Faculty of Pharmaceutical Science & Technology

Study and Evaluation Scheme

Of

Master of Pharmacy

(M.Pharm.)

(Applicable w.e.f Academic Session 2013-15 till revised)

AKS UNIVERSITY, SATNA

Study and Evaluation Scheme

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AKS University, Satna

Sherganj, Panna Road, Satna (MP) 485001

Study & Evaluation Scheme
of
Master of Pharmacy (Pharmaceutical Technology)
SUMMARY

Programme :	**M.Pharm**		
Duration :	Two year full time (Four Semesters)		
Medium :	English		
Minimum Required Attendance :	75 %		
Maximum Credits:	**95**		
Evaluation Assessment :	**Internal**	**External**	**Total**
	50	100	150

Internal Evaluation (Theory/ Practical Papers)

	Sessional-I	**Sessional-II**	**Continuous Assessment & attendance**
	10	10	10+20= 30

Duration of Examination :	**External**	**Internal**
	3 hrs.	2 hrs

To qualify the course a student is required to secure a minimum of 36% marks in aggregate including the semester end examination, internal assessment evaluation (Both theory & Practical Papers)

A candidate who secures less than 36% or Grade **'D**' of marks in a Subject/Paper(s) shall be deemed to have failed in that Subject/Paper(s). In case a student has secured less than 36% or Grade **'R'** in Subject/Paper(s), he/she shall be deemed to re-appear (ATKT Examination) in Subject/Paper(s) to achieve the required percentage (Min. 36%) or grade (Min. D) in the Subject/Paper(s).

Question Paper Structure

1. *The question paper shall consist of 26 questions in three Sections. Out of which Section-A shall be of Objective type 10 questions and will be compulsory. (weightage 2 marks each).*
2. *Section-B shall contain 10 Short answer type questions and students shall have to answer any eight (weightage 5marks each).*
3. *Out of the remaining six question s are long answer type questions, student shall be required to attempt any four questions. The weightage of Questions shall be 10 marks each.*

Faculty of Pharmaceutical Science & Technology

M.Pharm.

I Semester

TEACHING & EXAMINATION SCHEME

Sr. No.	Subject Code	Subject	Periods			Credit
			L	T	P	
1	62PY101	Modern Analytical Techniques	4	0	0	4
2	62PY102	Biotechnology & Biostatistics	4	0	0	4
3	62PY103	DRA, Intellectual Property Rights and Quality Assurance	4	0	0	4
4	62PY104	Product development and formulation	4	0	0	4
5	62SD105	SSD-Functional English-I	3	0	0	3
1	62PY151	Modern Analytical Techniques (LAB)	0	0	3	2
2	62PY152	Biotechnology & Biostatistics (LAB)	0	0	3	2
3	62PY153	Product development and formulation (LAB)	0	0	3	2
		Total				25

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II Semester

TEACHING & EXAMINATION SCHEME

Sr. No.	Subject Code	Subject	Periods			Credit
			L	T	P	
1	62PY201	Advance Physical Pharmaceutics	4	0	0	4
2	62PY202	Biopharmaceutics & Pharmacokinetics	4	0	0	4
3	62PY203	Advanced Pharmaceutical Formulation Technology	4	0	0	4
4	62PY204	Noval Drug Delivery System	4	0	0	4
5	62SD205	SSD-Functional English-II	3	0	0	3
1	62PY251	Advance Physical Pharmaceutics (LAB)	0	0	3	2
2	62PY252	Biopharmaceutics & Pharmacokinetics (LAB)	0	0	3	2
3	62PY253	Noval Drug Delivery System (LAB)	0	0	3	2
		Total				25

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III Semester

TEACHING & EXAMINATION SCHEME

Sr. No.	Subject Code	Subject	Periods			Credit
			L	T	P	
1	62PY351	Dissertation Part-I (Synopsis, Literature review, Seminar presentation)			40	20

Note: Dissertation part-I evaluated in out of 300 marks. 100 marks for report writing, 100 for presentation and 100 for viva voce.

