DEPARTMENT OF CHEMICAL TECHNOLOGY
NORTH MAHARASHTRA UNIVERSITY, JALGAON
SYLLABUS FOR M. TECH. (PHARMACEUTICAL TECHNOLOGY)

First Semester

Sub. No.	Paper	Teaching Scheme Hrs/ Week	Examination Scheme Marks		Total	Credit
			Internal	External		
PH-1.1	Formulation Technology	03	40	60	100	3
PH-1.2	Modern Methods of Instrumental Analysis	03	40	60	100	3
PH-1.3	Modern Methods of Instrumental Analysis (PR)	06	40	60	100	3
PH-1.4	Pharmaceutical Biotechnology	03	40	60	100	3
PH-1.5	Advanced Pharmaceutical Chemistry	03	40	60	100	3
PH-1.6	Drug Regulation & IPR	03	40	60	100	3
PH-1.7	Research Methodology	03	40	60	100	3
				Grand Total	**500**	**15**

Note:- PH-1.1, PH-1.2, PH-1.3 are compulsory. Select any two papers out of PH-1.4, PH-1.5, PH-1.6 and PH- 1.7

Second Semester

Sub. No.	Paper	Teaching Scheme Hrs/ Week	Examination Scheme Marks		Total	Credit
			Internal	External		
PH: 2.1	Bio-pharmaceutics & Pharmacokinetics	03	40	60	100	3
PH: 2.2	Medicinal Chemistry & Drug Discovery	03	40	60	100	3
PH: 2.3	Quality Assurance & Validation	03	40	60	100	3
PH: 2.4	Herbal Drug Technology	03	40	60	100	3
PH: 2.5	Science & Technology of nano-medicines	03	40	60	100	3
PH-2.6	Pollution Control in Chemical Industries	03	40	60	100	3
PH-2.7	Bio-Polymers	03	40	60	100	3
				Grand Total	**500**	**15**

Note:- PH-2.1, PH-2.2, PH-2.3 are compulsory. Select any two papers out of PH-2.4, PH-2.5, PH-2.6 and PH- 2.7

Third Semester

Sub. No.	Paper	Teaching Scheme Hrs/week	Examination Scheme		Total Marks	Credit
			Internal	External		
PH:3.1	Seminar	10	100		100	5
PH:3.2	Project	20	80	120	200	10
				Grand Total	**300**	**15**

Fourth Semester

Sub. No.	Paper	Teaching Scheme Hrs/week	Examination Scheme		Total Marks	Credit
			Internal	External		
PH: 4.1	Project	30	120	180	300	**15**
				Grand Total	**300**	**15**

FIRST SEMESTER

PH-1.1 Formulation Technology

Product development and testing of liquid orals

- Solutions, suspensions, emulsions-micro emulsions
- Selection of additives
- Manufacturing
- Evaluation
- Stability considerations
- Drug excipients interaction and incompatibilities

Solid dosage forms with reference to high speed continuous operations

- Tablets: Design and formulation, desirable properties of raw materials, types of tablets, manufacturing and evaluation, recent developments in tabletting
- Capsules, soft gelatin capsules, excipients, manufacturing, evaluation
- Coating sugar, film air suspension coating, equipment, procedure and evaluation

Product development and testing of sterile dosage forms with reference to high speed and continuous operations

- Parenterals: SVP, LVP
  - Methods of preparation and production facilities
  - Evaluation
  - Stability
  - Packaging
- Ophthalmics
  - Ocular toxicity and irritation
  - Preservatives
  - Method of preparation
  - Delivery to anterior and posterior segments

Cutaneous and topical drug delivery with reference to high speed and continuous operations

- Precutaneous absorption
- Factors affecting drug absorption from skin
- Topical applied products and their formulation
- Evaluation and stability

Aerosole technology

- Propellents
- Containers
- Formulation
- Evaluation
- Stability
- MDI

Cosmetic preparations: Formulation, stability, safety and performance of the following products such as

- Skin care: Moisturizers, cleansing products, sunscreens
- Hair care: Shampoos, hair dyes

Teransdermal drug delivery system: Concept, principle involved, permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches and evaluation of TDDS

Mucoadhesive drug delivery system: Buccal drug delivery system, transmucosal permeability, models of mucosal membrane, in vivo and in vitro methods of buccal absorptions, nasal and pulmonary drug delivery system and its applications.
Ocular drug delivery system: formulation and evaluation of ocular drug delivery of drugs, pilocarpine delivery system, ophthalmic inserts.

