Unit : 1  Preformulation Studies :
A) Goals of Preformulation, Preformulation parameters, methodology; Solid state properties, Solubility and Partition coefficient, stability, drug - excipient compatibility.
B) Dissolution : Theory, Mathematical models, types of dissolution equipments, sink condition and its importance, automation in dissolution and recent advances in dissolution testing. “In-vitro / In-vivo” correlations.

Unit : 2  Excipients used in Pharmaceutical Dosage forms :
A) Polymers : Types of polymers, selection criteria for pharmaceutical formulation.
B) Pharmaceutical Excipients : Selection criteria and properties viz., surfactants, viscosity promoters, plasticizers, preservatives, flavors and colors.

Unit : 3  Formulation Development :
A) Solid dosage forms :
   i) Tablets : Types of tablets; manufacture, production and evaluation of tablets; physics of tablet production; Computerization of In-Process quality control of tablets. Improved Production techniques for tablets: New materials processes, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology.
B) Powder Dosage Forms : Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.
Unit : 4  Liquid and Semi-solid dosage forms :
Recent advances in the formulation of monophasic liquid dosage forms, suspensions, dry syrups and semi-solid dosage forms.

Parenteral dosage forms :
Advances in the materials, filling machines and sterilizer's for parenterals. Manufacture, production techniques for small and large volume parenterals and quality control.

Unit : 5  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 : 6  Pilot Plant and Scale-up Techniques :
significance, pilot study of some important dosage forms such as tablets, capsules and liquid orals. Discussion on important parameters such as formula, equipments, product uniformity and stability, raw material process and physical layouts, personnel requirements and reporting responsibilities.

Unit : 7  Packaging Technology: Packaging materials, closures and containers, unit dose packaging, blister packing, strip packing. FDA regulations, for packaging of tablets, capsules, ointments and aerosols.
I/II M.PHARMACY (1st SEMESTER)
ADVANCED PHARMACEUTICAL TECHNOLOGY (PRACTICALS)

*01 Evaluation of preformulation parameters for the tablet dosage forms.
02 Stability studies for various dosage forms as per the ICH guidelines.
03 Evaluation of drug – excipient interaction by FT – IR, DSC and XRD studies.
04 Studies on equilibrium solubility analysis of few drugs in various solvent media.
05 Effect of magnesium stearate lubricant concentrations on tablet strength and dissolution test.
06 Effect of binder concentrations on the tablet strength of some drugs.
07 Pyrogen testing of injectables by LAL test method.
08 Microbiological testing of water for pharmaceutical use by most probable number method.
*09 Determination of rheological characteristics of sodium CMC at various concentrations using viscometer.
10 Preparation and evaluation of ointments for rheological properties and percentage drug.
*11 Evaluation of salicylic acid drug release rate from various semi solid bases using agar diffusion method.
12 Preliminary microbiological evaluation of air from laminar flow unit by agar plate method.
*13 Determination of partition coefficient of drugs by shake – flask method in various solvent systems.
*14 Determination of pKₐ of some drugs by different methods.
*15 Preparation and evaluation of cyclodextrin complexes of drugs.
REFERENCE BOOKS:

I/II M.PHARMACY (1ST SEMESTER)
ADVANCED PHARMACEUTICAL TECHNOLOGY (THEORY)
MODEL QUESTION PAPER

TIME: 3HOURS                                                                MAX MARKS: 70

ALL QUESTIONS CARRY EQUAL MARKS
ANSWER ANY FIVE QUESTIONS

01. a) Define and mention the objectives preformulation. Exemplify
the reformulation studies for poorly soluble for the formulation
of Parenteral dosage form

b) Describe various methods of drug excipient compatibility in the
preformulation studies.

02. a) Explain the role of polymorphism in the preformulation studies
with relevant examples.

b) What are polymers and classify different types of polymers used
in pharmaceutical formulation with suitable examples

03. a) Explain various types of viscosity modifiers used in the
formulation preparation of suspension.

b) Enumerate the role of flow properties in the formulation of solid
dosage forms and methods of assessment.

04. a) Explain the theories in binding of particles during
compression.

b) Discuss the need for dry syrups with examples and mention the
formulation requirements and evaluation methods.

