CHHATTISGARH SWAMI VEVEKANAND TECHNICAL UNIVERSITY, BHIALI

Scheme of Teaching and Examination

Bachelor of Pharmacy

VIII- Semester

S.No.	Board of Study	Subject Code (New)	Nomenclature and Name of the Subject	Periods Per Week			Scheme of Exam Theory / Practical				Credits L+(T+P)/2
				L	T	P	ESE	CT	TA	Total Marks	
1	Pharmacy	341811(41)	Pharmaceutics XI (Pharmaceutical Technology II)	3	1	-	70	20	10	100	**4**
2	Pharmacy	341812(41)	Pharmaceutics XII (Bio-pharmaceutics and Pharmacokinetics)	3	1	-	70	20	10	100	**4**
3	Pharmacy	341813(41)	Pharmaceutical Analysis III	3	1	-	70	20	10	100	**4**
4	Pharmacy	341814(41)	Pharmacology IV (Clinical and Drug Interactions)	3	1	-	70	20	10	100	**4**
5	Refer Table – I		Elective- I	2	1	-	70	20	10	100	**3**
6	Pharmacy	341821(41)	Pharmaceutics XI (Pharmaceutical Technology II) Lab	-		6	60	-	40	100	**3**
7	Pharmacy	341822(41)	Pharmaceutics XII (Bio-pharmaceutics and Pharmacokinetics) Lab	-		6	60	-	40	100	**3**
8	Pharmacy	341823(41)	Pharmaceutical Analysis III Lab	-		3	60	-	40	100	**2**
9	Pharmacy	341824 (41)	Major Project	-	-	6	120	-	80	200	**3**
Total				**14**	**5**	**21**	**650**	**100**	**250**	**1000**	**30**

Minimum Pass Marks: **Duration of Theory Papers: 3 Hours.**

(A) Theory and Sessional (combined): 50 Percent

(B) Practical and Sessional (combined): 50 Percent

Table – I

Elective - I

S.No.	Board of Study	Subject Code	Subject
1	Pharmacy	341831 (41)	Quality Assurance and Packaging Technology
2	Pharmacy	341832 (41)	Drug Regulatory Affairs therapeutic Drugs Monitoring

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Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Pharmaceutics – XI (Pharmaceutical Technology II) **Code: 341811 (41)**
Total Theory Periods: 40 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

Design, development, formulation and evaluation of controlled release formulations. Carriers for drug delivery systems, Prodrugs.

Microencapsulation: Theory, methods, technology and applications.
Transdermal Drug Delivery Systems: Theory, formulation and evaluation.
Targeted Drug Delivery Systems:

Concept of drug targetting, importance in therapeutics, methods in drug targeting, Nanoparticles, Liposomes, Erythrocytes etc.

Implants and Inserts: Types, design and evaluation, Osmotic pump.
Packaging of Pharmaceutical Products and Cosmetics:

Packaging components, types, specifications and methods of evaluation, stability aspects of packaging, packaging equipment, factors influencing choice of containers, legal and other official requirements for containers, Packaging testing.

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Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Pharmaceutics –XII (Bio- pharmaceutics and Pharmacokinetics) **Code: 341812 (41)**
Total Theory Periods: 40 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

Introduction to biopharmaceutics and pharmacokinetics development and their role in drug formulation.

Biopharmaceutics

Definition, passage of drugs across biological barrier, Physiochemical, Biological and Pharmacaceutical factors influencing biopharmaceutical performance of drugs.

1. **Gastrointestinal absorption of drugs**: Passage of drugs across biological membranes, nature of biological membranes, gastrointestinal absorption mechanisms.
2. **Factors affecting drug absorption**: Physiological factors, dietary factors, physicochemical factors, pH partition hypothesis, dosage form factors.
3. **Methods of studying gastrointestinal absorption**: *In vitro* and *in vivo* methods.
4. **Drug disposition**: Distribution in blood, cellular distribution, plasma protein binding, tissue protein binding.
5. **Drug Excretion:** Routes of drug excretion, renal excretion of drugs, factors affecting renal excretion, biliary and salivary excretion of drugs.
6. **Drug biotransformation:** Pathways of drug metabolism, drug metabolizing enzymes, factors affecting drug metabolism and drug response, inhibition and stimulation of drug metabolism.

