# UNIVERSITY OF DHAKA

## Syllabus of the
## Department of Pharmaceutical Technology
*for*
## Master of Philosophy (M. Phil.)
## and
## Doctor of Philosophy (Ph. D.) Programs

*For the*

**Sessions: 2014-2015 and Onwards**

**Department of Pharmaceutical Technology**
**Faculty of Pharmacy**
**University of Dhaka**

# Syllabus and Guidelines for Doctor of Philosophy (Ph. D.) in Pharmaceutical Technology Program Effective from 2014 and onwards

## ● Preamble

The Doctor of Philosophy (Ph.D.) in Pharmaceutical Technology is a specialized research oriented academic program offered by the Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Dhaka, leading to various fields of specialization in the field of Pharmaceutical Technology. The program has been designed to prepare highly educated and skilled professionals for careers in Pharmacy teaching and industry. The vast number of Pharmacy educational institutions commissioned in our country during the recent years faces a crucial demand of highly educated and expert teachers in the discipline of Pharmaceutical Technology. Moreover, the changing scenario of the pharmaceutical industries has opened new and competent career opportunities in product development, hi-tech production, regulatory affairs, international marketing, drug administration and similar areas. Realizing the present academic and industry requirements for generating skilled manpower, the Department of Pharmaceutical Technology has reorganized its Ph.D. program to cope with the current demands. Inclusion of dedicated modern laboratory facilities as well as supervision by expert Faculties for conducting the Ph.D. program, will, no doubt, contribute to the expansion of higher studies and research of this country.

## ● Eligibility for Admission

I. Candidates who have obtained B. Pharm. (Hons.) and M. Pharm. from any public university of Bangladesh and secured at least a CGPA of 3.50 (on a scale of 4.00) or a 1st class (previous non-grading system) are directly eligible to apply for admission in the Ph.D. program.

II. Candidates from any private university are not directly eligible for applying in the Ph. D program. However, interested candidates may apply for admission in the Ph. D. program, after successful completion of M. Phil program from this Department. The final decision about the admission of such a candidate will depend on the report of the Academic and Equivalence Committees.

III. Candidates who have obtained B. Pharm. (Hons.) and M. Pharm. from any foreign university and secured a CGPA of at least 3.50 (on a scale of 4.00) can apply for the Ph. D. program. However, the candidate should possess an M. Phil. degree obtained from any recognized university or must get enrolled in the M. Phil. program of the Department. The final selection and admission will depend on the report of the Academic and Equivalence Committee.

IV. Candidates from non-Pharmacy disciplines, such as medicine, public health, nutrition, food science and technology, biochemistry, microbiology, health economics, population sciences, veterinary science or any other relevant subjects may also apply for admission in the Ph. D. program. However, they must first get admitted in the M. Phil. program. The final decision about the admission of such a candidate will depend on the report of the Academic and Equivalence Committee. After successful completion of the program, students from non-Pharmacy disciplines will be awarded a generalized Ph. D. degree and not a professional Ph. D. degree in Pharmaceutical Technology.

V. For enrollment in Ph. D. program candidate must have at least two publications in recognized peer reviewed journals.

## ● Duration of the Program

The duration of the program will be of three academic years. The program may be extended for additional two years for justified reasons as per recommendation of the Academic Committee and rules of the University.

## ● Course Activities

The entire Ph. D. program of the Department is covered by the following activities:

| | | |
|---|---|---|
| (i) | Theoretical courses | Each student will be required to take one compulsory course and one optional course. The optional course will be taken in accordance with the field of research chosen by the student. These courses are to be taken and completed during the first academic year of the program. |
| (ii) | Research work and thesis submission | Each student will conduct a research work under the supervision of a Faculty Member of the Department and submit a dissertation within the stipulated period. One or two co-supervisors may be taken if desired by the Principal Supervisor. |
| (iii) | Seminar presentation | The Ph. D. student will be required to deliver at least two seminar presentations, preferably at the middle and end of each academic year, in order to report the progress of his/her research work. The last seminar will be considered as the final defense of the thesis work. |
| (iv) | Viva voce | The Ph. D. student will also be required to appear in an oral exam conducted by the Ph. D. examination committee after submission of the dissertation. |