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IV Semester

TEACHING & EXAMINATION SCHEME

Sr. No.	Subject Code	Subject	Periods			Credit
			L	T	P	
1	62PY451	Dissertation Part –II ((Research work,presentation &Viva- Voice)			50	25

Note: Dissertation part-II evaluated in out of 500 marks. 200 marks for Research work, 200 for presentation and 100 for viva voce.

M. Pharm.

Semester I

MODERN ANALYTICAL TECHNIQUES

Unit 1: UV-VISIBLE SPECTROSCOPY

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

INFRARED SPECTROPHOTOMETRY : Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

Unit 2: MASS SPECTROMETRY

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

RAY DIFFRACTION METHODS : Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit 3: THERMAL METHODS OF ANALYSIS

Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Colorimetry (DSC) and Thermo Mechanical Analysis (TMA).

ELECTROPHORESIS : Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

Unit 4:

NMR, C13 NMR, Origin of spectra, Chemical shifts, Spin-spin coupling, Coupling constant, Instrumentation and application for Structural elucidation.

RADIO IMMUNO ASSAY : Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and Applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT

Unit 5: CHROMATOGRAPHIC TECHNIQUES

a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.

b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.

c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

Practicals (Four hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2.Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
a. Vitamins
b. Oral antidiabetics
c. NSAIDs
d. Antimicrobials
e. Antihistamines
f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
7. Experiments on Electrophoresis.
8. Experiments of Chromatography.
(a) Thin Layer Chromatography.
(b) Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy – William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th edition.
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
11. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer,Franklin Book
14. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
18. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.

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Semester I
BIOTECHNOLOGY & BIOSATISTICS

Unit 1

Genetics: Structure & Function of DNA, DNA Replication & Repair, Expression of Genetic Information: Structure & Function of RNA, Transcription, Genetic code, Translation, Post translational modification.

Unit 2

Recombinant DNA Technology: Constructing Recombinant DNA molecules Restriction enzymes, Vectors, Gene Cloning, Genomic libraries, Polymerase Chain reaction – based DNA cloning, Restriction mapping, Blotting techniques, DNA sequencing, Pharmaceutical applications of recombinant DNA.

Unit 3

Gene Therapy: General Introduction, Potential target diseases for Gene therapy, Gene transfer methods, Clinical studies, Pharmaceutical production & Regulation.

Basics of Immunology, Monoclonal antibodies & Hybridoma technology & its Applications. Vaccines – Conventional vaccines, Modern Vaccine technologies, Genetically improved live vaccines, Genetically improved subunit vaccines, Pharmaceutical considerations.

Unit 4

Molecular, Structural and Chemical Biology in pharmaceutical research: Molecular biology of disease and invivo transgenic models, Genomic protein targets and recombinant therapeutics, Structural biology and rational drug design, Chemical biology and Molecular diversity, Gene therapy & DNA/ RNA targeted therapeutics. Future of pharmaceutical research.

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

Unit 5

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.

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.

Practical exercises based on the topics mentioned in theory syllabus

Recommended Readings

1. Lehninger ., ***Principles of Biochemistry***
2. Karp, G.,***Cell & Molecular Biology***.
3. Crommelin, D.J., A., and Sindelar R.D., ***Pharmaceutical Biotechnology***.

4. Templeton N.S., and Lasic. D.D., ***Gene Therapy.***
5. Benjamin Lewin, ***Genes***.
6. Watson and Trooze, ***Recombinant DNA Techniques***
7. Lesk., ***Introduction to Bioinformatiics***.
8. Watson, ***Molecular Biology of cell****.*
9. Old and Primrose, ***Principles of Gene Manipulations.***
10. Watson, J.D., Gilman, M.*,* ***Recombinant DNA Technology***
11. Baxevanis, A.D., Frana, Duelette, B.F.*,****Bioinformatics***
12. Alberts, B., Johnson, A., Lewin, J., Raff, M., Roberts, K., Walter, P.*,* ***molecular biology of the cell***
13. Paul, W.E*,* ***Fundamentals of Immunology***
14. Klug, W.S., Cummings, M.R., ***Essentials of Genetics***
15. Glick, B.R., Pasternak, J.J., ***Molecular Biotechnology***
16. Walker, J.M., Ripley, R., ***Molecular biology and Biotechnology***
17. Bolton, S***.,*** ***Pharmaceutical Statistics.***

1. Pharmaceutical Biotechnology: Vyas and Dixit.
2. Gene VII: Lewin Benzamin.
3. Industrial Microbiology: L.E. Casida.
4. Biotechnology- The Biological Principles: M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury.
5. Microbial Genetics: David Freifelder.
6. Immunology: J. Kuby.
7. Immunology: Weir.

