MASTER OF PHARMACY IN PHARMACEUTICAL TECHNOLOGY

Description of the Program

The **M. Pharm. in Pharmaceutical Technology** program is designed to provide students with advanced knowledge and technical expertise in the design, development, manufacturing, and evaluation of pharmaceutical dosage forms. The program emphasizes the application of scientific principles and modern technologies to ensure the quality, safety, and efficacy of pharmaceutical products, preparing graduates to contribute effectively to the pharmaceutical industry, research, and regulatory sectors.

This **40-credit program** integrates lectures, seminars, tutorials, laboratory-based practical sessions, research activities, and hands-on training in pharmaceutical formulation and process technology. It balances theoretical foundations with applied and experimental learning to develop strong analytical, problem-solving, and technical skills in pharmaceutical product development and industrial practice.

Students may enroll in either the **general (non-thesis) group** or the **thesis group**, allowing them to align their studies with specific career objectives, whether focused on industrial practice, regulatory affairs, or academic and research-oriented pathways.

Non-Thesis Group

Students enrolled in the **non-thesis (general) track** of the **M. Pharm. in Pharmaceutical Technology** program are required to complete a supervised project. Each student is assigned an academic supervisor who also acts as a personal tutor throughout the duration of the program. Students who are already in professional service are encouraged to align their project work with their current industrial or institutional responsibilities, and the Department may enter into confidentiality agreements where necessary to facilitate such collaborations.

The project must include a minimum of **eight weeks of laboratory- or industry-based work**, excluding the time required for report writing and final submission. The project should demonstrate the student's ability to apply pharmaceutical technology principles to practical problems such as formulation development, process improvement, quality evaluation, or regulatory documentation. Under special circumstances, and with prior approval from the Department, a **critical and systematic scientific review** in a relevant area of pharmaceutical technology may be accepted as an alternative to laboratory-based project work.

Thesis Group

Students enrolled in the **thesis group** of the **M. Pharm. in Pharmaceutical Technology** program are required to undertake extensive, original research in a relevant area of pharmaceutical technology. Under the supervision of an appointed faculty member, thesis students will engage in systematic investigations that may include formulation development, process optimization, novel drug delivery systems, pharmaceutical analysis, quality control, stability studies, or scale-up and validation–related research.

The research must demonstrate scientific rigor, generate new data or insights, and reflect the student's competence in designing, conducting, analyzing, and interpreting experimental research. Upon completion, students are required to prepare and submit a full dissertation in accordance with the Department's prescribed academic and formatting guidelines. The dissertation should include a comprehensive literature review, clearly defined objectives, detailed methodology, results, critical discussion, and evidence-based conclusions. Students must also defend their thesis before a duly constituted examination committee.

At the end of the program, students from both the **thesis** and **general (non-thesis)** tracks will complete **four weeks of industrial or laboratory-based training** in selected pharmaceutical manufacturing, research, or quality assurance facilities, providing practical exposure to real-world pharmaceutical technology practices and professional environments.

Structure of the Curriculum

a. Duration of the Program: 1 year comprising of 2 semesters for the general group and 1.5 years comprising of 3 semesters for the thesis group (1 semester means 6 months).

b. Admission Requirements: Students seeking admission to pursue the course for the degree of M. Pharm. in Pharmaceutical Technology should have passed the B. Pharm. (Hons.) from any recognized university/institute at home and abroad. A proposed candidate for this program must have a cGPA of at least 2.50 for M. Pharm. (General Group) and 3.00 for M. Pharm. (Thesis Group) in the B. Pharm. examination.

c. Total Minimum Credit Requirement to Complete the Program: The students are required to complete all the assigned credits (40) to attain the degree.

Structure of the Curriculum

a. Duration of the Program:

- **General Group:** 1 year (2 semesters)
- **Thesis Group:** 1.5 years (3 semesters)
  (Each semester is equivalent to six months.)

b. Admission Requirements:
Applicants must hold a **B. Pharm. (Hons.)** degree from any other recognized university/institution, nationally or internationally.

- Minimum **cGPA 2.50** for admission to the **M. Pharm. (General Group)**
- Minimum **cGPA 3.00** for admission to the **M. Pharm. (Thesis Group)**

c. Minimum Credit Requirement:
Students must successfully complete **40 credits** to qualify for the degree.

Master of Pharmacy in Pharmaceutical Technology

Non-Thesis Group:

First Semester

Course Code	Course Title	Credit
PHT 601	Advanced Pharmaceutical Technology	3
PHT 601 L	Advanced Pharmaceutical Technology Lab	1
PHT 602	Advanced Pharmaceutical Biotechnology	3
PHT 603	Research Methodology	3
PHT 604	Advanced Pharmacology	3
PHT 605	Advanced Pharmaceutical Chemistry	3
PHT 605 L	Advanced Pharmaceutical Chemistry Lab	1
PHT 606	Project Proposal Submission and Presentation	2
Total		19

