CHHATTISGARH SWAMI VEVEKANAND TECHNICAL UNIVERSITY, BHILAI

Course of Study and Scheme of Examination

Bachelor of Pharmacy

IV-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	341411(41)	Pharmaceutics - V (Pharmaceutical Engineering – II)	4	1	0	70	20	10	100	5
2	Pharmacy	341412(41)	Pharmaceutics –VI (Dosage Form Design)	4	1	0	70	20	10	100	5
3	Pharmacy	341413(41)	Pharmaceutical Analysis - I	4	1	0	70	20	10	100	5
4	Pharmacy	341414(41)	Pharmaceutical Biotechnology	4	1	0	70	20	10	100	5
5	Pharmacy	341415(41)	Pharmaceutical Microbiology	4	1	0	70	20	10	100	5
6	Pharmacy	341421(41)	Pharmaceutics –V (Pharmaceutical Engineering - II) Practical	0	0	3	60	-	40	100	2
7	Pharmacy	341422(41)	Pharmaceutics – VI (Dosage Form Design) Practical	0	0	3	60	-	40	100	2
8	Pharmacy	341423(41)	Pharmaceutical Analysis -I Practical	0	0	3	60	-	40	100	2
9	Pharmacy	341424(41)	Pharmaceutical Biotechnology Practical	0	0	3	60	-	40	100	2
10	Pharmacy	341425(41)	Pharmaceutical Microbiology Practical	0	0	3	60	-	40	100	2
			Total	**20**	**5**	**15**	**650**	**100**	**250**	**1000**	**35**

L- Lecture, T- Tutorial, P- Practical, ESE- End Semester Exam, TA- Teacher's Assessment

Minimum Pass Marks:

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

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

Duration of Theory Papers: 3 Hours.

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Total Theory Periods: 40 **Total Tut. Periods: 1**

Subject: Pharmaceutics- V (Pharmaceutical Engineering-II) **Code**: 341411(41)

Total Marks in End Semester Exam: 70

Minimum no. of class tests to be conducted: 2

Size Reduction and Size Separation -

Definition objectives and significance of size reduction, Factors affecting size reduction, Standard of powders, Sieves and their usage in grading of powders, Laws governing energy and power requirements of a mill, Classification of size reduction machines, Study of various types of mill including ball mill, hammer mill, fluid energy mill etc. Mathematical problems.

Evaporation -

Basic concepts, Factors affecting evaporation, Types of evaporators, Study of short tube evaporators, Forced circulation evaporators and Film evaporators, Single and multiple effect evaporation, Evaporation under reduced pressure, Evaporation capacity, Heat and material balance, Scale formation, Foam and entrainment, Mathematical problems.

Distillation -

General theory applied to binary mixtures, Boiling point and equilibrium diagrams, Raout's Law and Henry's Law, Constant boiling mixtures. Simple, steam and Equilibrium distillations. Rectification, Constructions of rectifying columns. Analysis of rectifying column**:** McCabe Thiel method and Lewis Sorel method for calculation of number of theoretical plates, Azeotropic and extractive distillations.

Drying -

Introduction, Theory of drying Rate of drying curves, Classification of dryers, Study of dryers used in pharmaceutical industries, Special drying methods, Mathematical problems.

Extraction -

Principles of solid-liquid and liquid- liquid extraction, Theories of extraction of drugs, Diffusion battery, Continuous counter-current extraction system.

Crystallization -

Importance of crystal purity, size, shape, geometry, habit, forms and types. Solubility curves and calculation of yields, Mier's supersaturation theory and its limitations, Nucleation and crystal growth, Classification of crystallizers, Principles underlying the design and operation of Tank, Swenson-walker, Krystal and Vacuum crystallizer. Crystallizer employed for producing large crystals, Caking of crystals and its prevention, Mathematical problems.

Mixing -

Theory of mixing, Solid-solid, solid-liquid and liquid- liquid mixers used in pharmaceutical industries.