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Semester I

DRA, INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE

Unit 1

1. Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 Series.
2. Drugs and Cosmetics Acts and Rules, Drug Regulatory Affairs.

Unit 2

1. Documentation – Protocols, Forms and Maintenance of records in Pharmaceutical industry.
2. Clinical Trials and toxicological evaluation of drugs. Preparation of documents for New Drug Approval and Export Registration.

Unit 3

1. Processing and its application, Intellectual Property Rights (Patent, Copy right and Trade marks).
2. Environment protection Act, Pollution Control, Factories Act.
3. Concepts in Validation, Validation of manufacturing, Analytical and Process validation and its Application.

Unit 4

1. Basic concept of Quality Control and Quality Assurance systems, Source and Control of Quality variation of Raw materials, Containers, Closures, Personnel, Environmental, etc.
2. In process quality control tests, IPQC problems in Pharmaceutical industries. ICH Guidelines

Unit 5

1. Sampling plans, Sampling and Characteristic curves.
2. Master formula generation and Maintenance, Standard Operating Procedure (SOP) for different dosage forms.

Books and References Recommended:

1. Willing, Tuckerman and Hitching, **Good Manufacturing Practices for Pharmaceuticals.**
2. Drugs and Cosmetic Acts and Rules.
3. Bharathi, **Drugs and Pharmacy Laws in India.**
4. Patel, **Industrial Microbiology.**
5. Loftus, B.T. and Nash,R.A., **Pharmaceutical Process Validation**.
6. Bolton, S., **Pharmaceutical Statistics**.
7. Banker, G.S. and Rhodes, C.T., **Modern Pharmaceutics**.
8. OPPI, **Quality Assurance.**
9. Carletiori, **Validation of Aseptic Pharmaceutical Process.**
10. Garfield, **Quality Assurance Principles for Analytical Laboratories**.
11. Indian Pharmacopoeia.
12. British Pharmacopoeia.
13. United State Pharmacopoeia.

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Semester I

PRODUCT DEVELOPMENT AND FORMULATION

Unit 1. Preformulation Studies

(a) Physical, Chemical and Pharmaceutical factors influencing formulation

(b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties

(c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form

(d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.

(e) Drug-excipient compatibility study

(f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).

(g) Preformulation studies of Biotechnological derived products and reference guidelines.

Unit 2

Solubilization: Theory of solubilization, methods of solubility enhancement and factor influencing solubility. Solids dispersion.

Dissolution Technology: Design of dissolution apparatus, dissolution media, dissolution testing of different types of dosage formulations, data interpretation, *in-vitro* and *in-vivo* correlation**.**

Drug Absorption

(a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.

(b) Method of studying bioavailability and bioequivalence.

(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

Unit 3

Pharmacokinetic parameters

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, absorption rate constant, elimination rate constant.

(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

Unit 4

Polymers: Classification, General method of synthesis, Properties, Characterization, Evaluation and Application in pharmacy. A detail account of biodegradable polymers.

OptimizationTechniques: Computers in pharmacy, Optimization techniques, Computer aided drug formulations.

Unit 5

Stability Study

(a) Basic concept and objectives of stability study,

(b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,

(c) Importance of accelerated stability study,

(d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.

(e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing, ICH guidelines, USFDA guidelines etc.
(f) Impurities in stability study.
(g) Applications of microcalorimetry in stability study.