Protein –peptide drug delivery : Preformulation, characterization of drug molecule, stability aspects, protein degradation pathways, general protein formulation strategies, routes of delivery

R&D : pilot scale to plant scale, pilot plant scale up studies, significance along with dosage forms like liquid orals, solid dosage forms and sterile dosage forms with equipments and SOPs, technology transfer from one plant to other, ICH, SUPAC

Preparation of flow diagram, material balance sheet, technical data sheet, material and inventory control, master formula generation and maintenance, SOPs for different dosage forms and activities

Industrial hazards; pollution and effluent treatment, hazard analysis and critical control process (HACCP), prevention measures in pharma industries.

PH-1.2 Modern Methods of Instrumental Analysis

Detail study of following sophisticated instruments with reference to construction, operation principle, applications and merits and demerits:

Gas Liquid Chromatography
High Performance Liquid Chromatography
Infra Red & FTIR Spectroscopy
NMR Spectroscopy
UV Visible Spectroscopy
Mass Spectroscopy
Differential Scanning Calorimeter
Thermo gravimetric Analysis
Scanning Electron Microscope
Transform Electron Microscope & Atomic Force Microscopy
XRD – crystalline phase analysis
Surface area determination by BET- method, Particle size by light scattering method, Zeta potential

PH-1.3 Modern Methods of Instrumental Analysis

PRACTICALS:

Minimum 8 experiments based on Instruments Studied in "**Modern Methods of Instrumental Analysis**".

PH-1.4 Pharmaceutical Biotechnology

Introduction to genetic organization in prokaryotes, protein biosynthesis and its regulation, gene transcription, RNA splicing
Protein immobilization; different methods like adsorption, entrapment, microencapsulation and bioreactors used in protein immobilization.
Introduction to R-DNA technology and their application in synthesis of insulin, growth harmon and interferon.
Transgenic plants definition need, production, analysis and application
Genetic mechanism of drug resistance with reference to antibiotics
Introduction and application of diagnostic proteins
Introduction to fermentation technology different techniques used in detail and applications of downstream processing in production of pencillin-G

PH- 1.5 Advanced Pharmaceutical Chemistry

Enzyme and enzyme inhibitors
- Enzyme structure- primary, secondary, tertiary and quaternary
- Enzyme kinetics
- Enzyme inhibitors
  - Reversible enzyme inhibitors
  - Irreversible enzyme inhibitors
  - Kcat inhibitors (Mechanism based)
  - Transition state analog
- Enzyme inhibitors as drug
  - ACE inhibitors
  - Cytochrome P450 inhibitors
  - HIV-reverse transcriptase, protease and integrase inhibitors
  - Luekotrienes and lipoxyhgenase inhibitors
  - Aromatase inhibitors

Molecular modeling and drug design
- Molecular mechanics – force field (potential energy function0
- Energy minimization methods- steepest descent, conjugate gradient and Newton response method
- Confirmational analysis
  - Systemic search
  - Montecards stimulation
  - Molecular dynamics simulation
- Structure based and ligand based drug design approaches
- 3D- pharmacophore modeling
- Drug docking and new chemical entity by use of suitable computer hardwar and software

Combinatorial chemistry
- Introduction
- Combinatorial approach to chemical diversity
- Combinatorial organic synthesis

QSAR

Parameters, Lipophilicity, partition coefficient, electronic and steric, polarizability
Quantitative models : Hansch analysis, free- Wilson analysis, mixed approach
Other QSAR approach: 3D-QSAR, CoMFA, CoMSIA, GFA
Application of Hansch analysis, free Wilson analysis

