उत्तर प्रदेश प्राविधिक विश्वविद्यालय, लखनऊ, भारत

Uttar Pradesh Technical University, Lucknow, India

Syllabus M.Pharm
(Pharmaceutics)

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutics) Effective From Session 2008 – 09 Semester-I

Sl. No	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total
		Theory	T	P	T	P	T	P	
1	PHAR 511	Modern Analytical Technique	4	-	30	-	70	-	100
2	PHAR 512	Pharmaceutical Biostatistics & Computer Application	4	-	30	-	70	-	100
3	PHAR 514	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100
4	PHAR 515	Product Development	4	-	30	-	70	-	100
5	PHAR 517	Pharm Biotechnology	4	-	30	-	70	-	100
Practical								Day to Day Evaluation	
6	PHAR 511P	Modern Analytical Technique		6		30	-	70	100
7	PHAR 515P	Product Development		6		30	-	70	100
								Total	700

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T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE- Theory exam is 3 hours and Practical exam is 6 hours.

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STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutics) **Semester-II**

Sl. No	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total
		Theory	T	P	T	P	T	P	
1	PHAR 521	Pharmaceutical Production Management	4	-	30	-	70	-	100
2	PHAR 522	Recent Advances in Drug Delivery System	4	-	30	-	70	-	100
3	PHAR 523	Biopharmaceutics & Pharmacokinetics	4	-	30	-	70	-	100
4	PHAR 525	Synopsis of the proposed dissertation		8					100
Practical								Day to Day Evaluation	
6	PHAR 522P	Recent Advances in Drug Delivery System	-	6	-	30	-	70	100
7	PHAR 523P	Biopharmaceutics & Pharmacokinetics	-	6	-	30	-	70	100
							Total		**600**

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE- Theory exam is 3 hours and Practical exam is 6 hours.

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STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutics) **Semester-III & IV**

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination

Sl. No	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total
		Theory	T	P	T	P	T	P	
1	PHAR 611	Dissertation							300
2	PHAR 612	Presentation & Viva Voce							200
								Total	**500**

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(First Semester)

PHAR-511 Modern Analytical Techniques

Unit - 1

UV-Visible Spectroscopy: Principle of UV-Visible Spectroscopy, Chromophores and their interaction with UV-visible radiation and their utilization in structural, qualitative and quantitative analysis of drug molecules. Woodward-Fieser rule, use of shiff reagents for elucidation of structures. Fundamentals of Optical Rotatory Dispersion. Cotton effect curves, octant rule, circular dichronism.

Unit - 2

Infrared Spectroscopy: Infrared radiation and its interaction with organic molecules, vibrational mode of bonds, instrumentation and applications, effect of hydrogen bonding and conjugation on absorption bands, interpretation of IR spectra. FTIR and ATR, X-ray diffraction methods.

Unit - 3

Nuclear magnetic resonance spectroscopy: Magnetic properties of nuclei, field and precession, chemical shift concept, isotopic nuclei, reference standards and solvents. ^{1}H NMR spectra, chemical shifts, multiplicity, coupling constants, integration of signals, interpretation of spectra, decoupling-double resonance and shift reagent methods.

Principles of FT-NMR with reference to ^{13}C NMR, free induction decay, average time domain and frequency domain signals. Spin-spin and spin-lattice relaxation phenomenon. Protein noise decoupled spectra. Nuclear overhauser enhanced ^{13}C NMR spectra, their interpretation and application. APT and DEPT techniques. Introduction of 2D NMR techniques, COSY, with application.

Unit - 4

Mass spectrometry: Basic principles and brief outline of instrumentation. Ion formation, molecular ion, metastable ion, fragmentation process in relation to molecular structure and functional groups. Relative abundance of isotopes, chemical ionization, FAB, ESI, Maldy, GC-MS and other recent advances in mass spectrometry.

Unit - 5

Chromatographic techniques: Principles of separation and application of Column, Paper, Thin layer and Gas chromatography, HPLC, HPTLC, Size exclusion chromatography, Affinity chromatography, Electrophoresis. Instrumentation of HPLC, Preparative and micropore columns, Reverse phase columns, Mobile phase selection and detectors in HPLC. Instrumentation and application of DCCC.