Pharmacokinetics

Absorption, distribution, metabolism and excretion of drugs, fluid compartment and circulatory system, protien binding, significance of plasma drug concentration measurement.

Compartment Models

Model selection criteria, one-compartment and two-compartment models, Wagner-Nelson and loo Riegelman methods for estimation of absorption constants. Curve fittings, regression procedure and area under blood level curves.

Clinical Pharmacokinetics

Urinary excretions, computation of pharmacokinetic parameters from urine data, hepatic clearance, biliary excretion, excretion ratio, dosage regimen adjustment in patients with and without renal failure, pharmacokinetic drug interactions and their significance in combination therapy.

Bioavailability and Bioequivalance

Bioavailability and Bio-equivalance, Federal requirements, Methods of determination of bioavailability using blood level and urinary excretion data, design and evaluations, bioavailability assessment.

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Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Pharmaceutical Analysis –III **Code: 341813 (41)**
Total Theory Periods: 40 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

Dosage forms evaluation as per monograph with special reference to I.P.
Development of new analytical methods. Concepts in validation, validation of manufacturing and analytical equipment, validation of analytical procedures.

Documentation: Protocols, forms and maintenance of records in pharmaceutical industries, preparation of documents for new drug approval and export registration to United States, United Kingdom, Europe and Africa.

Patent processing and its applications:

Requirement of GLP, ISO 9000, WHO and U.S. F.D.A. Basic concept of quality assurance, quality assurance system, sources and control of quality variation.

In-process quality control tests, IPQC problems in Pharmaceutical Industries, Total quality management.

Sampling plans, sampling and operating characteristics curves, Interpretation of analytical data. Regulatory control, regulatory drug analysis.

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Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Pharmacology –IV (Clinical and Drug Interactions) **Code: 341814 (41)**
Total Theory Periods: 40 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

Introduction to Clinical Pharmacy

Basic Principles of cell injury and adaption-

Causes of cell injury, pathogenesis, morphology of cell injury, intra cellular alterations in lipids, proteins and carbohydrates, cellular adaption, atrophy, hypertrophy.

Basic Mechanism Involved in the Process of Inflammation and Repair-

Alterations in vascular permeability and blood flow, migration of WBC's, acute and chronic inflammation, brief outline of the process of repair.

Basic Concepts of Pharmacotherapy-

a) Clinical Pharmacokinetics Individualization of Drug Therapy.
b) Drug Use During Infancy and in the Elderly (Paediatrics and Geriatrics)
c) Drug use during Pregnancy.
d) Drug induced disease.
e) The Basics of Drug interactions.
f) General principles of clinical laboratory tests.

Therapeutic Drug Monitoring

Concept of essential Drugs and Drug Use, Drug abuse

Principles of Toxicology

a) Definition of Poison, general principles of treatment of poisoning particular reference of barbiturates, Opoids, Organophosphorylation and Atropine poisoing.
b) Heavy metals and heavy metal antagonists.

Reference / Recommend Books:

1. **Herfindal, E.T. and Hirschman, J.L., Clinical Pharmacy and Therapeutics, William and Wilkins.**
2. **Katzung, B.G., Basic and Clinical Pharmacology, Prentice Hall International.**
3. **Laurence, D.R. and Bennet, P.N., Clinical Pharmacology, Churchill Livingstone.**

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Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Quality Assurance And Packaging Technology) **Code: 341831 (41)**
Total Theory Periods: 28 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

A) Quality control and Quality assurance. Sources and Control of quality variation. Control and assurance of manufacturing practices and finished products. Quality assurance during Packaging operation.

B) New concepts in pharmaceutical packaging. Packaging materials with special reference to polymers, metals glass and plastics, control of packaging materials. Control of packaging materials.

C) Blister and strip packaging. Testing of containers and closures, Pharmacopoeial tests and specifications. Defects in Packages. Stability of packages and packaging materials.

D) Sterilization of packaging materials. Packaging of parenterals, ophthalmic and aerosols. Legal requirement.

Semester: B. Pharma. VIII Sem. **Branch: Pharmacy**
Subject : Drug Regulatory Affirs and Therapeutic Drugs Montoring **Code: 341832 (41)**
Total Theory Periods: 28 **Total Tutorial Period - 12**
Total Marks in End Semester Exam: 70
Minimum number of class tests to be conducted: 2

A) History of the Federal Food Drug and Cosmetic Act.