Introduction to high throughput screening, genomics and proteomics in drug design

Synthon approach in drug synthesis
Defination of terms- disconnection, synthon, functional group interconversion (FGI), functional group conversion (FGC)
Basic rules in disconnection
By using synthon approach/retrosynthesis for the synthesized following compound; sulfisoxazole, ibuprofen, atenolol, haloperidol, indinavir, losatan, ranitidine, proxicam, glipizide, ciprofloxacin, captopril, diltiazem, nefazodone, linezolid and paclitaxel etc.

PH-1.6 Drug Regulation & IPR

History and need of drug regulation
Scientific and legal aspects of dug regulation
Legal aspects of drug regulation (India, Europe & USA)
Drug development cycle (includes IND, NDA and generic development cycles)
Contents of drug dossier
Drug registration norms worldwide
GMP compliance
Manufacturing plant need and requirements (includes manufacturing plants of all dosage forms; solid oral to parenterals and depot delivery system)
Validation requirements

Equipment validation (includes IQ, OQ, PQ…)
Process validation

GLP and GCP compliance
Concept and need for In vivo studies (includes bioavailability and bioequivalence and clinical trial norms)
Introduction to ICH guidance- quality, safety and efficacy guidance
Introduction to intellectual property and its relation with regulations
Introduction to patent to patent system in India and worldwide (Paris convention and TRIPS agreement)

PH- 1.7 Research Methodology

Research: Meaning, Objective of research, types of research
Selecting a problem and preparing research proposal for different types of research
Literature survey:
Use of library, books and journals, use of internet (different useful sites) patent search
Methods and tools in research:
Qualitative and quantitative studies enquiry forms, questionary, opionnarie
Data analysis:
Parametric and non parametric data
Hypothesis testing

Descriptive and inferential analysis
Statistical analysis of data including standard deviation, student t test, f test, ANOVA
Multiple regression and correlation coefficient
Documentation:
Research paper/ Thesis writing:
Different parts of the research paper
Presentation
Oral, poster
Sources of procurement of research grants
Industrial Institution Interaction

SECOND SEMESTER

PH-2.1 Biopharmaceutics and Pharmacokinetics

Absorption
Cell membrane, absorption mechanism, transcellular, diffusion paracellular transport, carrier mediated transport, ion pair transport, endocytosis
Factors affecting drug absorption

Physiological factors: Unstirred water layer, gastric emptying, presystemic metabolism, afflux system

Physiochemical factors: Drug lipophilicity, PKa, dissolution of drug, drug stability, complexation, absorption.

Formulation factors

Cell culture and other biopharmaceutical evaluation techniques
Drug absorption through other routes such as transdermal, nasal buccal ocular and sublingual
Drug distribution and metabolism:
Physiological barrier to the drug distribution: Capillary endothelial barrier, cell membrane barrier, barrier of the distribution of the drug to the brain, placental barrier, blood testis barrier
Factors affecting drug metabolism: Physiological properties, tissue size and perfusion and drug protein binding
Characterization of drug metabolism: General pathway of drug metabolism i.e. phase-I and phase-II reactions, enzymes in drug metabolism
Factors affecting drug metabolism: physiochemical properties, size induction and inhibition of biological factors
Excretion of drug:
Useful concept in the study of excretion metabolism, mechanism of renal drug excretion, factors affecting renal drug excretion, non-renal route of drug excretion, dose adjustment in renal failure, mode of testing drug excretion
Introduction to Pharmacokinetics
Pharmacokinetics model and multi compartmental perfusion model, non-compartmental model, statistical movement theory, area under curve
Method of Laplace transformation: 1 compartmental model, detailed deviation from laplace transform to obtain to obtain pharmacokinetics parameters for I. V. injections or infusion
First order absorption including methods of residual and sigma minus methods for pharmaceutical and urinary data
Introduction to multi-compartmental model and non-linear pharmacokinetics
Bioavailability and bioequivalence

Definitions', factors affecting bioavailability, significance of bioavailability, measurement of bioavailability, extent of bioavailability and rate of bioavailability, % absorbed v/s time plots, Wagler-nelson method, loop regime method, deconvolution method
Bioavailability- bioequivalence studies: testing methods, study design, significance, regulatory considerations, statistical treatment and determination, invitro –in vivo correlation.

