DESH BHAGAT UNIVERSITY, MANDI GOBINDGARH

Faculty of Pharmacy

Syllabi and Courses of Pre PhD Course work

PAPER		TITLE OF PAPER	HOURS/WEEK
PHD01		Research Methodology	4h
PHD02	(Group A)	General Analytical Techniques in Pharmaceutical Sciences	4h
PHD02	(Group B)	Advances in Pharmaceutics (Theory)	4h
PHD03	(Group A)	General Analytical Techniques Laboratory	4h
PHD03	(Group B)	Advances in Pharmaceutics	4h
PHD04		Elective	4h

Instruction of Paper Setters

1. The Papers PHD01 and PHD04 are common for all candidates. The candidates Pursuing PhD in all specializations except Pharmaceutics shall opt for Group A of papers PHD02 and PHD03. The candidates pursing PhD in Pharmaceutics specialization shall be opting Group B of papers PHD02 and PHD03.
2. The maximum marks for each paper shall be 100 only and out of it 50 marks shall be allocated for internal assessment. The paper setter shall be required to set the paper for maximum marks of 50 only.
3. The maximum time for each theory paper shall be 3 hours.
4. The maximum marks to pass the required examination shall be 50%
5. The paper I and Paper II shall have seven question and the candidate shall be required to attempt any five question.
6. Evaluation of Paper III shall be made by the external examiner based on the candidate's performance in the laboratory and viva-voce.
7. Evaluation of Paper IV shall be based on comprehensive review report submitted by the candidate in the selected elective subject and its presentation in the form of a seminar on the date fixed by the Head of the Department. The external shall participate in the seminar presented by the candidate.

Paper 1: Research Methodology

Max Marks: 50 Max Time 3h

Internal Assessment: 50 Marks 4h /Week

1. Research:
   (a) Definition of research. Application of research and types. Research process and steps in it. Deductive and inductive reasoning; Validity-conclusion, internal, construct and external.
   (b) Literature review- Need, Procedure- Search for existing literature, Review the literature selected, Develop a theoretical and conceptual framework, Writing up the review.
   (c) Formulating a research problem: Sources, Consideration, Steps in formulation of a problem, formulation of objectives, Definition of variables-Concepts, indicators and variables, Types of variables, Types of measurement scales, Constructing the Hypothesis, Null (Research) and alternative, one-tailed and tow-tailed, Hypothesis testing, errors in testing.
2. Research proposal writing: Contents- Preamble, the problem, objectives, hypothesis to be tested, study design, setup measurement procedures, analysis of data, organization of report; Displaying data- tables, graphs and charts, Writing a research report- Developing an outline, Key elements-Objective, Introduction, Design or Rationale of work, Experimental Methods, Procedures, Measurements, Results Discussion, Conclusion, Referencing and various formats for reference writing of books and research papers, Report Writing-Prewriting considerations, Thesis writing, Formats of report writing, Formats of publications in Research Journals.
3. Statistical analysis
   (a) Data tabulation and types of tabulation, Types of diagram, graphical representation, their utility and limitations.
   (b) Statistical hypothesis, Statistical significance, level of significance, degree of freedo, Student test, chi square test, Fischer's test, analysis of variance (ANOVA) and post hoc analysis.
   (c) Aims of sampling, Types of population, choice of sampling methods.
   (d) Software used in Pharmaceutical Statistical analysis e.g. Sigma Stat, Prism, SPSS and Stat Pro.
4. Intellectual property rights
   Brief concept of IPR. Introduction to Indian, US and international patenting process. Regulatory requirement for preclinical and clinical testing of pharmaceuticals.

Recommended Books (Latest editions unless specified)

1. Ranjit Kumar, (2006), Research Methodology- A Step-By-Step Guide for Beginners, (Pearson Education, Delhi) ISBN: 81-317-0496-3
2. Trochim, William M.K., (2003), 2/e, Research Methods, (Biztantra, Dreamtech Press, New Delhi), ISBN: 81-7722-372-0
3. Montgomery, Douglas C. (2007), 5/e, Design & Analysis of Experiment, (Wiley India) Montgomery , Douglas C., & Runger, Georg C. (2007), 3/e, Applied Statistics & Probability for Engineers, (Wiley, India)

4. Kothari, C.K., (2004), 2/e, Research Methodology –Methods and Techniques, (New Age International, New Delhi)
5. Ross, Philips J. (1996), 2/e Taguchi Techniques for Quality Engineering, (Mcgraw Hill, NY)
6. Besterfield, Dale H. (2005), 3/e, Total Quality Management, (Pearson Education, New Delhi)
7. Krishnaswamy, K.N. Sivakumar, Appa lyer and Mathirajan, M. (2006), Management Research Methodology: Integration of Principles, Methods and Techniques)Pearson Education, New Delhi).