Second Semester

Course Code	Course Title	Credit
PHT 607	Advanced Pharmaceutical Manufacturing	3
PHT 607 L	Advanced Pharmaceutical Manufacturing Lab	1
PHT 608	Advanced Biopharmaceutics and Pharmacokinetics	3
PHT 608 L	Advanced Biopharmaceutics and Pharmacokinetics Lab	1
PHT 609	Pharmaceutical Industrial Management	3
PHT 610	Advanced Pharmaceutical Marketing	3
PHT 611	Viva voce	2
PHT 612	Training on Industrial Management	2
PHT 613	Project work submission and Presentation	3
Total		21

Master of Pharmacy in Pharmaceutical Technology

Thesis Group:

First Semester

Course Code	Course Title	Credit
PHT 601	Advanced Pharmaceutical Technology	3
PHT 602	Advanced Pharmaceutical Biotechnology	3
PHT 603	Research Methodology	3
PHT 604	Advanced Pharmacology	3
PHT 605	Advanced Pharmaceutical Chemistry	3
PHT 606	Project Proposal Submission and Presentation	2
Total		17

Second Semester

Course Code	Course Title	Credit
PHT 607	Advanced Pharmaceutical Manufacturing	3
PHT 608	Advanced Biopharmaceutics and Pharmacokinetics	3
PHT 609	Pharmaceutical Industrial Management	3
PHT 610	Advanced Pharmaceutical Marketing	3
PHT 611	Viva voce	2
PHT 612	Training on Industrial Management	2
Total		16

Third Semester

Course Code	Course Title	Credit
	Thesis Work	5
	Viva	2
Total		7

PHT 601: Advanced Pharmaceutical Technology

1. **Advanced drug delivery system:**
   Oral modified release DDS, Mucosal DDS, Transdermal DDS, Pulmonary DDS, Gastro-retentive DDS, Protein & peptide drug delivery system, IUD.

2. **ICH guidelines:** Q 1- Q12

3. **Sample preparation techniques for analytical process:**

   Techniques for preparing samples for chemical, physical and microbiological analysis

4. **CTD or e-CTD, product registration process of ANDA:**

   Overview of CTD/e-CTD format, including quality, non-clinical, clinical and administrative modules, preparation and submission of ANDA, regulatory requirements for generic drug approval, dossier guidelines, data integrity and compliance with local and international authorities.

5. **Pharmacovigilance or complain of ANDA:**

   Principles of pharmacovigilance, ADR monitoring, signal detection, reporting, regulatory requirements for ANDA drugs, complaint handling, root cause analysis, risk management

6. **Product design, formulation and manufacturing by applying QbD (A Brief Study):**

   Introduction to Quality by Design (QbD) concepts in pharmaceutical development, defining quality target product profile (QTPP), identification of critical quality attributes (CQA) and critical process parameters (CPP), design space development, formulation and process optimization strategies, use of risk assessment tools and case studies illustrating successful implementation of QbD in product development.

7. **Pharmaceutical process validation:**

   Principles and stages of process validation including process design, qualification and continued verification, validation of solid, liquid, and sterile dosage forms, equipment (IQ/OQ/PQ) and cleaning validation, analytical method validation and documentation.

8. **Optimization techniques in pharmaceutical formulation and processing:**

   Application of optimization techniques in pharmaceutical formulation, Optimization parameters, Statistical design.

9. **Pharmaceutical facility design:**
   Master plan, Pilot plant scale up technique, Layout of solid, liquid, injectable and aerosol manufacturing, API manufacturing facilities.

10. **Materials of pharmaceutical plant construction:**

    Selection and use of materials for pharmaceutical plant construction including walls, floors, ceilings, doors and windows, corrosion-resistant materials for GMP compliance, HVAC-compatible materials, cleanroom finishes, piping and utility materials, storage and

handling surfaces, safety and contamination control and considerations for durability, maintenance and cost-effectiveness in facility design.

***References*:**

1. Lachmann and Libermann, Theory and Practice of Industrial Pharmacy, Third edition, Varghese Publishing House.
2. Banker and Rhodes, Modern Pharmaceutics, 4th edition, Marcel Dekker, New York, USA, 2002.
3. Remington's Pharmaceutical Sciences. Vol.I-II, 21st Edition.
4. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th edition, Lippincott Williams and Wilkins, 2006.
5. Rawlins, Bentley's Textbook of Pharmaceutics, ELBS and BailliereTindall.
6. Sidney H. Willig, Good Manufacturing Practices for Pharmaceuticals: A plan for total quality control, Second Edition.
7. Fra. R. Berry and Robert A. Nash, Pharmaceutical Process Validation, Vol-57, Second Edition. Revised and Expanded.
8. Ansel, Pharmaceutical Dosage Forms and Drug Delivery Systems.
9. ICH official guidelines.
10. Barker and Andrew, Quality by Experimental Design, 4th edition.
11. Walkiria and Gibson, Pharmaceutical Quality by design: A Practical approach, WILEY.
12. Feroz, Susan, Mansoor, Sheryl; Quality by design for Biopharmaceutical Drug Product Development, Springer.

PHT 602: Advanced Pharmaceutical Biotechnology

1. **Introduction to Biotechnology:**
   Biotechnology, Pharmaceutical Biotechnology, Recombinant DNA Technology,
   Monoclonal Antibody Technology, PCR, Peptide Technology, Basic Immunology.