05. a) What are nano suspensions? Describe the formulation and
evaluation of nano suspensions.

b) Explain about the production facilities of Parenteral unit

06. a) What is the role of pilot plant scale up process in the
production of various dosage forms? Explain schematic
representation of tablet pilot plant scale up process.

b) Describe various methods of aseptic processing of water for
pharmaceutical purpose

07. a) What are salient differences between blister packing and strip
packing

b) Write short notes on
   i) Pharmacopoeial tests for closures.
   ii) Heckel plots significance.
I/II M.PHARMACY (1ST SEMESTER)
MODEL QUESTION PAPER (PRACTICALS)

Time: 6 hrs  Max Marks: 70
1. Synopsis   :  15 Marks
*2. Major Experiment :  25 Marks
3. Minor Experiment :  15 Marks
4. Viva-voce    :  15 Marks

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).
Unit : 1 Production, Planning, Control and Documentation: Production scheduling, forecasting, vendor development capacity assessment (Plant, machines, human resources), production management, production organisation, objectives and policies. Productivity, good manufacturing practices, guide to pharmaceutical manufacturing practices, guide to pharmaceutical manufacturing facilities, tablets and liquid orals, materials management and cost controls.

Unit : 2 Inventory management, Material Management and Maintenance Management: Costs in inventory, inventory categories special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock-stock out, lead time-reorder time methods, modern inventory management systems, inventory evaluation. Materials-quality and quantity, value analysis, purchasing-centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposals of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unit-load, palletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.

Unit : 3 Human Resource Development: Personal training, job specification, job enlargement and enrichment, blue and white-collar jobs. Labor welfare.
Unit 4: Industrial hazards, pollution and effluent treatment:
Introduction, Factory act and rules, fundamentals of accident prevention, organizing for safety, electrical hazards, industrial chemicals and their health hazards, material handling, Fire prevention and control, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants. Effluent treatment procedure, treatment of some characteristic effluent.

Unit 5: ISO 9000 and 1400 Validation:
Sailent features, total quality management and productivity, process products and equipment and instrument validation.

Unit 6A: Quality Control:
Process and Dosage form, Process control, Control of manufacturing process, statistical quality control, control charts of automated process control, Dosage form control, Testing program and methods, product identification system, Adulteration and misbranding, Drug information profile.

B. Unit operations: An advanced study of the Unit operations with special reference to milling, mixing filtration and drying.

Unit 7: Optimisation techniques in Pharmaceutical and Processing:
Optimization parameters, statistical design and other applications, design development and optimization of in-vitro test systems to evaluate and monitor the performance of different types of dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evaluation and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.
REFERENCE BOOKS:
01. Evans, Anderson, Sweeney and Williams Applied production and operations management 3rd edition, West publishing company Ltd., St., Paul.
02. Peter F. Drucker, Management (tast, responsibility and practices) Allied publication, Bangalore.
03. H W Tomski A Text of Pharmacy management Kogan Page Ltd. London.
07. ISO 9000 and 14000 Series.
I/II M.PHARMACY (1ST SEMESTER)
ADVANCED INDUSTRIAL PHARMACY
MODEL QUESTION PAPER

TIME: 3HOURS
MAX MARKS: 70

ALL QUESTIONS CARRY EQUAL MARKS

ANSWER ANY FIVE QUESTIONS

01. a) Explain the role of production planning in bringing out a successful product.
    b) Enlist the manufacturing facilities required for the product of solid dosage form as per Schedule M

02. a) Write about the methods for vendor selection
    b) Explain the methods of purchase and inventory management.

03. Enumerate the optimization techniques in the product development.

04. Write in detail about the possible industrial hazards in pharmaceutical industry and their preventive measures.

05. a) Explain various levels of manager in an organization with suitable examples.
    b) Enumerate various methods of imparting job training and performance appraisal.

06. a) Enumerate various equipments and processing problems in tablet coating.
    b) Explain about pharmaceutical dryers. Mention merits and demerits.

07. Write a short notes on
    a) Total quality management
    b) Industrial safety
    c) Techniques of stores management
MPH 406 (T)

I/II M.PHARMACY (2nd SEMESTER)

PHARMACEUTICAL BIOTECHNOLOGY (THEORY)

UNIT : 1 Enzyme Technology : Sources of enzymes; production; isolation and purification of enzymes, applications of enzymes in pharmaceutical industry, in therapeutics and in clinical analysis. Production of amyloglucosidase, glucose isomerase, amylase, cellulase, takadiastase, trypsin, streptokinase and urokinase.