Biological standardization: Bioassay & Radioimmunoassay: ELISA, Radioimmunoassay of drugs like Digitalis & Insulin.

PHAR-511 P Modern Analytical Techniques

Practicals based on theory syllabus.

Books Recommended:

1. Willard, H.H., Merrit, L.L., Dean, J.A., Settle P.A., Instrumental Methods of Analysis, Van Nostrand.
2. Skoog, D.A., Heller, F.J., Nieman, T.A., Principles of Instrumental Analysis, WB Saunders.
3. Hunson, J.W., ed. Pharmaceutical Analysis, Modern Methods, part A & B, Marcel Dekker.
4. Schirmer, R.E., ed. Modern Methods of Pharmaceutical Analysis, Vols 1, 2. Boca Raton F.L., CRC Press.
5. Mann, C.K., et al., Instrumental Analysis Harper & Row.
6. Jaffe, H.H., Orchin M., Theory & Applications of Ultraviolet Spectroscopy, Willy.
7. Silverstein, Spectrometric identification of Organic Compounds, Willy.
8. Bovey, F., Jelinski, L., Miran, P., Nuclear Magnetic Resonance Spectroscopy, Sau: Diego Academic.
9. Stothers, J.B., Carbon-13 NMR.Spectroscopy, Academic.
10. Gordy, W., Theory & Applications of Electron Spin Resonance, Willy.
11. Haswell, S.J., ed. Atomic Absorption Spectroscopy, Elsevier.
12. Ardrey, R.E., Pharmaceutical Mass Spectra, Pharmaceutical Press, London.
13. Budzikiewicz, et al., Interpretation of Mass Spectra of Organic Compounds, Holden-Day San Francisco.
14. Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS.
15. Stahl, E., Thin Layer Chromatography- A laboratory Handbook, Springer-Verlag
16. Giddings, J.C., Principles and Theory- Dynamics of Chromatography, Marcel Dekker.
17. Sethi, P.D., Quantitative Analysis of Pharmaceutical formulations, CBS Publishers, New Delhi.
18. Kemp William, Organic spectroscopy, Pal grave, New York.
19. Kalsi, P.S., Spectroscopy of organic compounds, New age publishers, New Delhi.
20. Gross - Mass Spectrometry
21. WHO - Quality Assurance of Pharmaceuticals, Vol. I, II.
22. Sethi, P.D., HPLC, Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers, Delhi.
23. Sethi, P.D., HPTLC, Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers, Delhi.
24. Haffmann, Chromatography.
25. Sethi and Charcgankar, Identification of Drugs in Pharmaceutical Formulations by TLC.
26. Robert D. Braun, Introduction to Instrumental Analysis.
27. Wilfried, M.A. Niessen- Liquid Chromatography-Mass Spectrometry.
28. Harry G. Brittain, Spectroscopy of Pharmaceutical Solids.
29. George, S., Steroid Analysis in Pharmaceutical Industry.

30. Higuchi, Pharmaceutical Analysis.
31. Bidingmeyer, Practical HPLC Methodology and Applications.
32. Hoffmann, Mass Spectrometry: Principle and Application.
33. Scott, Techniques and Practice of Chromatography.
34. Wilkins, Identification of Microorganism by Mass Spectrometry.
35. Wu, Handbook for Size Exclusion Chromatography and related Techniques.

PHAR-512 Pharmaceutical Biostatistics and Computer Applications

Unit - 1

Methods of collection of data, classifications and graphical representation of data. Binomial and normal probability distribution. Polygon, histogram, measure of central tendency. Significance of statistical methods, probability, degree of freedom, measures of variation - Standard deviation, Standard error.

Unit - 2

Sampling, sample size and power. Statistical inference and hypothesis. Tests for statistical significance: student t-test ,Chi-square test, confidence level, Null hypothesis.

Unit - 3

Linear regression and correlation. Analysis of Variance (one way and two way). Factorial designs (including fraction factorial design). Theory of probability, Permutation and Combination , Ratios, Percentage and Proportion. Two way ANOVA and Multiple comparison procedures.