2. **Immobilization of enzymes:**
   Surface immobilization by covalent coupling, Adsorption, complexation and chelation. Within support immobilization and cell immobilization, Industrial application.

3. **Fermentation technology:**
   Fermentation process and optimization, Improvement of microbial strains. Structure and types of fermenter. Fermented pharmaceutical products (antibiotics and vitamins).

4. **Biotechnology products, Biopharmaceuticals and molecular tools:**

(i) Conventional vaccines, DNA vaccine, Genteically engineered Vaccine, Peptide vaccine, Biosimilars, Regulations for Biosimilars, Biosensors- Working and applications of biosensors, biomarkers, ELISA, Western Blot.

(ii) Formulation of biopharmaceuticals, Storage and maintenance, Handling and transportation requirements, Preparation and administration reimbursement, Stability issues.

5. **Ethics and patenting in biotechnology:**

(i) Ehtics: ELSI of biotechnology, recombinant therapeutic products for human health care, genetic modifications and food consumption, release of genetically engineered organisms, human embryonic stem cell research.

(ii) Patenting: Intellectual property rights (IPR), patent, types of patent applications, patent types: Conventional, divisional and patent of addition, specifications: provisional and complete forms and filing procedures, Plant breeders rights, biotechnology in developing countries, Biosafety and its implementation

References:

1. Daan J. A. Crommelin and Robert D. Sindelar, Pharmaceutical Biotechnology, An introduction to Pharmacist and Pharmaceutical Scientists, Edited by Hardwood, Academic Publishers, Singapore.
2. S P Vyas and V K Dixit, Pharmaceutical Biotechnology, CBS Publisher New Delhi, India.
3. Biopharmaceuticals Drug Design and Development. Eds. Wu Pong Sussanna, 2nd edition, 2008, Human press book.
4. Biopharmaceuticals: Biochemistry and Biotechnology, 2nd edition Gary Walls, Wiley publications.
5. Introduction to Food Science, Rick Parker, Thomson Learning Inc, USA.
6. Food Additives, Second Edition, A. Larry Branen, P. Michael Davidson, Marcel Dekker Inc.,USA.
7. Encyclopedia of Food Science and Technology-by Francis, The Computype Media, India.

PHT 603: Research Methodology

1. **Research concept methodology:**

The basic concepts of conducting research; about the working methods to execute the research.

2. **Design of research:**
Study and review literature; develop any hypothesis regarding the research; how to conduct a research.

3. **Application of instrument in applied research:** The instrumentation; characteristics.

4. **Research trends in different pharmaceutical areas:**
Natural product development, Product development, Purification technology, Analytical method development, Waste management, Reverse engineering technology, Life style products, Bioequivalence study, Veterinary sectors, Food and cosmetics, Biotech products.

5. **Documentation:**
Comprehend about the process, importance; the techniques of documentation for conducting a research work.

6. **Data collection, preparation, analysis & report writing/ Manuscript preparation:** Ways and importance of data collection, analysis; manuscripts preparation.

7. **Ethical guidelines in clinical research:**
The rules; regulations of conduction a clinical research work.

8. **Current trends in investment in research:**
Current trends of investments on research work in pharmaceutical arena by the Government, Pharmaceutical Industries; other research institution/organization.

9. **Cost analysis of the project – cost incurred on raw materials:**
How to manage the invested resources and obtain maximum output at minimum cost.

10. **Sources for procurement research grants:**
Find and get the research fund on relevant fields.

***References*:**

1. Dawson, Catherine, 2002, *Practical Research Methods*, New Delhi, UBS Publishers' Distributors.
2. Kothari, C.R., 1985, *Research Methodology- Methods and Techniques*, New Delhi, Wiley Eastern Limited.
3. Kumar, Ranjit, 2005, *Research Methodology- A Step-by-Step Guide for Beginners*, (2nd ed.), Singapore, Pearson Education.
4. Y.K. Sign, 2006, *Fundamental of Research Methodology and Statistics*, New Age International (P) Ltd.
5. C. Dewberry, 2004, *Statistical Methods for Organizational Research*, Routledge Taylor & Francis Group.
6. Research In Education- John V. Best, John V. Kahn 10th edition. Thesis projects in Science & Engineering - Richard M. Davis.
7. Presentation skills - Michael Hallon- Indian Society for Institute education.

8. Thesis & Assignment - Jonathan Anderson.
9. Writing a technical paper- Donald Menzel.
10. Protection of industrial Property rights- P. Das & Gokul Das.

PHT 604: Advanced Pharmacology

1. **Receptor Pharmacology:** Molecular and cellular mechanisms, pharmacological responses or pathogenic role by their (receptors) activation and clinical importances of a) serotonin receptor b) glutamate receptors c) GABA and its receptors d) catecholamine receptors (α- and β-adrenoceptors, dopamine receptors) e) acetylcholine receptors (nicotinic andmuscarinic receptors) f) opioid receptors

2. **Pharmacology of Ion Channels and Enzymes:** a) Plasma membrane structure, active transport and passive diffusion of ions and molecules, diversity of ion channels b) Ligand gated ion channels: internal & external ligand, structure & function: Nicotinic acetylcholine receptor, GABA receptor, Benzodiazepam receptor c) Voltage gated ion channels: types of voltage gated ion channel, structure and function, gatting mechanism of Na+ channel, Ca+2 channel, K+ channel, Cl- channel d) Na+/K+ ATPase & Gap Junction: properties, structure and functionb & mechanism. Diseases related with malfunction of different types of channels.