Paper-II (Group A): General Analytical Techniques in Pharmaceutical Sciences

Max Marks: 50 Max Time 3h
Internal Assessment: 50 Marks 4h/Week
Total Marks: 100

1. Basic principles and application (excluding instrumentation) of UV, IR, NMR and Mass spectral techniques in structure elucidation and quantitative analysis of drugs.
2. Principles and application of bioassays for in vivo and in vitro pharmacological evaluation of drugs (anti-anxiety, antiepileptic, anti-inflammatory, nootropic, oxytocic, neuroprotective and cholinergic drugs) and of ELISA and Radioimmuno Assays.
3. Principles, merits and demerits of different extraction methods (Microwave-assisted extraction, ultrasonic extraction, pressurized liquid extraction (PLE), supercritical fluid extraction (SFE), Rationale for selection of different methods for extraction.
4. General principles of various separation techniques (Flash, vacuum liquid, and centrifugal chromatography, HPTLC, droplet counter current chromatography, gas chromatography, HPLC, electrophoresis and their applications in quantitative analysis of synthetic drugs and phytopharmaceuticals. Brief introduction to and application of hyphenated techniques (GC-MS, LC-MS and MC-NMR)
5. Validation of analytical methods.
6. Good clinical practices, Protocol designing of clinical trials, Randomization methods, Pharmacovigilance, Therapeutic drug monitoring, Monitoring and auditing of clinical trails.

Recommended books (Latest editions unless specified):

1. M. Orchin and H.H-Jaffe-Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
2. R.M. Silverstein, G.S. Bassler and T.C. Morrill, Spectrometric Identification of Organic Compounds, 6th edition, John Wiley and Sons lnc., New York, U.S.A.,2003
3. J.R. Dyer-Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall London)
4. Wim Kok: Capillary Electrophoresis: Instrumentation and Operation.
5. R.J. Hamilton-Introduction to High Performance Liquid chromatography, Chapman and Hall, London).
6. S. Ahuja and N. Jespersen (Eds.), Comprehensive Analysis Chemistry Volume 47, Elsevier.

7. William Kemp, Organic Spectroscopy, 3rd edition, ELBS, Mac Millan, Hampshire, U.K., 1991.
8. D.L. Pavia, G.M. Lampman & G.S. Kriz, Introduction to Spectroscopy-A guide for students of organic chemistry, 3rd edition, Harcourt College Publisher,2001.
9. J.T. Dipiro, R.L. Talbert, P.E. Hayers, G.C. Yee and L.M. Possy(eds), Pharmacotherapy: A Pathophysiologic Approach, 5th edition Appleton Lange, U.S.A.,2002
10. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 3rd edition, Hilton & Company, Kolkata, India, 2005.
11. H.G. Vogel and W.H. Vogel (eds.) Drug Discovery and Evaluation- Pharmacological Assays, 2nd edition Springer Verlag. Berlin, Germany, 2002.
12. H. Wagner, S. Bladt, E.M. Zgeinski, Plant Drug Analysis, Springer Verlag, New York, U.S.A., 1984.
13. Egon Stahl, Thin-layer Chromatography, 2nd edition, Springer Verlag, New York, U.S.A., 1969.

Paper-II (Group B): Advances in Pharmaceutics (Theory)

Max Marks:50 Max Time 3h
Internal Assessment: 50 Marks 4h/Week
Total Marks:100

Session-A

Critical consideration in dosage form design-Criteria for selection of drug candidate, drug dosing, Excipients and their properties.

1. Oral drug delivery systems: Oral disintegrating tablets, dispersible tablets, sustained release dosage form (gastro retentive dosage form, OROS, SMEDDS and colon targeted drug delivery systems.
2. Transdermal drug delivery systems.
3. Bioadhesive drug delivery systems: buccal, nasal gastric, vaginal,
4. Carriers for drug delivery: Liposomes, niosomes, ethosomes, elastic liposomes nanoparticles, SNEDDS

Section-B

Evaluation techniques for

1. Drug identification, purity (introduction to method like spectrophotometry, spectroflourimeter, HPLC)
2. Formulation

Particle size distribution, zeta potential

Drug entrapment, Pharmacopeial tests for oral dosage forms (Weight variation, friability, disintegration test, dissolution tests, similarity factor, dissimilarity facto, IVIVC)

Introduction to transepidermal water loss for evaluation of permeation enhancers

Introduction to texture analyzer for evaluation of bioadhesive strength.