Unit - 4

Non-parametric tests, Experimental design in clinical trials, Statistical quality control, Validation, Optimization techniques and Screening design. Correlation and regression, least square method, significance of coefficient of correlation, nonlinear regression.

Unit - 5

Bioassays-calculations of doses response relationships, LD_{50}, ED_{50}, probit analysis.
Applications of software for statistical calculation viz. SPSS, foxtron.
Application of computers in Pharmaceutical sciences.

Book Recommended:

1. Bolton, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.
2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.
3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.
4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.
5. Finney, D.J., Statistical Methods in Biological Assays, Hafner, New York.

6. Montgomery, D.C., Introduction to Statistical Quality Control, Willy.
7. Khan, Irfan A., Biostatistics for Pharmacy.
8. Khan, Irfan, A., Fundamentals of Biostatistics.
9. Gauthaman, Biostatistics for Pharmacy students.
10. Lipschutz, Introduction to Probability and Statistics.
11. Liwan Po, Statistics for Pharmacist.
12. William E. Fassett, Computer Application in Pharmacy.
13. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.
14. Nageswara Rao and Tiwari, Biostatistics and Computer Applications.

PHAR-514 Drug Regulatory Affairs and Intellectual Property Rights

Unit - 1

Drug & Cosmetics Act with special reference to schedule Y and M, schedule of medical devices.

Unit - 2

Concept of total quality management, requirements of GMP, GLP, GCP, Regulatory requirements of drugs and Pharmaceutical (USFD-NDA/ ANDA)

Unit - 3

Documentation and Maintenance of records.

Unit - 4

Intellectual property rights patents, Trademarks, Copyrights, Patents Act.

Unit - 5

Environment protection Act, Pollution Control, Factories Act.

Books Recommended:

1. Willing, S.W., & Stoker, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
2. Guarino, R.A., New Drug Approval Process, Marcel Dekker, New York.
3. Drug & Cosmetic Act.
4. Patents Act.
5. Consumer Protection Act.
6. Environmental Protection Act.
7. Federal Food, Drug & Cosmetic Act.
8. Bansol, IPR Guidelines for Pharm students and Researchers.
9. Pisano-FDA Regulatory Affairs.
10. Phillip W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology.

PHAR-515 PRODUCT DEVELOPMENT

Unit-1
Introduction
Drug information resources,

Unit-2
Pre- formulation studies, Pediatric & geriatric aspects of formulation.

Unit -3
A detailed study of Formulation Additives, Drug –Excipient interactions and incompatibilities, methods to detect Drug –excipient interactions.

Unit-4
Stability-Theoretical considerations, Degradative pathways, Stability indicating assays, Influence of packaging components on dosage form stability, Stabilization of Pharmaceutical (solid, liquid and semi solid formulations). formulations

Unit-5
Evaluation of Pharmaceutical formulations-in vitro and in vivo studies and their correlation. Levels and types of IV-IVC.

Unit -6
Polymers- Types, Pharmaceutical Application, Molecular Weight Determination, Conformation of dissolved linear macromolecules, Polymer solutions, Polymer in solid state, Fabrication.
Packaging Development- Packaging materials, Types, Labeling, Per formulation screening of packaging components.

Books Recommended:

1. Bannker GS & Rhodes C.T., ‘ Modern Pharmaceutics’, Marcel Dekker, New York.
2. Liberman H.A. et al, ‘Pharmaceutical Dosage Forms-Tablets.’ Marcel Dekker, New York.
3. Gennaro A.R.,Remington, ‘The Science & Practice of Pharmacy.’ Lippincott. William & Wilkins.
4. Lachman L, Lieberman H.A. & Kanig J.L. ‘The Theory & Practice of Industrial Pharmacy.’ Varghese Publishing Home.
5. Aulton M.E., ‘ Pharmaceutics-The Science of Dosage form Design ‘ Churnchill Livingstone.
6. Osborne D.W. & Amann A.H. ,’Topical Drug Deliverry Formulation ‘ Marcel Dekker, New York.
7. Bontempo J.A.,’ development of Bio-Pharmaceutical Parenteral Dosage Forms’ Marcel Dekker, Nerw York.