3. Cardiovascular Pharmacology:

a)Molecular and pathological basis of cardiovascular diseases: Atherosclerosis, angina, myocardial infarction, myocarditis, dilated cardiomyopathy, congestive heart failure, cerebrovascular disease etc.

b)Lipid lowering agents: Biosynthesis and metabolism of cholesterol; type of lipoproteins and their characteristics, lipoprotein transport in blood, genetic classification of hyperlipidemia; anti-hyperlipidemic drugs, (i) Statins or 3hydroxy-3-methylglutaryl- coenzyme A (HMG-CoA) reductase inhibitors: atorvastatin, simvastatin, rosuvastatin etc. (ii) Fibrates: fenofibrate, ciprofibrate, gemfibrozil etc. (iii) Bile acid sequestrants: colesevelam, colestipol, cholestyramine etc. (iv) Inhibitors of cholesterol absorption: ezitimibe (v) Niacin or nicotinic acid and its derivatives, (vi) fish oil derivatives.

c)Drugs affecting blood disorder: Hemostasis and thrombosis, blood coagulation, coagulation cascade, drugs act on coagulation cascade (i) Antiplatelet drugs: aspirin, clopidogrel and ticlopidine, abciximab, eptifibatide, dipyridamole, tirofiban (ii) Anticoagulants: heparin, lepirudin, enoxaparin, dalteparin, foundaparinus, warfarin (iii) Thrombolytics: streptokinase, alteplase, reteplase, urokinase (iv) Treatment of bleeding: aminocaproic acid, aprotinin, protamine sulfate, tranexamic acid, vitamin K (v) Treatment of anemia: cyanocobalamine, erythropoetin, folic acid, iron and hydroxyurea.

4. Neuropharmacology:

a) Functional areas of the brain; neurotransmission of the CNS; causes of neurodegenerative disorders: inflammation and oxidative stress, aging of the brain, protein misfolding, excitotoxicity, genetic abnormalities b) Alzheimer's disease: Clinical features, pathogenesis, drugs used in the Alzheimer's disease (i) Acetylcholinesterase inhibitors (Tacrine, donepezil, galantamine, rivastigmine), (ii) NMDA receptor antagonists (Memantine) c) Parkinson's disease: Clinical features, etiology (genetic, pathogenic, environment), role of substantia nigra in Parkinson's disease, drugs used in Parkinson's

disease (i) Levodopa and carbidopa, (ii) Catechol-O-methyl transferase (tolcapone, entacapone), (iii) Dopamine-receptor agonists (bromocriptine, ropirinole, pramipexole, rotigotine) (iv) Selegiline and rasagiline (v) Amantidine (vi) Antimuscarinic agents d) Huntington's disease, Amyotrophic lateral sclerosis, Creutfeldt-Jacob disease: sign and symptoms, causes and treatment pattern of these diseases.

5. Cancer Biology and Therapy: Modes of treatment includes-

a)Radiotherapy-Classification, purpose, and basic mechanism of radiation therapy. Details of external, internal and systemic radiation therapy with monoclonal antibody therapy.

Potential side effect, plan and dose of radiation therapy

b)Biological therapy, including gene therapy and immunotherapy-History, techniques, and purpose of gene therapy. Basic mechanism of gene therapy, vectors and its importance to transfer gene, types of gene therapy. Details of ex vivo and in vivo gene transfer. Immunomodulating, including immunostimulating, cytokines insertion, and protection of stem cell

Surgery-Stages of cancer, goals, techniques and side effects of surgery Stem cell therapy

6. Immunopharmacology:

Pharmacological aspects of clinical conditions involving immunological mechanism including hypersensitivity, autoimmunity, immunodeficiency and immunomodulators; Fc receptors and their modulation for as a therapeutic approach for the treatment of infection, autoimmune disorders and malignant disorders, monoclonal antibody therapy for malignancies; immunotherapeutics including vaccines, plasma-derived immunoglobulins, immunostimulants in cancer therapy; and immunopharmacology of probiotics and prebiotics.

7. Pharmacogenetics and Pharmacogenomics:

a) Introduction of pharmacogenetics (PGt) and pharmacogenomics (PGx): Allele, genotype, phenotype, single nucleotide polymorphism (SNP), copy number variation (CNV), structural variation (SV), genetic polymorphism in drug metabolism, transport and drug targets, global distribution of Cytochrome P450 (CYP), ABCB1 and SLCO1B1 genetic polymorphisms, modulation of PK/PD properties by considerations of genetic variants, adverse drug reactions (ADRs) related to PGx/PGt variations, importance and clinical application of PGx/PGt, challenges in clinical application of PGx/PGt.

b) PGx/PGt considerations and PGx/PGt-based dosing guidelines /recommendations for the following drugs: (i) Cardiovascular drugs (clopidogrel, warfarin, simvastatin), (ii) Anti-cancers (6-MP, irinotecan), (iii) Anti-epileptics (carbamazepine, phenytoin), (iv) Anti-depressants (TCAs, SSRIs), (v) Anti-psychotics (risperidone).