UNIT : 2 Immobilized enzyme engineering : Different techniques of immobilization of enzymes, kinetics of immobilized enzyme, design and operation of immobilized enzyme reactors, multi step immobilized enzyme systems, applications and future of enzyme engineering.

UNIT : 3 Computer control of fermentation process : Optimization of fermentation parameters.

UNIT : 4 Biosynthesis of microbial metabolites : General consideration of metabolic pathways, biosynthesis of alcohol, citric acid, antibiotics (Penicillin, Streptomycin, Tetracycline & Erythromycin), ergot alkaloids, riboflavin, vitamin $B_{12}$ and Glutamic acid.


UNIT : 6 Bio-Informatics : Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons.

I/II M.PHARMACY (2nd SEMESTER)  
PHARMACEUTICAL BIOTECHNOLOGY (PRACTICALS)

Practicals based on Theory

*01 Screening of soil for antibiotic producing microorganisms
02 Fermentative production of Pharmaceutically important enzymes: amylase
03 Fermentative production of Pharmaceutically important enzymes: cellulase
*04 Fermentative production of Pharmaceutically important enzymes: proteases
05 Effect of pH on the process of fermentation.
06 Effect of temperature on the process of fermentation
07 Effect of substrate concentrations on the process of fermentation
08 Estimation of Pharmaceutically important enzymes: amylase, cellulase and proteases
09 SDS PAGE for enzyme estimation
10 SDS PAGE for isozymes
*11 Immobilization of Pharmaceutically important enzymes
12 Effect of pH and temperature on stability of immobilized enzymes
*13 Isolation of DNA from Microbes and plants
14 Isolation of RNA from Microbes and plants
15 Isolation of plasmids from Microbes
16 Agar gel electrophoresis for Nucleic acids
17 Quantitative determination of individual bases in DNA
18 Isolation of mitochondria by density gradient centrifugation
19 Isolation of chloroplast by density gradient centrifugation
20 Production of Polyclonal Antiserum
*21 Quantitative estimation of polyclonal antiserum by immuno-diffusion assay
REFERENCE BOOKS:

01. Selected topics in enzyme Engineering by Wingard Jr., L.B.edited for items 1 and 2.
02. Immobilized enzymes by Messing for item 2
03. Chapter 1, 2, 7 in Advances in Applied Microbiology Vol. 15, 1972 on enzymes. Immobilized enzymes and Animal and plant cell culture.
05. Molecular Biotechnology by Glick
06. Therapeutic Peptides and Proteins; Formulation, processing and delivery systems; Ajay K Banga
07. Industrial Biotechnology : vedpal S Malik and Padma Sridhar
MPH 406 (T)

I/II M.PHARMACY (2ND SEMESTER)

PHARMACEUTICAL BIOTECHNOLOGY (THEORY)

MODEL QUESTION PAPER

TIME: 3HOURS MAX MARKS: 70

ALL QUESTIONS CARRY EQUAL MARKS

ANSWER ANY FIVE QUESTIONS

01. a) Explain the steps involved in the production of amylase and its application in pharmaceutical industry.
    b) Explain the steps involved in the purification of streptokinase broth medium and mention its applications.

02. a) Explain the methods of immobilization of enzymes by giving emphasis on various types of polymers used for specific enzymes
    b) mention the various applications of enzyme engineering in the field of pharmacy

03. Explain computer control optimization steps involved in upstream processing

04. a) Explain the biosynthetic pathway involved in the production of penicillins and add a note on regulation
    b) write the scheme for the biosynthesis of the ergoline ring system.

05. a) Explain the genetic engineering principles involved in the production of various recombinant interferons
    b) describe various genetic modifications involved in production of insulin

06. a) Write the principle, procedure and advances made for the identification test given below
    i) Malaria   ii) VDRL
    b) discuss the current status of HIV vaccine

07. a) Explain the principle and procedure involved in screening and production of monoclonal antibodies
    b) Write the importance of monoclonal antibodies and permanent immunoclonal

MPH 307 (P)

I/II M.PHARMACY (2ND SEMESTER)

MODEL QUESTION PAPER (PRACTICALS)

Time: 6 hrs Max Marks: 70

1. Synopsis : 15 Marks
2. Major Experiment : 25 Marks
3. Minor Experiment : 15 Marks
4. Viva-voce : 15 Marks

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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MPH 408 (T)

I/II M.PHARMACY (2nd SEMESTER)

ADVANCES IN DRUG DELIVERY SYSTEMS (THEORY)

**Unit : 1** Controlled drug delivery system: Fundamentals, Advantages and disadvantages over conventional dosage forms, Factors affecting design and performance, Polymers used in controlled drug delivery.