## ● Assessment of Activities and Conferring of Award

There will be no grading system for the assessment of the program activates. The student will be required to pass in all the activities and get satisfactory comments in order to be eligible to get the Ph. D. degree. Each theory course will be of 100 marks out of which 50 marks will be considered as pass marks. Thesis, seminar presentation and viva voce will be evaluated as either 'satisfactory and accepted' or 'unsatisfactory and not accepted.'

## ● Regulations regarding Thesis Work

I. A student of the program will be required to conduct a research on a relevant field of Pharmaceutical interest under the supervision of a Faculty member recommended / approved by the Academic Committee.
II. The enrolled student must report to the supervisor on regular basis about the progress of his / her research. Failure to do so will be considered as a disqualification and the Supervisor may report such anomaly to the Chairman for taking disciplinary action.
III. A supervisor may even recommend to the Academic Committee to cancel admission of a student in the Ph.D. program if his / her performance is unsatisfactory for doing research work or for involving in any sort of unlawful or illegal activity.
IV. A thesis student must abide by the rules and regulations of the laboratories including Good Laboratory Practices (GLP) and should strictly follow the instructions of Laboratory Coordinators / Officers.
V. A thesis student must get clearance from all concerned authorities including the Department and pay all dues, if any, after completion of the research work. Publication of the final result may be halted in such cases.

VI. In addition to the abovementioned guidelines, the general rules and regulations endorsed for the Ph. D. / M. Phil. programs of the University shall also be applicable to the students.

VII. Under any circumstance which is not covered by the abovementioned guidelines, the decision made by the Examination Committee, Academic Committee or University Authority, whichever is appropriate to that situation, will be considered as final.

**● Research Areas and Courses Offerings**

| Course Code | Course Title | Type |
|---|---|---|
| PHT 801 | Research Methodology in Pharmaceutical Sciences | Compulsory |
| PHT 802 | Recent Developments in Pharmaceutical Technology | Optional |
| PHT 803 | Product Development and Formulation Technology | Optional |
| PHT 804 | Advanced Research in Biopharmaceutics and Pharmacokinetics | Optional |
| PHT 805 | Advanced Pharmaceutical Marketing | Optional |
| PHT 806 | Recent Trends in Food Technology and Cosmetology | Optional |
| PHT 807 | Advances in Herbal and Traditional Medicine Research and Development | Optional |
| PHT 808 | Drug Discovery and Bioorganic Medicinal Chemistry | Optional |

## DETAIL SYLLABUS OF THE THEORETICAL COURSES

**Course code: PHT 801**
**Course title: Research Methodology in Pharmaceutical Sciences**
**Course type: Compulsory**

1. **Introduction to Research**
   Definitions and characteristics of research; types of research (Qualitative, Quantitative, Exploratory); main components of any research work

2. **Research Methods**
   Required for Choosing a Basic Method of Research

3. **Research Design Formulation**
   Literature Review, Topic Selection (Problem Identification); Analysis and Statement of the Problem (analyzing the problem and formulating the problem statement), Objectives of a Research, Measurement & Scaling, Questionnaire Design

4. **Data Collection, Preparation, Analysis & Reporting**
   Basic Methods of Collecting Data, Sampling Techniques, Fieldwork & Data Preparation, Application of one or more statistical packages (SPSS)

5. **Research Trends in Different Pharmaceutical Areas**
   Product Development, Natural Product Chemistry, Bioorganic Chemistry, Public Health, Rational Use of Drug, Analytical Method Development, Food and Cosmetics

6. **Selected Applications of Marketing Research**
   Identifying Pharmaceutical Market Segments; Pharmaceutical Product Research, Pharmaceutical Market, & Sales Analysis

**Required Texts:**

1. Harper W. Boyd, Ralph Westfall & Stanley F. Stasch; Marketing Research: Text and Cases; 7th edition, published by Richard D Irwin; February 1989
2. Naresh K Malhotra; Marketing Research: An Applied Orientation (6th Edition); Prentice-Hall Inc.