8. Liberman H.A. et al , 'Pharmaceutical Dosage Forms-Parenterals, Marcel Dekker, New York.
9. Carstensen J.T., 'Drug Stability-Priciples & Practice ' Marcel Dekker, New York.
10. Malmsten M. , ' surfactants and Polymers in Drug Delivery' Marcel Dekker ,New York.
11. Dressman J.B. & Lennernas H. ,' oral Drug Absorption: Prediction and Assessment' Marcel Dekker, New York.
12. Gordon A.et al, 'Transport Process in Pharmaceutical Systems' Marcel Dekker, New York.
13. Brittain .H.G. 'Polymorphism in Pharmaceutical Solids' Marcel Dekker, New York.
14. Parikh D.M.' Handbook of Pharmaceutical Granulation Technology' Marcel Dekker, New York.
15. Alderborn G.& Nystrom C ' Pharmaceutical Powder Compactiopn Technology' Marcel Dekker, New York.
16. Welling P.G. et al ,' Pharmaceutical Bioequivalence' Marcel Dekker, New York.
17. Weiner M.L., & Kotkoskie L.A., 'Excipient Toxicity & Safety' Marcel Dekker, New York.
18. Ansel H.A.- Pharmaceutical Dosage Forms.
19. Sarfaraz K.Niazi, Handbook of Preformulations: Chemical, Biological and Botanical Drugs.

PHAR-515P- PRODUCT DEVELOPMENT

Practical Based on Theory

PHAR-517 Pharmaceutical Biotechnology

Unit –1

Status and Scope of Biotechnology in Pharmacy Enzyme immobilization- Principles and Pharmaceutical applications.

Unit-2

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

Unit-3

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

Unit-4

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

Unit-5

Introduction to Bio-informatics.

Book Recommended:

1. Wiseman A.,ed, Principles of Bio-technology", Chapman & Hall.
2. Antebi E, Fishlock D., " Biotechnology- Strategies for life", Cambridge.
3. Higgins 1.1., Best, DJ & Jones " Biotechnology, Principles & Applications" Blackwell Scientific Publications, Oxford.
4. Stanbary P.F. and Whitaker, A " Principles of Fermentation Technology" Pergamon Press, Oxford.
5. Golub E " The limits of Medicine: How Science shapes our Hope for the cure " Time Books, New York.
6. Bickerstaff GF. " Enzymes in Industry and Medicine,New Studies in Biology" Edwin Arnold, London.
7. Glick. BR, Pasternak J.I., "Molecular Biotechnology-Principles and Applications of Recombinant DNA" ASM Press Washington.

(Second Semester)

PHAR- 521 PHARMACEUTICAL PRODUCTION MANAGEMENT

Unit-1

Status of Pharmaceutical industry with special reference to post GATT scenario.
Project planning and implementation.
Transfer of Technology.

Unit-2

Master formula generation and SOP.
Pilot plant scale up techniques.

Unit-3

Factory layout, Material Management:

Unit-4

Process optimization and automation in pharmaceutical manufacturing.

Unit-5

Inventory control. Different Systems of inventory control. Import and Export regulations laws and methods to obtain I & E licenses, I and E regulations USA, EU and Japanese perspectives.

Books Recommended:

1. Banker GS & Rhodes C.T., ' Modern Pharmaceutics' Marcel Dekker, New York.
2. Remington- 'The Science & Practice of Pharmacy,' Lippincott. William & Wilkins.
3. Lachman L, Lieberman H.A. & Kanig J.L. ' The Theory & Practice of Industrial Pharmacy' Varghese Publishing Home.
4. Aulton M.E. 'Pharmaceutics – The Science of Dosage form Design' Churncill Livingstone.
5. Levin M.A.' Pharmaceutical process Scale up ' Marcel Dekker, New York.
6. Dutta A.K.'Material Management' Prentice Hall India.
7. Chary S.N. 'Production and Operative Management " Tata-Mcgraw Hill, India.
8. DeSpautz.J.F.'Automation and Validation of information in Pharmaceutical Processing' Marcel Dekker, New York.
9. Kennedy T. 'Pharmaceutical Project Management' Marcel Dekker, New York.