PH- 2.2 Medicinal Chemistry and Drug Discovery

Mechanism, Stereochemistry and application of:
Rearrangement: Pinacol and related, rearrangements involving migration to electron deficient nitrogen
Oxidation: Oppennaur
Reductions: Birch, Clemmensons, MPV, Wolf-Kishner using metallic hydrides
Commercial synthesis of
Chloroquine, thambutaol, ibuprofen, diazepam, mebendazole, Vit. B6, dapsone
Receptors in drug discovery and development:
Receptor concept, theories, nomenclature and types
Technology involved in pharmaceutical manufacturing (unit processes in synthesis):
Acylation, esterification, alkylationamination, halogenations, esterification, amination, hydrolysis, nitration, reduction, oxidation
Production: detailed manufacturing aspects, processes and operations involved in asprin, benzocaine, chlramphenicol, adrenaline

PH- 2.3 Quality Assurance & Validation

Basic concept & principles of quality management
-Total quality management
-Quality assurance
-Quality control
-Quality audit
Good manufacturing practices in pharmaceutical industry
Documentation related to NDA application, ANDA application
-SOP document
Introduction to quality system
-ISO, WHO, USFDA, ICH
Technology transfer from R & D to manufacture
Concept of Statistical quality control
Introduction to drug master file & contents
Validation
- Defination, types
Process validation:
Types, approaches, organization, scope, validation, protocol and report
Validation of process like mixing, granulation, drying, compressing, filling
Analytical method validation
Validation of electronic data

PH-2.4 Herbal Drug Technology

General methods of extraction, isolation and purification of phytoconstituents
Isolation, identification tests and estimation methods for the following phytoconstituents with special emphasis on HPLC, HPTLC and other advancd techniques
Aloin from Aloes
Vasicine from Adhatoda vasica
Andrographolides from andrographis paniculata
Curcumin from Curcuma longa
Piperine from Piper longum
Phytochemical study
Defination, occurance, chemistry, isolation, estimation and biogenesis of alkaloids, glycosides, plant phenols, resins, terpenes and terpenoids, phospholipids and steroids
Marine natural products
Introduction, chemistry and biology of marine natural products
Marine toxins, marine biomedicinals falling under the class of cardiovascular, anticancer, antimicrobial, anti-inflammatory and antibiotic drugs
Screening procedures for herbal drugs with current innovations in following therapeutic classes
Antihypertensive
Antioxidant
Antipyretic & anti-inflamatory
Antidiabetic
Anticancer
Antihepatotoxic
Immunomodulatory
Herbal product development
Lipid orals, tablets, capsules, dermatologic and herbal cosmetics
Methods involved in monoherbal and polyherbal formulations with their merits and demerits
Excipients used in herbal formulations
Compatibilities studies
Biavailability & pharmaceutical equivalence
Quality control of finished herbal medicinal products

PH-2.5 Science & Technology of Nano Medicines

Present status of pharmaceuticals and fine chemicals, Concept of nanomedicines, physical properties of molecules and super molecular complexes within cell.
Molecular machinery and manufacturing with due stress on programmable medical micro machines, tiny supercomputers through molecular computing, concept of nanorobots/ molecular robotics smaller than a cell and their role in elimination of cancer, infections, clogged articles etc., retardation of aging phenomenon.
Role of nanotechnology in biotechnology, engineered enzymes, coated colloids in cosmetics and pharmaceuticals, encapsulated drugs for sustained release(Concept of Drug delivery), Sunscreen and UV protective cosmetics, Biomedical tagging and bio magnetic separation, Diagnostic content agent, biomedical implants.