Cosmetic, Dental and Herbal products

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Book Recommended:

1. Remingtons "Pharmaceutical Sciences" 19th edition.
2. Lachman "The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing by Banaker.
8. United States Pharmacopeia.
9. Techniques of Solubilization of Drugs by Yalkowsky.
10. Drug stability (Principles and Practices) by Jens. T. Carstensen.
11. Stability of drug and dosage forms by Yoskioka.
12. Applied Biopharmaceutics and pharmacokinetics by Leon Shargel, 4th edition.
13. Pharmacokinetics by Welling and Tse.
14. Pharmacokinetics by Gibaldi and Perrier
15. Biopharmmaceutics and pharmacokinetics: An introduction by Notari.
16. Pharmacokinetics for pharmaceutical scientist by John Wagner.
17. Dissolution, Bioavailability and Bioequivalence by Abdul.
18. Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.
19. Novel Cosmetic Drug Delivery Systems, by Magdassi and Touitou.
20. Cosmetics by Sagerin.
21. Perfumes, Cosmetics and Soaps by Poucher.

Practicals - Six hours per week

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.
10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.
18. Industrial Visit.
Any other practical related to the Theory portion of this syllabus.

SSD - FUNCTIONAL ENGLISH-1

I Semester

MBA/MCA/M PHARM/M.Sc.BT/MSW

Unit-I

May and can for permission and possibility
Could for permission in the past
May/Might for possibility.
Can and be able for ability.
Ought, should, must, have to, need for obligation.
Must, have, will and should for deduction and assumption.
The auxiliaries dare and used
Command, requests, invitations, advice, suggestions

Unit-II

The Present Tense:
Present Continuous, Simple present (Form and use)
The past and perfect tenses:
Simple past, The past continuous, The present perfect, The present perfect continuous, The past perfect, The past perfect continuous. (Form and use)

Unit-III

The Future: Future simple, the future continuous (Form and use)
The sequence of tenses, The conditional sentences

Unit-IV

Articles: Definite, Indefinite and Zero, The Passive voice; Active tenses and their passive equivalents, use of passive

Unit-V

The infinitive, The Gerund, The Participle, Preposition.

NOTE: Coverage of 1220 Regular (600) and Irregular Verbs (620) with their meaning and uses.

(Teachers are required to Introduce 25 verbs from the given verb list in every lecture)

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Semester II

Advanced Physical Pharmaceutics

Unit-I: Solubility: Solubility of solid in liquids, Theory of solution formation.

Solubilisation techniques using surfactants, cosolvents, complexation, inclusion compounds, drug derivatization and solid state manipulation.

Unit-II: Physical characteristics of Pharmaceutical solids:

Crystal properties and polymorphism, techniques for study of crystal properties; solid state stability, flow properties of powders. Polymorphism and pseudo polymorphism, Salt forms of the drug.

Unit-III: Biopharmaceutical and Pharmaco-technical characteristics of Drugs:

Diffusion: Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, thermodynamics of diffusion.

Dissolution: Theories of dissolution, dissolution models. Sink conditions in dissolution and its importance. In-vitro - in-vivo correlations.

Unit-IV: Polymer Science

Types of polymers, properties of polymers, thermodynamics of polymer solution and polymers in solid state. Applications of polymers in pharmaceutical formulations.

Unit-V

Kinetics and Drug stability: Rate equation, kinetics of decomposition, stability testing protocol, drug degradation and methods of stabilization, methods of accelerated stability testing in dosage forms, freeze-thaw methods, centrifugal methods

Text books:

1. Physical Pharmacy by Martin, 4^{the} Edition.

2. Physical pharmacy by CVS Subra hmanyam, Latest edition.

3.Theory and Practice of Industrial Pharmacy by L. Lachman

Reference books:

1. Bentley's Text Book of Pharmaceutics by E.A. Rawlin.

2. Pharmaceutical dosage forms: Tablets I, II, III.

3. Physicochemical Principles of Pharmacy by A.T. Florence and D. Altwood.

4. Pharmaceutical preformulation by J.T. Cartensen.

Advanced Physical Pharmaceutics Practicals:

1. To perform the preparation of emulsion and its evaluation with reference to pH, viscosity and physical stability.

2. Studying the stability of suspensions using the data on sedimentation volume and degree of Flocculation

3. Determination of the critical micellar concentration of various surfactants by drop Weight method or any other suitable method.

4. Determination of the optimum concentration of the surfactant for solubilisation (eg. Peppermint oil with tween 20).

5. Effect of hardness of the tablets on disintegration time.

6. To study the influence of various different disintegrates on disintegration of tablets.

7. Study on the effect of various excipients on the dissolution rate of tablets.

8. Determination of particle size and size distribution of selected drugs by microscopy, Sieving,

sedimentation (using Andreasen pipette) etc.

