

Course of Study and Scheme of Examination

Bachelor of Pharmacy

IV-Semester

(New Scheme)

To be implemented for student admitted in I Year BE in July-Aug 2005

Subject Code (New)	Subject Code (Old)	Nomenclature and Name of the Subject	Teaching (Hrs/Week)			Examination				
			L	T	P	Number of Papers	Duration (Hrs.)	Max. Sem. Marks	Sessional Marks	Total Marks
PY401	IV -T - 1	<u>Pharmaceutics- V (Pharmaceutical Engineering – II)</u>	4	0	0	1	3	70	30	100
PY401	IV – P - 1	<u>Pharmaceutics –V (Pharmaceutical Engineering - II) Practical</u>	0	0	3	1	6	60	40	100
PY402	IV – T -- 2	<u>Pharmaceutics –VI (Dosage Form Design)</u>	4	0	0	1	3	70	30	100
PY402	IV -P - 2	<u>Pharmaceutics – VI (Dosage Form Design) Practical</u>	0	0	3	1	6	60	40	100
PY403	IV -T - 3	<u>Pharmaceutical Analysis - I</u>	4	0	0	1	3	70	30	100
PY403	IV - P - 3	<u>Pharmaceutical Analysis -I Practical</u>	0	0	3	1	6	60	40	100
PY404	IV -T - 4	<u>Pharmaceutical Biotechnology</u>	4	0	0	1	3	70	30	100
PY404	IV -P - 4	<u>Pharmaceutical Biotechnology - Practical</u>	0	0	3	1	4	60	40	100
PY405	IV - T - 5	<u>Anatomy, Physiology and Health Education –II</u>	4	0	0	1	3	70	30	100
PY405	IV - P – 5	<u>Anatomy , Physiology and Health Education –II Practical</u>	0	0	3	1	4	60	40	100
	Total		20		15					1000

Minimum Pass Marks:

Duration of Theory Papers: 3 Hours.

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

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

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
			L	T	P	
IV-T-1	Pharmaceutics-V (Pharmaceutical Engineering-II) (Theory)	PY 401	4	0	0	Max.Marks-70 Duration-3hrs.

Branch: Pharmacy-IV Semester

Course: PY 401 Pharmaceutics-V (Pharmaceutical Engineering-II) (Theory)

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. Fluid classification methods. 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, Raoult'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, Podbielnaik extractor, 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.

Compaction and Compression -

Adhesion and Cohesion of particles, Strength of granules, Factors affecting strength of tablets, Physics of tablet compression.

Pilot Plant Scale Up Techniques -

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

Course Contents

Category of Course	Course Title	Course Code	Credit		
			L	T	P
IV-P-1	Pharmaceutics-V (Pharmaceutical Engineering-II)	PY 401			
			0	0	3

Branch: Pharmacy IV Semester

Course: PY 401 Pharmaceutics-V (Pharmaceutical Engineering-II (Practical))

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. Fluid classification methods. 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.

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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.

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Pilot Plant Scale Up Techniques -

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Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
			L	T	P	
IV-T-2	Pharmaceutics-VI (Dosage Form Design) (Theory)	PY 402	4	0	0	Max.Marks-70 Duration-3hrs.

Branch: Pharmacy-IV Semester

Course: PY 402 **Pharmaceutics-VI (Dosage Form Design) (Theory)**

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 Sweetness agents, Viscosity enhancers, Materials for Ointment; Cream and Suppository bases, Drug-excipient interactions and incompatibilities.

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. In-vivo methods of evaluation, statistical treatment.

Standard operating process for different dosage formulations, Process optimization, New Product launch.

Course Contents

Category of Course	Course Title	Course Code	Credit		
IV-P-2	PY 402 Pharmaceutics-VI (Dosage Form Design) Practical	PY 402	L	T	P
			0	0	3

Branch: Pharmacy-IV Semester

Course: PY 402 **Pharmaceutics-VI (Dosage Form Design) (Practical)**

IV-P-2 PHARMACEUTICS-VII (DOSAGE FORM DESIGN)

PRACTICALS

Experiments based on theory.

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
IV-T-3	Pharmaceutical Analysis (Theory)	PY 403	L	T	P	Max.Marks-70 Duration-3hrs.
			4	0	0	

Branch: Pharmacy-IV Semester

Course: PY 403 Pharmaceutical Analysis (Theory)

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) Precipitation titrations.
- 4) Gravimetric analysis.
- 5) Non-aqueous titrations.
- 6) Complexometric titrations.
- 7) Conductometry.
- 8) Potentiometry.
- 9) **Polorography & Amperometry**

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

Course Contents

Category of Course	Course Title	Course Code	Credit		
IV-P-3	Pharmaceutical Analysis (Practical)	PY 403	L	T	P
			0	0	3

Branch: Pharmacy-IV Semester

Course: PY 403 Pharmaceutical Analysis (Practical)

IV-P-3 PHARMACEUTICAL ANALYSIS-I PRACTICALS

- 1) Semi-micro qualitative analysis of inorganic mixtures containing six radicals including interfering radicals like phosphate, borax, oxalate, tartarate, citrate.
- 2) Assay of pharmaceutical substance / products as per I.P. by the analytical techniques mentioned under theory.
- 3) Instrumental analysis involving refractometer, polarimeter, conductometer, pH meter and potentiometer.
- 4) Exercises involving diazotisation, Kjeldahl and Karl-fisher methods.

