forms Series by Herbert Lieberman
6. Bernard R. Glick Molecular Biotechnology: Principles and Applications of Recombinant DNA.
7. Remington: The Science and Practice of Pharmacy (Remington the Science and Practice of Pharmacy) Lippincott Williams & Wilkins.

Elective Course II
Course Code: SOS/DPH/LE-104
Subject Title: Advanced Drug Delivery Systems (Theory)

4 Credits (4-0-0)

Unit 1

Preformulation: Introduction and concept, need, advantages, Organization, Techniques: Solubility & pKa, Spectroscopy, Chromatography, Thermal Analysis, X-Ray Diffraction: Techniques to generate and characterize amorphous and crystalline forms. Stability. Brief account of preformulation of i) Conventional tablet- Compaction of powders with

particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; effect of particle size, moisture content, lubrication, lubricant sensitivity ii) Oral liquids, Suspension iii) Semisolid iv) Aerosol products.

Unit 2

Polymer Sciences: Introduction and classification, preparation methods of synthetic polymers, Molecular weight determination, Thermal Characterization and rheology of polymers, Introduction to biodegradable and non-biodegradable polymers.

Unit 3

Stability: Concept of stability of pharmaceuticals. Understanding of statistical aspects in expiry period. Degradation pathways, physical instabilities and evaluation methods. Overages and ICH guidelines.

Unit 4

Excipients: Overview of excipients used in formulations. Factors affecting the selection. Introductory aspects of drug excipient and excipient, package interactions. Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants- micelle formation, liquid crystal phase, thickners. Standardization of excipients.

Unit 5

Optimization: Definition, need, advantages, Meaning of general terms involved in optimization process. Classification of optimization methods. Brief description and importance of experimental design with special reference to designs adequate for large number of variables. Introduction of correlation and regression analysis and mathematical model, contour plots. Basic understanding with atleast one example of following optimization techniques: Simplex methods, langarengian method, EVOP, Grid search method.

Recommended Books:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann. Third edition, Varghese Publishing House
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann. Second EdPharmaceutical dosage forms: Disperse systems, Vol, 1,2,3; By Leon Lachmann. Second Ed
3. Modern Pharmaceutics: By Gilbert and S. Banker. Fourth Edition. Vol 121.
4. Remington's Pharmaceutical Sciences Vol I-II, 21st ed.
5. Advances in Pharmaceutical Sciences Vol 1-5; By H. S. Bean & A. H. Beckett.
6. Physical Pharmacy; By Alfred martin. 4 ed. Published by B. I. Waverly Pvt. Ltd.
7. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, by Sidney H. Willig, 2 Ed.
8. Pharmaceutical Preformulations; by J.J. Wells.
9. Applied production and operations management; by Evans, Anderson, Sweeney and Williams.

Elective Course III
Course Code: SOS/DPH/LE-105
Subject Title: Advanced Pharmaceutical Technology (Theory)
4 Credits (4-0-0)

Unit 1

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.
Scale up: Importance, technology transfer from R & D to pilot plant scale, process scale up for tablets, capsules, liquid orals, parenterals, semisolid, NDDS products- stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

Unit 2
Equipment Qualification: Importance, IQ, OQ, PQ for equipments- autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

Unit 3
Improved Production Techniques for tablets: New materials, processes, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, Physics of tablet compression and computerization for in-process quality control of tablets.

Unit 4
Process Validation: importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

Unit 5
Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, Characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

Recommended Books:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY
2. Pharmaceutical production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The Theory & Practice of Indusrial Pharmacy, L.Lachmann, H. A. Lieberman, Varghese Publ, Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical Dosage Forms, Tablets, Vol 1,2,3 by Lachmann, Liberman, Marcel Dekker, NY.
7. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1,2 by K. E. Avis, Marcel Dekker, NY.

Elective Course IV
Course Code: SOS/DPH/LE-106
Subject Title: Advanced Medicinal Chemistry (Theory)

4 Credits (4-0-0)

Unit 1

Microorganism in drug development: Microbial conversions of drugs like steroids, prostaglandins and antibiotics. These should include some biotechnology-oriented chapters like enzymes immobilization techniques.

Unit 2

Molecular concept of drug receptor interactions: Advances in following classes of receptors and their drug ligands, Opioid, Dopamine, Adrenergic, Cholinergic, Histamine, 5-HTIA, GABA.

Unit 3

Synthesis of following drugs describing reaction conditions, mechanisms and strategies involved in synthesis**:** Gefitinib, Cetrizine, Fexofenadine, Linezolide, Risperidone, Ziprasidone, Diazepam, Dapsone, Ethinyl estradiol, Vit. B, Diphenhydramine.

Unit 4

Combinatorial Chemistry: solid phase synthesis, different types of polymer supports, linkers, strategies of library synthesis and characterization

Solid phase strategies

a. General strategies and concepts
b. Specific implementation issues
   Solid support, anchoring chemistry, Coupling chemistry, protection schemes, analytical methods
c. Solution phase analysis

Unit 5

Computer Aided Drug Design: Basic concepts of computational chemistry like Quantum mechanics, molecular mechanics, force fields, energy minimization, conformational reactions, molecular dynamics. Ligand based drug design based on active site of receptor/enzyme

Indirect drug design: Analog approach, Pharmacophore mapping, Template forcing, excluded volume and shape analysis, artificial intelligence methods..

Recommended Books:

1. Foye: Principles of Medicinal Chemistry, 6th ed. (Lippincott).
2. Ariens: Medicinal chemistry series
3. Ellisa and West: Progress in medicinal chemistry series.
4. Butterworthser: Progress in medicinal chemistry series.
5. Burgers Medicinal chemistry- The Basis of medicinal chemistry by Manfred E. Wolff part-I (John Wiley & sons).
6. Medicinal chemistry- The role of organic chemistry in drug research by S. M. Roberts and B J Price.

Elective Course V
Course Code: SOS/DPH/LE-107
Subject Title: Advanced Industrial Pharmacy (Theory)

4 Credits (4-0-0)

Unit 1
A detailed study involving machinery and theory of pharmaceutical unit operations like milling, mixing, filtration, drying and sterilization.

Unit 2
Materials of construction of pharmaceutical equipment and packaging materials. Study of the principles, production techniques and scale up techniques in large scale production of tablets, capsules, emulsions, suspensions, sterile products, semisolids and liquid pharmaceuticals, ophthalmic products.

Unit 3
Production management: Production organization, objectives and policies, GMP, layout of buildings, services, equipment and their maintenance, materials management, handling and transportation, inventory management and control, production and planning control. Sales forecasting, budget and cost control, industrial and personal relationship.

Unit 4
Quality control, Process and Dosage form: Process control, control of manufacturing process, statistical quality control, control charts of automated process control, dosage form control, testing programme and method, product identification system, adulteration and misbranding, drug information profile.

Unit 5
Process Validation: Regulatory basis, Validation of solid dosage forms, sterile products, liquid dosage forms. Process validation of raw materials, Validation of analytical methods, equipment and process.

Recommended Books:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann
3. Pharmaceutical dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical dosage forms: Parenteral medications, Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics: By Gilbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol 1-5; By H. S. Bean & A. H. Beckett.
8. Physical Pharmacy by Alfred Martin.
9. Bentley's Textbook of Pharmaceutics- Rawbins.
10. Quality Assurance Guide by Organization of Pharmaceutical producers of India.