Filtration and Centrifugation -

Theory of filtration, Factors affecting filtration, Filter media, Filter aids, Classification of filters, Industrial filters including Filter press, Rotary filter, Membrane filter etc. Mathematical problems. Principles of centrifugation, Industrial filters and centrifugation sedimenters.

Pilot Plant Scale Up Techniques -

Concepts of pilot plant, scale up techniques in pharmaceutical industries.

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Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutics - VI (Dosage Form Design) **Code: 341412(41)**
Total Theory Periods: 40 **Total Tut. Periods: 1**
Total Marks in End Semester Exam: 70
Minimum no. of class tests to be conducted: 2

Preformulation studies:

Study of physical, chemical and pharmaceutical factors influencing drug formulation, stability and bioavailability.

Study of different types of formulation additives like –

Diluents, Binders Disintegrators, Lubricants, Solvents, Co-solvents and Vehicles, Antioxidants, Preservatives, Suspending, Emulsifying, Coloring, Flavoring and Sweetening agents, Viscosity enhancers, Materials for Ointment; Cream and Suppository bases, Drug-excipient interactions and incompatibilities.

Polymers:

Polymers and biodegradable polymers, Classification, Properties, Characterization and Evaluation, Mechanism of biodegradation in the body, Pharmaceutical applications of polymers.

Stability Studies:

Stability testing protocols for various pharmaceutical dosage forms, Determination of expiry date (shelf life) and overage calculations, Stabilization of pharmaceutical formulations.

Design, development and process validation methods for pharmaceutical operations involved in manufacturing of dosage formulations with special reference to solid and liquid dosage forms.

Performance evaluation methods :

1. In-vitro dissolution studies for solid dosage forms: Methods, Interpretation of dissolution data.
2. Bioavailability studies and bioavailability testing: Protocols and Procedures.
3. In-vivo methods of evaluation, statistical treatment.
   Standard operating process for different dosage formulations, Process optimization, New Product launch.

Reference/Recommended Books:

1. B M Mithal-TB of Pharma Formulation (Vallabh)
2. Jain/Sharma-TB of Professional Studies (Vallabh)
3. Banker-Modern Pharmaceutics (D &P Series) KMV
4. Cole GC- Pharma Production Facilities (f 99.00-CBS, No)
5. Hillery et al - Drup Delivery & Targettirs (l 35.00- CBS No)
6. Jain N K – Controlled & Novel Drup Delivery (CBS, No)

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Analysis - I **Code:** 341413(41)
Total Theory Periods: 40 **Total Tut. Periods: 1**
Total Marks in End Semester Exam: 70
Minimum no. of class tests to be conducted: 2

Fundamentals, Significance of quantitative analysis in quality control, Different techniques of analysis.

Theoretical considerations and pharmaceutical applications; with special reference to Indian pharmacopoeia; of the following analytical techniques -

1) Acid-Base titrations.
2) Oxidation-Reduction titrations.
3) Precipititation titrations.
4) Gravimetric analysis.
5) Non-aqueous titrations.
6) Complexometric titrations.
7) Conductometry.
8) Potentiometry.

Miscellaneous methods of analysis like diazotisation titrations, Kjeldahl method of nitrogen estimation, Karl-fisher titrations.

Reference/ Recommended Books:

1. P. Parimoo-Pharmaceutical Analysis (CBS)
2. Willard-Instrumental Methods of Analysis (CBS)
3. B K Sharma- Instrumental Methods of Analysis (Krishna-Meera)
4. Kasture/Gokhale-Pharma Analysis (pt I+II) Nirali/Prapa
5. Chatwal-Instr Methods of Analysis (Himalaya Pub.)

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Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Biotechnology **Code:** 341414(41)
Total Theory Periods: 40 **Total Tut. Periods: 1**
Total Marks in End Semester Exam: 70
Minimum no. of class tests to be conducted: 2

Historical Development -

Immunology and Immunological Preparations:

Principles, Antigens and antibodies, Antigen-antibody reactions and their applications, Immune system. Cellular humoral immunity, Immunological tolerance, Hypersensitivity, Immunological and diagnostic preparations: Methods of their preparation, standardization and storage.