PHT 605: Advanced Pharmaceutical Chemistry

1. **Drug Design:** Synthesis of compounds in accordance with the molecular structure, biological activity concept with special references to analgesics, neuromuscular blocking agents, anti-fertility drugs and compounds containing bridge head nitrogen atom and bactericidal & bacteriostatic agents (sulphonamides, mercury compounds and antiseptics)

2. **Design and Application of Prodrugs:** Prodrug concept, choice and function of pro-moiety, bioreversible derivatives for various functional groups, prodrugs to improve patient acceptability, drug solubility, drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

3. **Molecular Mechanism of Drug Resistance:** Causes for drug resistance, drug resistance with reference to cancer and infectious diseases, strategies to combat drug resistance in antibiotics therapy, genetic principles of drug resistance.

4. **Receptor Theory and Drug-Receptor Interactions:** Macromolecular structures, dose response relationship, drug receptor geometry, general features of receptor site, drug related binding complexes, nature of drug receptor bonds, agonists vs antagonists.

5. **Antioxidants and Free Radicals**: Antioxidants. Natural body antioxidants; Super oxide theory and Oxygen Toxicity, ROS (Reactive Oxygen Species) and LP (Lipid Peroxidation) in human pathology and diseases. Antioxidant defense system; Healing power of H2O2; formation of free radicals, free radical chain reaction, free radicals and useful species, free radicals in ageing process and diseases like arteriosclerosis, ischemic heart diseases and neurodegradative conditions, toxicity of free radicals and prevention of free radical damage by antioxidants.

6. **Metabolite Antagonism**: Historical development, sulfonamides and Fildes theory of antimetabolites, active site-directed irreversible enzyme inhibitors, mechanism-based enzyme inhibitors, antifolates, sulfonamides and sulfones, dihydrofolate reductance inhibitors, synergism of sulfonamides and dihydrofolate reductance inhibitors, amino acid antagonists, vitamin antagonists, pyrimidine and purine antimetabolites.

7. **Rational Design of Enzyme Inhibitors:** Enzyme kinetics and principles of enzyme inhibitors, enzyme inhibitors in medicine, enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors

8. **Chemistry of Synthetic Drugs:** Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents
9. **Peptidomimetics and Nucleic Acids as Drug Targets:** Introduction, design and therapeutic applications of peptidomimetics. Nucleic acids (NA) as targets for drug action, NA-interactive agents, NA alkylation, NA-strand breaking and their importance in drug action.

PHT 607: Advanced Pharmaceutical Manufacturing

1. **Preformulation Studies for Product Development:**
   Advanced preformulation testing methods – Thermal analysis (DSC, DTA, TGA), Chromatography (TLC, HPLC), Microscopy (TEM, SEM), X-ray diffraction (PXRD); applications in studying polymorphism, compatibility and interaction, purity, particle characterization.

2. **Tablet Formulation and Design:**
   Modern approach to tablet formulation design, factors affecting tablet formulation, developing and optimizing tablet formula by QbD approach, validation data of tablet formulation.

3. **Pharmaceutical Granulation Processes:**
   Bonding mechanisms in granules, mechanisms of granule formation, evaluation of granules, granulation machineries and processing variables.

4. **Physics of Tablet Compression:**
   Bonding in tablets, compression cycles, instrumented tablet machines, measurement of compression force, transmission of compression force, energy consideration in tableting process, tablet machine tooling.

5. **Advanced Film Coating Processes:**
   Theories of film coating, evaluation of film coatings, physico-mechanical properties of polymer films, diffusion properties of polymer films, processing conditions for aqueous and organic coating systems, problems associated with film coating process and their remedies.

6. **Concepts and Design of Controlled Release Drug Delivery:**
   Design and development of controlled release drug delivery system: Rate- preprogrammed drug delivery systems, Activation-modulated drug delivery systems; Feedback regulated drug delivery systems, Site-targeting drug delivery systems.

7. **Polymer properties and applications:**
   Polymer chemistry, polymer classification, properties of polymers, polymer synthesis and fabrication, pharmaceutical and medical applications of polymers.

8. **API Development, Manufacturing and Regulation:**
   The bulk drugs process development task, unit operations in API manufacturing, regulatory affairs related to API manufacturing, quality of API.

9. **Pellet Processing Technology:**
   Introduction, mechanism of pellet formation and growth, pelletization process and formulation, machineries for pelletization, evaluation and characterization of pellets.

10. **Industrial handling of solids:**

Blending and blend homogeneity - importance in manufacturing low dose tablets, Powder flowability - factors affecting powder flow, measurement and improvement of powder flowability, Milling - particle size analysis and size reduction methods. Automated Process Control Systems in manufacturing.