**Course code: PHT 802**
**Course title: Recent Developments in Pharmaceutical Technology**
**Course type: Optional**

1. **21 CFR Part 11**
   Introduction, Regulatory Background, Implementation in Industry, Contents, Selected articles

2. **Controlled Release Dosage Forms**
   Rationale, General Design Principle for Controlled - Release Drug Delivery Systems, Physicochemical and Biological Factors Influencing Design and Performance of Controlled - Release Formulations, Physicochemical Factors, Biological Factors, Controlled - Release Oral Dosage Forms, Design and Fabrication of Controlled – Release Dosage Forms, Technologies for Developing Transdermal Dosage Forms, Ocular Controlled - Release Dosage Forms, Vaginal and Uterine Controlled - Release Dosage Forms, Release of Drugs from Controlled - Release Dosage Forms, Time - Controlled - Release Dosage Forms, Stimuli - Induced Controlled - Release Systems

3. **Microencapsulation Technology**
   Introduction, Microencapsulation techniques and description, Achievment and limitations, Recent advances in Microencapsulation Technology, recent applications of microparticle systems

4. **Liposomes And Drug Delivery**
   Introduction, Liposome Structure and Characteristics, Phospholipids: Structure Stability and Characterization of Lipid Membranes, Physicochemical Properties of Liposomes, Preparation of Liposomes, Functionalization of Liposomes, In Vivo Distribution, Conventional Liposomes, Long - Circulating or PEGylated Liposomes, Other Routes of Administration, Applications of Liposomes in Therapeutics, Anticancer Drug Delivery

5. **Isolators For Pharmaceutical Application**
   Introduction, Technical Guidelines and standards, Applications, Design considerations, Construction, Cleaning and sanitization

6. **Radiopharmaceutical Manufacturing**
   Introduction, Radiopharmacy, Ideal Characteristics, Radioactive Decay, Principles of Radiation Protection, Product Development, Radionuclides, Carrier Molecules/Active Ingredients, Manufacturing Aspects, Design of Manufacturing Sites, Design of Production Processes, Design of Production Equipment, Cleaning and Sanitation, Environmental Control, Sterilization of Radiopharmaceutical, Labeling and Packaging, Production of Radionuclides, Production of Radiopharmaceuticals, Quality Considerations, Documentation, Qualification of Personnel, Quality Control, Validation and Control of Equipment and Procedures, Stability Aspects of Radiopharmaceuticals, Extemporaneous Preparation of Radiopharmaceuticals

7. **Automation in Pharmaceutical Technology**
   Introduction, Computer application, Data and Information Management Systems, Material inventory system, Formulation information system, Stability information systems, Analytical information systems, Document Management and Publishing Systems Quality assurance information system, Expiry Date Prediction, Laboratory Automation, Process Control and Automation, Building Automation

**Required Texts:**

1. Pharmaceutical manufacturing handbook: Production and process, by Shayne Cox GAD, John Wiley & Sons, Inc., USA, 2008
2. Encyclopedia of Pharmaceutical Technology, by James Swarbrick, 3rd edition, Informa Healthcare, USA, 2007
3. Modern Pharmaceutics, by Banker and Rhodes, 4th edition, Marcel Dekker, USA, 2007

**Course code: PHT 803**
**Course title: Product Development and Formulation Technology**
**Course type: Optional**

1. **Preformulation Predictions:**
   Initial Physicochemical Characterization, Initial Solubility, Initial Stability Investigations, Crystallinity, Crystal Morphology, Hygroscopicity, Salt Selection

2. **Biopharmaceutical Support in Candidate Drug Selection**
   Drug Dissolution and Solubility, Luminal Interactions, Absorption/Uptake over the GI Membranes, Models for Studying the Absorption Potential of Drugs, Permeability Coefficients versus Fa, In Vivo Techniques for Studies in Man, Vehicles for Absorption Studies, Functional Use of Absorption Models, In Vitro Dissolution, Bioavailability Studies, In Vitro/In Vivo Correlations, Animal Models, Imaging Studies