Enzyme Immobilization -

Techniques of Immobilization of enzymes, kinetics and factors affecting enzymes kinetics, Enzymes electrodes, Enzymes based sensors, Study of enzymes such as Hyaluronidase, Penicillinase, Strepto-kinase, Amylases, Proteases etc. Immobilization of bacteria and plant cells, Applications of Immobilization.

Genetic Recombination:

Transformation, Conjugation, Transduction, Protoplast fusion, Gene cloning and their applications, Monoclonal antibodies and hybridoma technology, Recombinant DNA technology: Concepts, Methodology and Pharmaceutical applications. Study of drugs produced by biotechnology such as Activase, Humulin, Humatrope, Intron A, Monoclate, Orthoclone OKT3, Referon-A, Recombivax HB etc. Drug delivery systems in Gene therapy.

Microbiological Transformation -

Introduction, Types of reactions mediated by microorganisms. Design of biotransformation processes, Selection of organisms, Biotransformation processes and its improvements with special reference to steroids.

Industrial Biotechnology -

Historical development, Fermenter and its design, Control of different parameters in fermentation process, Isolation of mutants, Use of mutagenic agents, Factors in influencing rate of mutation. Design of fermentation process, Fermentative, production of Alcohol, Acetic acid, Penicillin, Streptomycin, Riboflavin, Vitamin B_{12}.

Reference/Recommended Books

1. R.S. Setty/GR Veena – Biotechnology I (New Age, New Delhi)
2. Setty/Sreekrishna – Biotechnology II (New Age, New Delhi)
3. S Mahesh– Biotechnology III (New Age, New Delhi)
4. Mahesh/Vedamurthy – Biotechnology IV (New Age, New Delhi)
5. M K Mahesh – Biotechnology V (New Age, New Delhi)
6. K Trehan-Biotechnology (New Age, New Delhi

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY,

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Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Microbiology **Code:** 341415(41)
Total Theory Periods: 40 **Total Tut. Periods: 1**
Total Marks in End Semester Exam: 70
Minimum no. of class tests to be conducted: 2

Introduction to the Microbiology -

Historical development, contribution of great scientists and scope of microbiology.

Microbiological Taxonomy -

Classification of Bacteria and Viruses.

Identification of Microbes -

Working of different types of microscopes, Electron microscopy, Stains and types of staining techniques.

Structure and Morphology of bacteria and viruses.

Nutritional requirements, Cultivation and Isolation of bacteria and viruses.

Microbial genetics and variation.

Control of microbes by physical and chemical methods:

Disinfection: Factors influencing disinfection, dynamics of disinfection, Disinfectants and antiseptics, and their evaluation.

a) **Sterilization:** Different methods, Validation of sterilization methods and equipments.

Sterility testing of pharmaceutical products:

Infection and factors influencing infection, Immunity, Primary and Secondary defensive mechanisms of body, Microbial resistance, Interferon.

Microbial assay of antibiotics and vitamins.

Food spoilage and Preservation of food.

Sewage and Sewage Disposal -

Industrial Sewage, Sewage treatment methods, BOD, COD etc.

Reference/Recommended Books:

1. N K Jain - Pharmaceutical Microbiology (Vallabh)
2. Shah-Shah – A TB of Pharma Micro (BS Shah)
3. K R Aneja – Expts in Microfiol & Biotech (New Age)
4. L E Casida – Indurtrial Microbiology (New Age)
5. Kale-Bhnsari – Microbiology (Himalaya Pub)
6. Singh/Dwivedi – Environmental Microbio1 & Biotech (New Age)

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutics- V (Pharmaceutical Engineering-II) Practical **Practical Code**: 341421(41)

Total Practical Periods: 3
Total Marks in End Semester Exam: 60

Exp.1 - To illustrate principles of size reduction laws governing energy & power requirements of size reduction.