References:

1. Lieberman, Lachman and Schwartz, Pharmaceutical Dosage Form: Tablets, Volume 1, 2 and 3, 2nd edition, Marcel Dekker, New York, USA, 1990.
2. Augsburger and Hoag, Pharmaceutical Dosage Form: Tablets, Volume 1, 2 and 3, 3rd edition, Informa Healthcare, New York, 2008.
3. Mark Gibson; Pharmaceutical Preformulation and Formulation, CRC Press, USA, 2004.
4. M. E. Aulton; Pharmaceutics: The Science of Dosage Form Design, various editions, Churchill Livingstone, UK.
5. Banker and Rhodes, Modern Pharmaceutics, 4th edition, Marcel Dekker, New York, USA, 2002.
6. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th edition, Lippincott Williams and Wilkins, 2006.
7. Yie W. Chien, Novel Drug Delivery Systems, 2nd edition, Marcel Dekker, New York, USA, 1992.
8. Isaac Ghebre-Sellassie, Pharmaceutical Pelletization Technology, Marcel Dekker, New York, USA, 1989.
9. Lawrence and Attwood, Physicochemical Principles of Pharmacy, 2nd edition, Macmillan, London, 1988.
10. Walter Lund, The Pharmaceutical Codex – Principles and Practice of Pharmaceutics, 12th edition, The Pharmaceutical Press, London, 1994.
11. J. T. Carstensen, Pharmaceutical Preformulation, CRC Press, 1998.
12. James Swarbrick, Encyclopedia of Pharmaceutical Technology, Third edition, Informa Healthcare, USA, 2007.
13. J. T. Carstensen, Advanced Pharmaceutical Solids, Marcel Dekker, New York, USA, 2001.
14. Gareth A. Lewis, Didier Mathieu, Roger Phan-Tan-Luu. Pharmaceutical Experimental Design.
15. Stanley Nusim. Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation.
16. Y. Oiu, Y. Chen and G. G. Z. Zhang: Developing Solid Oral Dosage Forms Pharmaceutical Theory & Practice, 1st edition, Elsevier Inc. New York, 2009.

PHT 608: Advanced Biopharmaceutics and Pharmacokinetics

1. **Nonlinear Pharmacokinetics:**
   Introduction, Characteristics of drugs that follow enzymatic saturation kinetics and examples, estimation of drug following Michaelis-Menten kinetics, Drug elimination by capacity limited pharmacokinetic process, In-vivo estimation of KM and Vmax, Determination of KM and Vmax in patients and by direct methods, Relationship between the area under the plasma concentration versus time curve and the administered dose or dependence of dose on clearance, chronopharmacokinetics and time dependent pharmacokinetics, circadian rhythms and its influence on drug response.

2. **Biopharmaceutic Considerations in Drug Product Design:**
   Introduction, Rate-Limiting steps in drug absorption, Pharmaceutic factors affecting drug bioavailability, formulation factors affecting drug dissolution, Dissolution and drug release testing, Compendial methods of dissolution, problems of variable control in dissolution testing, In-vitro Invivo Correlation, Failure of Correlation of In-Vitro Dissolution to In-Vivo Absorption, Biopharmaceutic consideration in designing drug products, Clinical examples.

3. **Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products:**
   Introduction, examples of modified-release oral dosage form, Biopharmaceutic factors, advantages and disadvantages of modified release products, kinetics of modified release dosage forms, pharmacokinetic simulation, types of modified release products, considerations in the evaluation of modified release products, evaluation of modified- release products, Introduction of Target Drug Delivery system, Biotechnology of protein drug, monoclonal antibody, antisense drug and gene therapy, Drug carriers and targeting, General Considerations in Targeted Drug Delivery.

4. **Relationship between Pharmacokinetics and Pharmacodynamics:**
   Introduction, relation of dose to pharmacologic response, relationship between dose and duration of activity, effect of elimination of half-life on duration of activity and clinical example, DrugReceptor theory relating pharmacologic effect and dose, Pharmacodynamic models, Maximum effect (Emax) model, pharmacokinetic pharmacodynamic models with an effect compartment, pharmacodynamic models using an effect compartment, Hysteresis of pharmacologic response, Simulation of in-vitro pharmacodynamic effect involving Hysteresis.

5. **Application of Pharmacokinetics to Clinical Situations:**
   Introduction, Individualization of drug dosage regimens, methods for determination of individual patient parameters, therapeutic drug monitoring (TDM), pharmacokinetic evaluation, design of dosage regimens, conversion from intravenous infusion to oral dosing, determination of dose, effect of changing dose and dosage interval on Cαmax and Cαmin and Cαav, determination of frequency of drug administration, determination of route of administration, dosing of drugs in infant, pediatric, obese and elderly patient, examples.

6. **Physiologic Pharmacokinetic Models, Mean Residence Time, and Statistical Moment Theory:**
   Introduction, physiologic pharmacokinetic models, physiologic pharmacokinetic models with binding, Application and limitations of physiologic pharmacokinetic models, statistical moment

theory, introduction to mean residence time, Mean residence time for multi- compartment model with elimination from the central compartment, Mean Absorption Time (MAT) and Mean Dissolution Time (MDT), selection of pharmacokinetic models.