Application of DSC for evaluating drug-polymer, polymer-polymer interaction only

Brief introduction to CSLM, AFM and electron microscopy in evaluating vesicular/ nanoparticulate drug delivery systems.

Stability testing condition according to ICH guidelines for zone I-IV for pharmaceutical products (excluding methodology).

Books recommended

1. J.R. Robinson and V.H. Lee (Eds.) Controlled Drug Delivery: Fundaments and Application, 2nd edition, Marcel Dekker Inc., New York, U.S.A. 1987.
2. J.I. Wells, Pharmaceutical Preformulation: The physiological properties of Drug Substances, Ellis Horwood, Chicheater, U.K.
3. Y.W. Chien (Eds.) Transdermal Controlled Systemic Medication, Marcel Dekker Inc. New York, U.S.A.
4. S.P. Vyas and R.K.Khar, (Eds.) Targeted and Controlled Drug Delivery CBS Publishers and Distributors, New Delhi, 2007.
5. N.K. Jain, Progress in Controlled and Novel Drug Delivery Systems CBS, Publisher and Distributors, New Delhi.
6. Honey, Rai, P., V. and Tiwary, A.K. Orally Disintegrating Systems: Innovations in Formulation and Technology, Recent Patents on Drug Delivery & Formulation 2: 258-74 (2008).
7. Kaur,G., Jain, S. and Tiwary, A.K. Recent approaches for colon drug delivery. Recent Patents in Drug Delivery and Formulation 1: 222-229 (2007).
8. Sapra, B., and techniques. Recent Patents on Drug Delivery and Formulation 1:23-36 (2007).
9. B. Sapra, S. Jain and Tiwary A.K. Dissolution In: Preclinical Development Handbook; ADME and Biopharmaceutical Properties, S.C. Gad (Ed.), Chapter 15, 483-544, John Wiley and Sons, Inc., NJ, USA (2008).

Paper-III (Group A): General Analytical Techniques Laboratory

Max Marks:50 Max Time 8h
Internal Assessment: 50 Marks 4h/Week
Total Marks:100

1. Introduction to general techniques in synthetic medical chemistry.
2. Interpretation of UV, IR, NMR and mass spectra of some drug.
3. Estimation of drug using HPLC
4. Validation of analytical methods
5. Introduction to general microscopic techniques
6. Evaluation of physico-chemical parameters like ash values, moisture content, extractive extraction values etc and phytochemical screening
7. Simple extraction exercises (by maceration, soxhlet appartus etc)
8. Study of TLC profiles of extracted constituents
9. General handling of laboratory animals
10. Different routes of administration
11. Tissue and blood sampling
12. Evaluation of CNS active, anti-diabetic and analgesic and anti-inflammatory drugs.
13. Biochemical tests for total lipid profile, liver function test, kidney function test using animal and human blood.
14. Analysis of patient focused case histories to develop Pharmacotherapeutic skills.
15. Protocol designing of clinical trails

16. Prescription audit
17. Acetylator status determination
18. Evaluation of analgesic activity using human pain model.

Paper-III (Group B): Advances in Pharmaceutics (Practical)

Max Marks:50 Max Time 8h
Internal Assessment: 50 Marks 4h/Week
Total Marks:100

1. Evaluation of IR oral dosage form (conventional, ODT's, dispersible).
2. Evaluation of sustained release/delayed release tablets.
3. Evaluation of PSD of disperse systems
4. Determination of film adhesive strength of tablets using Texture analyzer (TA).
5. Determination of crushing strength of tablets using Texture analyzer (TA).
6. Evaluation of tensile strength of polymeric films using TA.
7. Evaluation of bioadhesive strength of polymeric films using TA.
8. Evaluation of TEWL of skin after different treatment.
9. Determination of tensile strength of packaging material using TA.
10. To carry out the viscosity analysis of polymeric solution using Brooke field viscometer.
11. To study the effect of cross linking on spectral attributes of polymers.
12. To carry out the stability testing of dosage forms according to ICH guidelines

BOOKS RECOMMENDED

1. USP 30 NF 25.2007
2. BRITISH PHARMACOPOEIA, 2008
3. INDIAN PHARMACOPEIA, 2007

Paper-IV: Elective

Max Marks:50 Max Time 1h
Internal Assessment: 50 Marks 4h/Week
Total Marks:100

Recent advances in

1. Pharmaceutics
2. Pharmacology
3. Pharmaceutical chemistry
4. Pharmacy Practice
5. Pharmacognosy

A subtopic will be chosen by the candidate in any one of the above mentioned area as per his/her interest. The candidate will explore the literature in consultation with the supervisor so as to write a comprehensive review which the candidate will submit by the end of the course for evaluation.