PH-2.6 Pollution control in Chemical Industries

Identification, Segregation and Control of solid / liquid/ gases Pollutants from following Chemical Industries:

Petrochemical and Petroleum refinery
Vanaspati Edible oil Refinery and Oleochemical industry
Fermentation Beverage Dairy and Sugar Industries
Plastic Processing Industry
Polymer and Resin Industry
Control of Volatile Organic Emissions in Paint Industry
Pharmaceutical and Fine Chemicals Industry

PH-2.7 Biopolymers

Chemistry And Biochemistry Of Polymer Degradation : Introduction, enzymes – enzyme nomenclature – enzyme specificity – physical factors affecting the activity of enzymes – enzyme mechanism, Chemical degradation initiates biodegradation, Hydrolysis of synthetic biodegradable polymers. **Particulate Starch Based Products** - Development of Technology, Current objectives, relative starch technology, Manufacture of master batch, Conversion technology – processing precautions – moisture and temperature – rheological considerations, cyclic conversion process, physical properties of products – sample preparation – physical testing methods – test results, Quality control testing of degradation – auto oxidation measurement – biodegradation assessment – soil burial test.
Biopolyesters: Introduction, History, biosynthesis, Isolation – solvent extraction - sodium hypo chloride digestion, enzymatic digestion, Properties – crystal structure – nascent morphology, degradation - Intracellular biodegradation - extra cellular biodegradation – thermal degradation – hydrolytic degradation – environmental degradation – effects of recycling, applications, economics, future prospects.
Test Methods & Standards For Biodegradable Plastics Introduction, defining biodegradability, criteria used in the evaluation of biodegradable polymers, tiered systems for evaluating biodegradability, choice of environment, choosing the most appropriate methodology, description of current test methods – screening test for ready biodegradability, tests for inherent biodegradability, tests for simulation studies, other methods for assessing biodegradability – petri dish screen – environmental chamber method – soil burial tests, Test method developments for the future.

TEXTBOOKS

1. G.J.L Griffin Blackie(ed.), Chemistry & Technology of biodegradable polymers Academic & Professional London 1994.

2. Yoshiharu Doi , Kazuhiko Fukuda(ed.) Biodegradable plastics & Polymers Elsevier 1994

EFERENCES

1.Abraham J.Donb & others(ed.) Handbook of Biodegradable polymers
2.Harvard academic publishers Australia 1997.

Third Semester

PH-3.1 Seminar

Presentation on selected topics with due emphasis on latest developments.

PH 3.2 Project

Finalization of particular research problem thorough literature review, preliminary experimental work, Presentation of Project report and viva - voce based on project work.

Semester IV

PH-4.1 Project

The entire semester will be devoted for detail experimental work on a research problem selected in III semester. The student will present his findings in the form of neatly typed and bound thesis within one month after approval of his synopsis. He will have to appear before panel of experts for defending his Thesis.

UNIVERSITY DEPARTMENT OF CHEMICAL TECHNOLOGY
NORTH MAHARASHTRA UNIVERSITY, JALGAON

M.Tech. –Pharmaceutical Technology

Admission

Candidates holding B. Sc. Tech. or B. Tech. (Pharmaceutical & fine Chemicals Technology)/ B. Pharmacy/ M. Sc. (Drug Chemistry) with 55 % marks or any equivalent degree recognized by North Maharashtra University, Jalgaon shall be eligible for admission to M. Tech. (Pharmaceutical Technology). Relaxation for the reservation candidates shall be as per norms. Preference will be given to candidates holding valid gate score.

Notes:-

1. The students of M. Tech. Course will have to attend 75% of lectures, practical and any other term work as may be prescribed by the university. The conduct and behavior of the student must satisfy the Head of the Department.

2. The Head of the Department will certify that the student has attended the course as prescribed and has conducted himself satisfactorily. In absence of such certificate, the student shall not be permitted to the University Examination.

3. The University examinations for all the terms shall be conducted at the end of the term.

4. The student shall have to appear personally to all parts of the examination.