7. **Drug Dosing in Special Populations – Renal and Hepatic Disease, Dialysis, Cardiac Disease, Obesity, Diabetic Patient and Drug Interactions:**

   Introduction, renal disease, estimation of drug dosing and pharmacokinetic parameters using creatinine clearance, Dialysis, drug characteristics that effect dialysis removal , Hemodialysis, methods to measure hemodialysis clearance, Peritoneal dialysis, methods to measure peritoneal dialysis clearance, Hepatic disease, estimation of drug dosing and pharmacokinetic parameters for liver metabolized drugs, implications of hepatic disease on serum drug concentration monitoring and drug effects, drug dosing in heart failure and obese patients, Drug interactions, Plasma protein binding displacement drug interactions, inhibition drug interactions, induction drug interactions.

8. **Pharmacogenetics:**

   Introduction, Examples of polymorphisms, Pharmacogenomics, Adverse Drug Reactions attributed to genetic differences, Genetic polymorphism: Cytochrome 450 isozymes, Genetic polymorphism in drug transport: P-glycoprotein and multidrug resistance, Genetic polymorphism in drug targets, Pharmacokinetics/ pharmacodynamics (PK/PD) considerations and Pharmacogenetics / Pharmacogenomics (PGT/PGX).

9. **Bioavailability, Bioequivalence and Regulatory Requirements:**
   Introduction , Determination of the area under the plasma concentration–time curve and the cumulative amount of drug eliminated in urine, Methods and criteria for bioavailability testing, Characterizing drug absorption from plasma concentration versus time and urinary data following the administration of a drug via different extravascular routes and/or dosage forms, Equivalency terms, Food and Drug Administration codes, Fallacies on bioequivalence, Evidence of generic bioinequivalence or of therapeutic inequivalence for certain formulations approved by the Food and Drug Administration. Guiding principles for human and animal research, Boundaries between practice and research, basic ethical principles, WMA declaration of Helsinki, Generic Biologics (Biosimilar Drug Products), Generic Substitution, Types of transdermal and topical dosage forms, in vivo animal studies, in vitro diffusion, skin stripping, micro dialysis, near IR, human testing, a two-layer diffusive model for describing the variability of transdermal drug permeation, Mathematical models of skin permeability.

***References*:**

1. Leon Shargel, Susanna Pong and Andrew B. C. Yu, Applied Biopharmaceutics & Pharmacokinetics by Fifth Revised Edition, The McGraw-Hill Companies, Inc, USA. 2005.
2. Milo Gibaldi and Donald Perrier, Pharmacokinetics, Second Edition, Revised and Expanded, Published by Informa Healthcare USA, Inc. 2007.
3. Larry A Bauer, Applied Clinical Pharmacokinetics, Second Edition, Published by The McGraw-Hill Companies, USA, Inc. 2008.
4. Sunil S Jambhekar and Philip J Breen, Basic Pharmacokinetics, First Edition, Published by the Pharmaceutical Press, London. 2009.

PHT 609: Pharmaceutical Industrial Management

1. **Total Quality Management (TQM) and Productivity and Six Sigma and Kaizen**
   (a) Costs of quality, the evolution of TQM, features of the TQM philosophy, tools for identifying and solving quality problems, quality certifications.
   (b) Definition, productivity measurement, factors affecting productivity, labor productivity, Single-factor productivity (SFP) and multi-factor productivity (MFP), case studies

2. **Manufacturing site design and requirements:**

   (a) Guidelines for the setup of medium scale plant construction, regulatory requirements related to cGMP practices in pharmaceutical industry

   (b) Documentation: master manufacturing instruction, batch production record, batch packaging record, raw material specification Sheet, analytical control sheet, standard testing procedure, standard operating procedure

   (c) Factors affecting complete plan design: site and plant layout, capacity assessment (machine, plant and human resources), storage, waste disposal, health and safety, materials handling.

3. **Industrial management:**

   (a) Manufacturing Area Management: Environmental issues, dispensing area, granulation area, blending Area, compression area, coating area, liquid manufacturing area, sterile manufacturing area, packing area, finished goods area. (b) Quality Control Area Management: Sample storage, inprocess control, raw material testing, packaging material testing, finished product testing, reagent storage and distribution, chemical handling, potential hazard management. (c) Warehouse Management: Material storage zone, Quarantine Zone, Product Release (sampling and finished), Shipping Package and Distribution. (d) Industrial safety and hazards control: chemical, fire, dust and waste disposal.

4. **Supply chain management:**
   Material requirement planning (MRP), distribution resource planning (DRP), procurement process, specifying supplier requirements, Analyzing supply market, supply strategies, selection of offer, price and cost analysis, various modes of discounts, demand and supply planning, supply chain inventory management, supply chain automation and integration, Internet-enabled supply chains : e-procurement and e-market places, customer relationships management, supply chain performance measures.