**Unit : 2** Design, Fabrication, Evaluation and applications of the following controlled release systems:
1. Controlled release oral drug delivery systems.
2. Parenteral controlled release drug delivery systems
3. Transdermal therapeutic systems and iontophoresis.
4. Ocular delivery systems.
5. Bioadhesive drug delivery systems.
6. Proteins and peptide drug delivery.

**Unit : 3** Design, Fabrication and applications of Organo specific depot systems:
1. Implantable therapeutic systems
2. Intrauterine delivery systems

**Unit : 4** Biochemical and molecular biology approaches to controlled drug delivery:

**Unit : 5** Targeted drug delivery systems: Introduction, Concepts, levels of drug targeting, carrier systems used for targeted drug delivery.

**Unit : 6** Drug targeting to particular organs:
1. Drug delivery to respiratory system.
2. Problems of drugs delivery to the brain and targeting to brain.
3. Drug delivery to eye.
4. Drug targeting in neoplastic diseases.

**Unit : 7** Drug carrier systems targeted to widely dispersed cells:
1. Delivery to Macrophages.
2. Delivery to lymphoid cells of Immune network.
3. Delivery to lysosomal storage diseases.
MPH 409 (P)

I/II M.PHARMACY (2ND SEMESTER)
ADVANCES IN DRUG DELIVERY SYSTEMS (PRACTICALS)

Practicals based on Theory will be conducted.
01. Preparation and evaluation of buccal tablets
02. Preparation and evaluation of matrix tablets
*03. Preparation and evaluation of microspheres
*04. Preparation and evaluation of microcapsules
05. Preparation and evaluation of liposomes
*06. Preparation and evaluation of neosomes
*07. Preparation and evaluation of floating tablets
08. Preparation and evaluation of transdermal patches
09. Preparation and evaluation of mucoadhesive tablets

REFERENCE BOOKS & JOURNALS:
6. Indian Journal of Pharmaceutical Sciences (IPA)
7. Indian Drugs (IDMA)
8. Journal of controlled release (Elsevier Sciences) {desirable}
9. Drug Development and Industrial Pharmacy (Marcel & Decker) {desirable}
I/II M.PHARMACY (2ND SEMESTER)
ADVANCES IN DRUG DELIVERY SYSTEMS (THEORY)
MODEL QUESTION PAPER

TIME: 3HOURS                                                                MAX MARKS: 70

ALL QUESTIONS CARRY EQUAL MARKS
ANSWER ANY FIVE QUESTIONS

01. a) Explain different types of oral controlled release systems. Discuss the diffusion controlled oral drug delivery system.

b) Describe the various types of parenteral controlled release systems.

02. a) Explain the various approaches of transdermal therapeutic systems. Explain different evaluation tests for transdermal systems.

b) Discuss the design & development of ocular controlled drug delivery systems.

03. a) Discuss in detail design and evaluation of protein and peptide drug delivery systems.

b) What are liposomes? Describe various methods used in the preparation of liposomes and mention their applications.

04. a) Write the different methods for the characterization of nanoparticles? Mention their applications.

b) What is blood brain barrier? Discuss various methods developed to target brain.

05. a) Describe the various approaches of drug targeting in neoplastic diseases.

b) Write a notes on
   i) Drug delivery to lymphoid cells.
   ii) Drug delivery to lysosomal storage diseases.

06. a) Explain in detail various factors affecting the design of controlled release systems.

b) What are resealed erythrocytes? Explain various methods of drug loading in erythrocytes.

07. a) Write an account on Targeted drug delivery with special focus on monoclonal antibodies.

b) Discuss various aspects influencing the delivery of drug to lungs. Write a note on metered dose inhalers.
MPH 409 (P)

I/II M.PHARMACY (2ND SEMESTER)
MODEL QUESTION PAPER (PRACTICALS)

Time: 6 hrs                                                                 Max Marks: 70

1. Synopsis : 15 Marks
2. Major Experiment : 25 Marks
3. Minor Experiment : 15 Marks
4. Viva-voce : 15 Marks

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).