Exp.2 - Determination rate of evaporation.

Exp.3 - Experiment based on steam, extractive & azeotropic distillation.

Exp.4 - Experiment to illustrate the influence of various parameter on the rate of drying.

Exp.5 - Determination of rate of drying.

Exp.6 - Determination of heat transfer coefficient.

Exp.7 - Experiments based upon extraction.

Exp.8 - Experiments based on crystallization.

Reference / Recommend Books:

1. Brown. C.G., et el., Unit Operation, Asia Publishing House Mumbai.
2. K. Sambhamurty, Pharmaceutical Engineering.
3. Caretr. S. J., Cooper, and Gunn's, Tutorial Pharmacy, CBS Publisher, New Delhi.
4. Perry's Chemical Engineer's hand Book.
5. Bentley's Text Book of Pharmaceutics, ELBS London.
5. C.V.S. Subrahmanyam, Pharmaceutical Engineering Principle & Practice, Vallabh Prakashan, New Delhi.

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutics - VI (Dosage Form Design) Practical **Practical Code**: 341422(41)
Total Practical Periods: 3
Total Marks in End Semester Exam: 60

Exp.1 - Estimation of bulk density, & percentage of carr's index.

Exp.2 - To find out the angle of repose.

Exp.3 - To find out the particle size analysis.

Exp.4 - Drug excipients compatibility study.

Exp.5 - Stability testing –

a) Accelerated stability study.

b) Force degradation study.

Exp.6 - Moisture pick- up study.

Exp.7 - To find out the percentage of drug release with the help of dissolution apparatus of some marketed pharmaceutical products.

Reference / Recommend Books:

1. Raemigton's Pharmaceutical Sciences – Gennaro A.R., ed.,19th Edition, Mack, Publishing Co.,Easton, P.A.1995.
2. Arisel, H.C., Introduction to Pharmaceutical dosage forums, K.M. Verghese & Co.,Mumbai.
3. Aulton, M.E., Pharmaceutics – The Science of dosage form design, ELBS, London.
4. Mithal , B.M., Text Book of Pharmaceutical Formulations, Vallabh Prakashan, New Delhi.
5. Lachman , L., Liberman, H.A. , Theory and practice of Industrial – Pharmacy, Lea & Febiger Philadelphia, USA.

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Analysis – I Practical **Practical Code**: 341423(41)

Total Practical Periods: 3

Total Marks in End Semester Exam: 60

Exp.1 - Calibration of Analytical balance.

Exp.2 - To estimate the normality of unknown $Kmno_4$ solution by the help of standard N/30 Ferrous Sulphate solution.

Exp.3 - Practical Non Aqueous Titration –

a) Preparation & Standardization of Perchloric acid & Sodium/ Potassium/ Lithium Methoxide solution.

b) Estimation of some pharmacoepial products.

Exp.4 - Complexometric Titration –

a) Prepration & standerization of EDTA solution.

b) Some exercise to pharmacoepial assays By complexometric titration.

Exp.5 - Miscellaneous determination.

a) Karl – fischer titrations.

b) Diazotisation titrations.

c) Kjeldahl method of Nitrogen estimation.

Exp.6 - Exercise based on acid base titration in aqueous & non aqueous media.

Exp.7 - Exercise based on oxidation reduction titration using potentiometric techniques.

Exp.8 - Determination of acid base dissociation constant & plotting titration curve using pH meter.

Exp.9 - Exercise based on conductometric titration of some pharmaceutical products.

Reference / Recommend Books:

1. A Textbook of Pharmaceutical Analysis – Conors.
2. Pharmaceutical Analysis – L.G.Chatten.
3. Vogels "Text Book of Quantitative Inorganic Analysis."
4. Backett and Stenlake "Practical Pharmaceutical Chemistry – Part-I."
5. Dr.K.R.Mahadik, Dr.H.N.More.,Pharmaceutical analysis –I and II , Instrumental Methods. Nirali Prakashan ,Pune.
6. Ashutosh Kar,Pharmaceutical and Drug Analysis.