B) Definition of drug, New drug, Label, New animal drug under the Federal Food, Drug and Cosmetic act.

C) New drug, NDA, ANDA, SNDA, Recalls, GMP, FDA.

D) Intellectual and Industrial property. Patent information resources in pharmacy and the Pharmaceutical Science. Drug literature, Clinical analysis.

E) Bioavailability and Bioequivalence testing. Adverse Drug Reaction and its monitoring. Drug interactions, Drug abuse. Design of dosage Regimens.

Semester: B. Pharma. VII Sem. **Branch: Pharmacy**
Subject: Pharmaceutics -XI (Pharmaceutical Technology- II) Lab **Code: 341821 (41)**
Total Practical Periods: 72
Total Marks in End Semester Exam: 60

Experiments to be Performed :

Formulations, evaluations and stability testing of preparations concerning dosage forms mentioned in theory.

Reference / Recommend Books:

1. **Rawlins, E.A., Text Book Of Pharmaceutics, Bailliere Tindall.**
2. **Lachman, L. , Liberman, H.A. and Kanig, J.L., The Theory and Practice of Industrial Pharmacy, Lea and Febiger, Philadelphia.**
3. **Liberman, H.A., lachman, L. and Ker Inc. New York.**
4. **Pharmacopoeia Of India, Ministry of Health and family Welfare, Govt. of India, New Delhi.**
5. **Avis, K.E., Lachman, L. and Liberman, H.A., Pharmaceutical Dosage Forms-Parenteral Medication Vol.1-2, Marcel Decker Inc., New York.**
6. **Banker G.S. and Rhode C.T., Modern Pharmaceutics, Marcell Decker Inc., New York.**

Semester: B. Pharma. VII Sem. **Branch: Pharmacy**
Subject: Pharmaceutics -XII (Bio- pharmaceutics and Pharmacokinetics)Lab **Code: 341822 (41)**
Total Practical Periods: 72
Total Marks in End Semester Exam: 60

Experiments to be Performed :

Exp.1 Experiments designed for the estimation of various pharmacokineticsparameterswith given data.
Exp.2 Invitro evaluation of different dosage forms for drug release.
Exp.3 Absorption studies invitro and insitu.
Exp.4 Statistical treatment of pharmaceutical data.

Reference / Recommend Books:

1. **Gennaro, A.R., ed Remington's The science and Practice of Pharmacy, Mac Publishing Co. Pennsylvannia, USA.**
2. **Notari, Biopharmaceutics and Pharmacokinetics an Introduction, 2nd ed Lea & Febiger, NY 1982.**
3. **Gibaldi and D. Perrier, Pharmacokinetics, 2nd ed, marcel Dekker Inc., NY 1982.**
4. **Milo Gibaldi. Biopharmacokinetics and Clinical Pharmacokinetics, 3rd., Le & Febizer, Phidelphia 1984.**
5. **Brahmankar's Biopharmaceutics and Pharmacokinetics , Vallabh Prakashan, Delhi.**
6. **Rowland & Tozer's Clinical Pharmacokinetics, Concepts and applications,3rd ed., Lea & Febiger Publication, USA.**

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Semester: B. Pharma. VII Sem. **Branch: Pharmacy**
Subject: Pharmaceutical Analysis -III Lab **Code: 341823 (41)**
Total Practical Periods: 40
Total Marks in End Semester Exam: 60

Experiments to be Performed :

Exp.1 Evaluation of dosage formation as per I.P. monograph.
Exp.2 Q.C of the herbal drug preparation as per the WHO guideline.
Exp.3 Assay of marketed dosage form as per I.P. & USP.
Exp.4 Validation of manufacturing and analytical equipments.
Exp.5 Preparation of GLP

Reference / Recommend Books:

1. **Willing, S.H., IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker Inc., New York.**
2. **Loftus, B.T. and Nash R., Pharmaceutical Proce3ss Validation, Marcel Dekker Inc., New York.**
3. **Svehla, g. Vogel's Text Book of micro and Semi Micro Qualitative Inorganic Analysis, Orient Longman, Hyderabad.**
4. **Beckett, A.H. and Stenlake, J.BN., Practical Pharmaceutical Chemistry, the Athlone Press of the university of London.**
5. **Pharmacopoeia of India, Ministry of health and Family Welfare, Govt. of India, New Delhi.**