PHAR- 522 Recent Advances in Drug Delivery System.

Unit-1

Formulation considerations with special emphasis on release patterns.

Sustained and Controlled release- oral, dental, nasal, ocular & parenteral systems.

Unit-2

Fast Release- Introduction, formulation & evaluation.

Unit-3

Transdermal Drugs Delivery System- Factors influencing transdermal delivery, formulation & evaluation including Iontophoresis and Ionophoresis.

Unit-4

Target Orriented Drug Delivery Systems- prodrugs, Liposome, Niosome, nanoporticles Microspheres and microparticles. Lioproteins Activated ,Carbons, Cellular Carriers, Antibodies, DNA, Low Molecular Weight Proteins.

Hormones, Dextran & Polysaccharides, Synthetic Polymers, Nanoparticles, , Microparticles fabrication techniques (Latest Advances).

Unit-5

Nutraceuticals- introduction & scope.

PHAR-522 P Recent Advances in Drug Delivery Systems

Practicals based on theory Syllabus.

Books Recommended:

1. Chien YW., ‘ Novel Drug Delivery Systems-Fundamentals, Developmenttal concepts.’ Biomedical Assessment , Marcel Dekker, New York.
2. Chien YW., ed., ‘Transdermal Controlled Systemic Medications ‘ Marcel Dekker, New York.
3. **Schreier ,H ,’ Drug Targeting Technology Physical, Chemical 7 Biological Methods,’ Marcel Dekker, New York.**
4. Banker GS & Rhodes C.T. ,’Modern Pharmaceutics’, Marcel Dekker, New York.
5. Gennaro A.R., ‘Remington, The Science & Practice of Pharmacy,’ Lippincott. Williams & Wilkins.
6. Lachman L, Lieberman B.A & Kanig IL.’ The Theory & Practice of Industrial Ph 2 Tmacy’, Varghese Publishing Home.
7. Aulton M.E.,’Pharmaceutics-The Science of Dosage form Design’ Churchill Livingstone.
8. Mathiowitz, E. et al ‘ Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development’, Marcel Dekker, New York.
9. Bronaugh RL & Maibach H.I. ‘ Percutaneous Absorption Drugs-Cosmetics-Mechanism-Methodology’, Marcel Dekker, New York.
10. Potts R.O. & Guy R.H., ‘ Mechanism of Trans dermal Drug Delivery’, Marcel Dekker, New York.

11. Cohen S & Bernstein H, 'Microparticulate Systems for the Delivery of Proteins and Vaccenes,' Marcel Dekker, New York.
12. Rathbone MJ,' Oral Mucosal Drug Delivery ' Marcel Dekker, New York.
13. Benita S. ' Microencapsulation : Methods and Industrial Application', Marcel Dekker , New York.
14. Kreuter J, 'Colloidat'al Drug Delivery Systems' Marcel Dekker, New York.
15. Rolland A. 'Particulate carriers: therapeutic Applications' , Marcel Dekker, New York.

PHAR-523 Bio-pharmaceutics & Pharmacokinetics.

Unit-1
Drug Absorption Distribution & Disposition.

Unit-2
Pharmacokinetics. Open one compartment,two compartment & three compartment models & their limitations.
Non-compartmental pharmacokinetics. Graphical methods of calculating pharmacokinetic parameters.

Unit-3
Factors influencing bio-availability, evaluation ofbioavailability, bio-equivalence with reference to BCS.

Unit-4
Dosage Regimens, Repetitive dosing and dose adjustments in renal and hepatic failure, individualization of dosage regimen.

Unit-5
Pharmacokinetic applications in Clinical practice. Principles of clinical trial.

PHAR- 523 P Bio-pharmaceutics & Pharmacokinetics.

Practicals based on Theory Syllabus.

PHAR-525 Synopsis of the proposed Dissertation & Vivo-Voce.

(Third & Fourth Semester)

PHAR- 611 Dissertation
PHAR- 612 Presentation & Viva-Voce