9. Determinations of flow properties of powders by Angle of repose and flow through an orifice with, and without glidants.

10. Determination of stability of emulsions by studying the globule size.

11. Estimation of optimum concentration of the various glidants for the flow of granules using angle of repose.

12. Accelerated stability studies on various formulations, with reference to:
Temperature dependence. Effect of buffers.

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Semester II

Biopharmaceutics and Pharmacokinetics

Unit-I : Basic concepts of pharmacokinetic

Compartment modeling – One and two compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches.

Application of these models to determine various pharmacokinetic parameters pertaining to.

i) Absorption: Mechanism and path ways of drug absorption, absorption rate constant, absorption half life, lag time and extent of absorption, AUC.
ii) Distribution: Physiological influence of drug distribution, protein binding of drug, determination of protein binding sites, clinical significance of drug protein binding. Apparent volume of distribution and its determination.
iii) Elimination: Over all apparent elimination rate constant, and half life.

Using conditios like Intravenous bolus injection, Intravenous infusion, Single dose oral administration and Multiple dosage oral administration
Non-linear pharmacokinetics– Concepts of linear and non linear pharmacokinetics, Michaelis – Menton kinetics characteristics, basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.

Unit-II
Kinetics of multiple dosing: Dosing regimens, loading and maintenance dose, one and two compartment models intravenous administration and first order absorption in multiple dosing.
Excretion of Drugs: Renal and non-renal excretion, Concept of clearance - Renal clearance, Organ clearance & Hepatic clearance.

Unit-III
Bioavailability and Bioequivalence- Objective, significance and factors affecting on bioavailability and bioequivalence, study design and assessment methods for bioavailability and bioequivalence, correlation of in-vitro dissolution in vivo bioavailability, statistical concepts in estimation of bioavailability and bioequivalence, regulatory requirements.

Unit-IV
Non-compartmental pharmacokinetics:
i) Physiologic Pharmacokinetic Models
Concepts, Concept, applications and limitation of physiologic pharmacokinetic models,
ii) Statistical moments theory: Concept and applications, Mean Residence Time (MRT), Statistical Moments Theory, Mean Absorption Time (MAT), Mean Dissolution Time (MDT).

Unit-V

Clinical Pharmacokinetic: Concept, absorption, distribution and renal clearance and elimination

Drug Absorption: Gastrointestinal absorption of drugs, mechanism of drug absorption, physico-chemical, biological factors influencing absorption, buccal absorption, salivary excretion of drugs.

Text Books

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985

Reference Books:

1. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
2. Biopharmaceutics and Pharmacokinetics by Robert E.Notari.
3. Pharmaceutical Codex.
4. Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B.C.Y

Biopharmaceutics and Pharmacokinetics (Practicals)

1. Improvement of dissolution characteristics of slightly soluble drugs by Various Solid dispersion techniques and solvent deposition systems. (4 experiments)
2. Comparison of dissolution of two different marketed products /brands. (2 experiments)
3. Influence of polymorphism on solubility and dissolution. (2 experiments)
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug. (2 experiments)
5. Bioavailability studies of Paracetamol by salivary data.(1 experiment)
6. Calculation of Ka, Ke, t 1/2, Cmax and Tmax for two sets of data. (2 experiments)
7. Calculation of bioavailability from the given urinary excretion data for two drugs. (2 experiments)
8. Calculation of AUC and bioequivalence from the given data for two drugs. (2 experiments)

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Semester II

Advanced Pharmaceutical Formulation Technology

Unit-I: Formulation Development of

(a) Solid dosage forms:

Improved production techniques for tablets: New materials, process, 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.

(b) Powder dosage forms:

Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

Unit- II Formulation Development of

(a) Liquid and Semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.

(b) Parenteral dosage forms:

Advances in materials and production techniques, filling machines, sterilizers and aseptic processing.

Unit-III Formulation Development of

Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, manufacture and quality control.

Unit-IV 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.

Unit-V

Pilot Plant Scale up Techniques:

Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.

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.