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
IV-T-4	Pharmaceutical Biotechnology (Theory)	PY 404	L	T	P	Max.Marks-70 Duration-3hrs.
			4	0	0	

Branch: Pharmacy-IV Semester

Course: **PY 404** Pharmaceutical Biotechnology (Theory)

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 micro organisms. 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 B₁₂.

Course Contents

Category of Course	Course Title	Course Code	Credit		
IV-P-4	Pharmaceutical Biotechnology (Practical)	PY 404	L	T	P
			0	0	3

Branch: Pharmacy-IV Semester

Course: PY 404 Pharmaceutical Biotechnology (Practical)

IV-P-4 PHARMACEUTICAL BIOTECHNOLOGY PRACTICALS

Experiments based on theory.

Course Contents

Category of Course	Course Title	Course Code	Credit-4C			Theory Paper (ES)
			L	T	P	
IV-T-5	Anatomy, Physiology & Health Education-II (Theory)	PY 405	4	0	0	Max.Marks-70 Duration-3hrs.

Branch: Pharmacy-IV Semester

Course: PY 405 Anatomy, Physiology & Health Education-II (Theory)

Digestive System -

Gross anatomy of the gastrointestinal tract, Functions of its different parts including those of liver, pancreas and gall bladder, Various gastrointestinal secretions and their role in the absorption and digestion of food. Disorders of digestive system.

Respiratory System -

Anatomy of respiratory organs, Functions of respiration, Mechanism and regulation of respiration, Respiratory volumes and vital capacity.

Central Nervous System -

Function of different parts of brain and spinal cord, Neurohumoral transmission in the central nervous system, Reflex action, Electroencephalogram, Specialized functions of the brain, cranial nerves and their functions.

Autonomic Nervous System -

Physiology and functions of the autonomic nervous system. Mechanism of neurohumoral transmission in the A.N.S.

Urinary System -

Various parts, Structures and functions of the Kidney and Urinary tract. Physiology of urine formation and acid-base balance. Diseases of urinary system.

Reproductive System -

Male and female reproductive systems and their hormones, Physiology of menstruation, coitus and fertilization, Sex differentiation, spermatogenesis and oogenesis, Pregnancy - its maintenance and parturition.

Endocrine System -

Basic anatomy and physiology of the Pituitary, Thyroid, Parathyroid, Adrenals, Pancreas, Testis and Ovary, their hormones and functions.

Sense Organs -

Basic anatomy and physiology of the eye (vision), ear (hearing) taste buds, nose (smell) and skin (superficial receptors).

Health Education -

Brief outline of communicable diseases, Their causative agents, Mode of transmission and Prevention - Chicken pox, Measles, Influenza, Diphtheria, Whooping, cough, Tuberculosis, Poliomyelitis, Hepatitis, Cholera, Typhoid, Food poisoning, Helminthiasis, Malaria, Filariasis, Rabies, Trachoma, Tetanus, Syphilis, Gonorrhoea and AIDS.

Course Contents

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IV-P-5	Anatomy, Physiology & Health Education-II (Practical)	PY 405	L	T	P
			0	0	3

Branch: Pharmacy-IV Semester

Course: PY 405 **Anatomy, Physiology & Health Education-II (Practical)**

IV-P-5 ANATOMY, PHYSIOLOGY & HEALTH EDUCATION-II PRACTICAL

1. Study of different systems with the help of charts and models.
2. Microscopic studies of different tissues of various systems mentioned in their.
3. Simple experiments involved in the analysis of normal and abnormal urine : Collection of specimen, appearance, determination of pH, sugars, proteins, urea, creatinine.

Course Contents

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			L	T	P	
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Branch: Pharmacy-IV Semester

Course: PY 405 Anatomy, Physiology & Health Education-II (Theory)

Digestive System -

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Course Contents

Category of Course	Course Title	Course Code	Credit		
IV-P-5	Anatomy, Physiology & Health Education-II (Practical)	PY 405	L	T	P
			0	0	3

Branch: Pharmacy-IV Semester

Course: PY 405 **Anatomy, Physiology & Health Education-II (Practical)**

IV-P-5 ANATOMY, PHYSIOLOGY & HEALTH EDUCATION-II PRACTICAL

4. Study of different systems with the help of charts and models.
5. Microscopic studies of different tissues of various systems mentioned in their.
6. Simple experiments involved in the analysis of normal and abnormal urine : Collection of specimen, appearance, determination of pH, sugars, proteins, urea, creatinine.