5. **Complaince:**

   (a) Concept and importance of compliance in pharmaceutical industry, regulatory compliance (FDA, EMA, WHO, ICH guidelines), GMP and GLP compliance requirements, documentation and data integrity in compliance, compliance auditing and inspections. (b) Handling non-compliance: corrective and preventive actions (CAPA) (c) Ethical and legal aspects of compliance. (d) Case studies of compliance failures and lessons learned.

6. **QMS/EMS:**

   Introduction to QMS and EMS in pharmaceutical industries, Quality Incident Reports (QIR) and deviation handling, Root Cause Analysis (Fishbone diagram, 5 Whys, FMEA), Change Control (CC) process and documentation, internal quality audits and risk-based quality management, ISO 9001,

ISO 14001 and OHSAS 18001 (Occupational Health and Safety Assessment Series 18001) overview, integration of QMS and EMS for sustainable pharmaceutical manufacturing.

7. **Pilot plant scale up tecniques**

Objectives and importance of pilot plant in pharmaceutical R&D, design and layout of a pilot plant facility, scale-up considerations for solid dosage forms (tablets, capsules), scale-up considerations for liquid dosage forms (syrups, suspensions), scale-up considerations for semi-solid dosage forms (ointments, creams, gels), scale-up of sterile/aseptic products, process validation during scale-up, equipment selection and scale-up issues (mixers, granulators, fluid bed dryers, tablet presses), documentation during scale-up including master formula, process validation protocols and technology transfer, case studies of successful and failed scale-ups.

References:

1. Griffins, Management (7th edition)
2. R.M. Mehta, Pharmaceutical Industrial Management.
3. Noe, Hollenback, Gerhart and Wright, Human Resource Management.
4. R. Dan Reid and Nada R. Sanders, Operations Management: An Integrated Approach (3rd edition).
5. E. Roberts Alley, Water Quality Control Handbook.
6. Brian K. Nunnally & Jhon S. McConnell, Six Sigma in the Pharmaceutical Industry.
7. Ray Tricker & Bruce Sherring-Lucas, ISO 9001:2000 in Brief.
8. Quality Assurance of Pharmaceuticals, WHO Guideline.
9. Risk Analysis, ICH Guideline.
10. Colin Scott, Henriette Lundgren, Paul Thompson, Guide to Supply Chain Management.
11. Lawrence D. Fredendall, Ed Hill, Basics of supply chain management.
12. Sanjoy Banerjee, Industrial Hazard & Plant Safety.

PHT 610 : Advanced Pharmaceutical Marketing

1. **Brand Management:**
   Importance of brands, branding in pharma, role of brands in the market, factors affecting branding, personal and global branding, brand equity diamond, umbrella branding, brand name, brand strategies, brand element and extensions, growth strategies, case studies.

2. **Pharmaceutical Economics:**
   Environment of a pharmaceutical industry, patent protection, global market impact WTO- TRIPS, demand supply and price of pharmaceutical products, analysis of (i) cost minimization, (ii) cost utilization, (iii) cost effectiveness and (iv) cost benefit.

3. **Sales Management:**
   Selling as a part of marketing, concepts and theories associated with managing a sales force, Salesmanship, selling skills, process of personal selling, techniques of sales forecasting, formulating selling strategies, territory planning, analyzing market demand and sales potential, Evaluating sales force performance.

4. **International Marketing:**
   Difference between domestic and international marketing, scanning of international environment: social, political, legal, economic and cultural environment for overseas markets, factors affecting international trade, methods of entry, international product planning, product design strategies, methods of pricing, distribution- direct or indirect channel, promotion strategy in overseas market, global advertising regulations.

5. **Market Research and Intelligence in Pharma:**

   Designing and conducting pharmaceutical market research, primary and secondary data sources, sampling techniques and data collection methods, analysis of prescription patterns and physician behavior, competitor analysis and market intelligence tools, case studies of launching new molecules based on market insights.

6. **Regulatory and Ethical Issues in Pharmaceutical Marketing:**

   Drug promotion guidelines from WHO, FDA, EMA, and DGDA (Bangladesh), ethics of marketing to healthcare professionals, direct-to-consumer advertising and comparative advertising regulations, code of pharmaceutical marketing practices, transparency and conflict of interest in pharma marketing, case studies on unethical promotion and enforcement action**s.**

References:

1. D.W. Cravens and N.F. Piercy. Strategic Marketing.
2. M Corstjens. Marketing Strategy in the Pharmaceutical Industry.
3. Philip Kotler. Marketing Management.
4. Griffin. Management.
5. H. Sherman, A.J. Rowley and B R. Armandi. Strategic Management: An Organization Change Approach.
6. Nickels, McHugh and McHugh. Understanding Business.

7. M McGee. Economics: In terms of The Good, The Bad and The Economist.
8. Roger A. Arnold. Micro Economics, 10th edition.
9. Code of Marketing Practices, DDA, Ministry of Health and Family Welfare, Bangladesh.
10. Price Fixation Policy. As adopted by the Price Fixation Committee on 28-5-1992.
11. National Drug Policy 1982 and then 2004, Compiled by The Directorate of Drug Administration; Government of Bangladesh, Ministry of Health and Family Welfare.
12. R.M. Mehta. Pharmaceutical Industrial Management.