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Biotechnology Practical **Practical Code**: 341424(41)

Total Practical Periods: 3

Total Marks in End Semester Exam: 60

Exp.1	-	Prepare & evaluate enzyme immobilized calcium alginate beads.
Exp.2	-	To extract tyrosinase from potato and study the substrate specificity on different substrate.
Exp.3	-	Determine the enzyme kinetics of pepsin.
Exp.4	-	Enzyme immobilization with gelatin gel solution.
Exp.5	-	DNA isolation from onion.
Exp.6	-	Treat yogurt fermentation with lactobacillus bacteria.
Exp.7	-	Perform isolation of RNA from yeast cell.
Exp.8	-	A, B, O Blood group typing of own blood IgM mediated agglutination reaction.
Exp.9	-	Estimate total protein content in alginate beads by biurate reagents.
Exp.10	-	Isolate enzyme urease & determine its practical yields.
Exp.11	-	Batch submerged Fermentation of broken's yeast.
Exp.12	-	Isolation of lecithin from egg yolk.
Exp.13	-	Isolation of glutein from wheat flour.
Exp.14	-	Separation of Amino acids by using TLC.
Exp.15	-	Preparation of alcohol by using fermentation process.

Reference / Recommend Books:

1. Carter, S.J., Cooper and Gunn's Tutorial Pharmacy, CBS Publishers,Delhi.
2. Rawlins, E.A., Bentley's Text Book of Pharmaceutics, ELBS Balliere tindall.
3. Hugo, W.B. and Russell, A.D., Pharmaceutical microbiology, Blackwell Scientific Pubication, Oxford.
4. Wiserman, A.ed., Handbook of enzyme biotechnology, Ellis Harwood Ltd., Chichester
5. Cassida Jr.,L.E., Industrial Microbiology, Wiley , eastern Limited, New Delhi.
6. Donald M.Weir, John Stewart, Immunology, Churchill Livingstone, London.

CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI

Semester: 4th **Branch:** B. Pharm

Subject: Pharmaceutical Microbiology Practical **Practical Code**: 341425(41)
Total Practical Periods: 3

Total Marks in End Semester Exam: 60

Exp.1 - Study of different types of Microscopes.

Exp.2 - Study of Hot air oven.

Exp.3 - Study of Auto clave.

Exp.4 - Study of Incubator.

Exp.5 - Identification of microorganism by different method.

Exp.6 - To prepare & sterilize Nutrient Agar.

Exp.7 - To prepare & sterliseThioglycolate media.

Exp.8 - Microbial assay's of antibiotics.

Exp.9 - Microbial assays of vitamins.

Exp.10 - To study the lactose fermenting bacteria from milk sample using differential plating.

Exp.11 - Testing the sterility of pharmaceutical products.(Creams & ointments)

Exp.12 - To perform sterility test for aqueous solution & suspension.

Exp.13 - To perform sterility test for water for injection.

Exp.14 - To study the effect of pH of the culture media on the growth of microbes.

Exp.15 - To study the effects of osmotic pressure on growth of microbes.

Reference / Recommend Books:

1. Carter, S.J.Cooper and Gunns, Tutorial Pharmacy, 6th ed. CBS Publishers, Delhi,1986.
2. Carter, S.J.Cooper and Gunns, Dispensing for Pharmaceutical Students, CBS Publishers,New Delhi,1987.
3. Pharmaceutical Microbiology ,N.K.Jain.
4. Hugo,W.B. and Russell A.D., Pharmaceutical Microbiology, Blackwell Scientific Publication Oxford.
5. Ralins, E.A. , Bentley's Text Book of Pharmaceutics 8th ed., Balliere Tindall,1977