Text Books

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Remington‘s Pharmaceutical Sciences.
3. Bentley‘s Textbook of Pharmaceutics – Rawbins.

Reference Books

4. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
5. Physical Pharmacy; By Alfred martin
6. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
7. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

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Semester II

Novel drug delivery system

Unit-I

Fundamentals of controlled drug delivery systems, terminology, potential advantages, drug properties relevant to formulation, pharmacokinetic and pharmacodynamic basis of controlled drug delivery systems.

Design, fabrication, evaluation and applications of the following controlled release systems:

1. Controlled release oral drug delivery systems.
2. Modulated GI retentive drug delivery systems

Unit-II

1. Parenteral controlled drug delivery systems
2. Implantable therapeutic systems.
3. Transdermal therapeutic systems.

Unit-III

1. Bioadhesive drug delivery systems.
2. Proteins and peptide drug delivery
3. Resealed erythrocytes

Unit-IV

1. Colloidal drug delivery systems: Liposomes, microspheres, nanoparticles and polymeric micelles
2. Ocular Drug Delivery Systems
3. Intrauterine Drug Delivery Systems

Unit-V

Targeted drug delivery systems: Concepts and drug carrier systems

Approaches to active drug targeting: Monoclonal antibodies, Magnetic microspheres, Targeting to particular organs such as brain, lungs, liver and targeting to neoplastic diseases.

Text Books

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

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

Reference Books

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

4. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

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

6. Online journals

Practicals:

1. Preparation and study on invitro dissolution of various sustained action products and comparison with marketed products (3 expts.)
2. Formulation and in-vitro evaluation of Floating tablets. (2 expts)
3. Preparation of sustained release matrix matrix tablets using various polymers like PVP etc and studying their release patterns (2 expts.)
4. Preparation and evaluation of microcapsules by different microencapsulation techniques like:
   (a) Coacervation by temperature changes : Ethylcellulose in cyclohexane for phenobarbitone.
   (b) Complex coascervation technique
5. To perform sugar coating and nonenteric and enteric film coating on tablet and their evaluation (3 expts.)

SSD- CSEP(COMMUNICATION SKILLS ENHANCEMENT PROGRAM)

FUNCTIONAL ENGLISH-2

2nd Semester

MBA/MCA/M.Pharm/MSc. BT/MSc.(Ag)/MSW

Objectives:

- To help students revise the main problem areas of Functional English Grammar.
- To enable them to recognise differences in meaning through the use of different grammatical items.
- To improve students' command of spoken English by practicing the functional language needed in different situations

Unit-1

Conceptual Sessions: Subject verb agreement, Conjunction: Co-ordinating and Subordinating, Sentences-Simple, Compound and Complex
Activity: Speaking Activities Based on Themes (College/University, Beauty and Physical attractiveness, Food and eating, Dreams, Entertainment)
Assignment : Progress Test-1

Unit-2

Conceptual Sessions: Special Expressions: Asking for Information/directions/someone to repeat/expressing uncertainty, Interrupting politely, apologizing, Giving instructions, Sequencing actions, Making suggestions, Accepting an invitation, Expressing a preference, Making recommendations, Giving permission, Agreeing and Disagreeing, Common Errors in English,.
Activity: Speaking Activities Based on Themes (Vacation, Behaviour, Facebook, Computers)

Assignment : Progress Test-2

Unit-3

Conceptual Sessions: Presentation Skills: Meaning, Need for Oral presentation, Planning of presentation, use and types of Visual aids, Kinesics: Gesture, posture, facial expressions, Eye contact, Proxemics, voice and tone, Appearance and accessories.

Activity: Speaking Activities Based on Themes (Childhood, celebrities, Films in your own language)

Assignment : Progress Test-3

Unit-4

Conceptual Sessions: Reading comprehension, Vocabulary: Antonyms, Synonyms, Phrasal verbs, British English vs. American English, Business vocabs, Dictionary of formal and Informal English, List of personality Adjectives.

Activity: Story creation and Picture description.

Assignment : Progress test-4

Unit-5

Conceptual Sessions: Business letter writing: Parts and layout, Enquiry letter, Order letter, Complaint letter, Job application and leave application

Activity: Dialogue writing

Assignment : Progress test-5