3. **Product Design**
   The Importance of Product Design, Product Design Considerations

4. **Product Optimization**
   Product Optimization Purpose and Scope, Excipient and Pack Optimization Considerations, Sources of Information, Expert Systems, Experimental Design, Stability Testing, Developing Specifications, Process Design, Process Optimization and Scale-Up, Validation and Launch

5. **Parenteral Dosage Forms**
   Guiding Principles for Simple Parenteral Solutions, Choice of Excipients, Sterility Considerations, Strategies for Formulating Poorly Soluble Drugs, Strategies for Formulating Unstable Molecules, Strategies for the Formulation of Macromolecules, Liposomal Delivery Systems, Sustained-Release Parenteral Formulations, In Vitro and In Vivo Testing Methods, Packaging of Parenteral Products, Manufacturing of parenteral Products, Administration of Parenteral Products, Parenteral Products and the Regulatory Environment

6. **Inhalation Dosage Forms**
   Lung Deposition, Particle Sizing, Dry Powder Inhalers, Metered Dose Inhalers, Nebulisers, Standards, Future

7. **Oral Solid Dosage Forms**
   Powder Technology, Powder Flow, Mixing, Compaction, Solid Dosage Forms, Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules

8. **Ophthalmic Dosage Forms**
   Ocular Topical Drug Delivery Issues and Challenges, Drug Candidate Selection, Product Design Considerations, Product Optimisation Considerations, Processing Considerations

9. **Aqueous Nasal Dosage Forms**
   Nasal Anatomy and Physiology, Formulation Selection Considerations, Device Selection Considerations, Regulatory Aspects, Special Considerations for Peptide Nasal Delivery

10. **Topical and Transdermal Delivery**
    The Skin and Percutaneous Absorption, Drug Candidate Selection and Preformulation, Formulation

**Required Texts:**

1. Pharmaceutical preformulation and Formulation, by Mark Gibson, CRC Press, USA, 2004
2. Pharmaceutical dosage form: Tablets, by Liebarman, Lachman and Schwartz; Vol: 1, 2 & 3, 2nd edition, Marcel Dekker, USA, 1990
3. Modern Pharmaceutics, by Banker and Rhodes, 4th edition, Marcel Dekker, USA, 2007
4. Ansel's Pharmaceutical dosage forms and drug delivery systems, by Allen, Popovich and Ansel, 8th edition, Lippincott Williams & Wilkins, USA, 2005
5. Handbook of Preformulation: Chemical, Biological, and Botanical Drugs, by Sarfaraz K. Niazi, Informa Healthcare, USA, 2007

**Course code: PHT 804**
**Course title: Advanced Research in Biopharmaceutics and Pharmacokinetics**
**Course type: Optional**

1. **Pharmacokinetic Characteristics for Bioequivalence Studies (Single- and Multiple-dose)**
   Introduction, Pharmacokinetic Characteristics (Metrics) for Single Dose Studies, Pharmacokinetic rate and Extent Characteristics (Metrics) for Multiple-Dose Studies

2. **Basic Statistical Considerations**
   Introduction, Additive and Multiplicative Model, Hypotheses Testing, the RT/TR Crossover Design Assuming an Additive Model

3. **Assessment of Average Bioequivalence in the RT/TR Design**
   Introduction, the RT/TR Crossover Design Assuming a Multiplicative Model, Test Procedures for Bioequivalence Assessment

4. **Power and Sample Size Determination for Testing Average Bioequivalence in the RT/TR Design**
   Introduction, Challenging the Classical Approach, Exact Power, and Sample Size Calculation, Modified Acceptance Ranges, Approximate Formulas for Sample Size Calculation, Exact Power, and Sample Size Calculation by nQuery®

5. **Presentation of Bioequivalence Studies**
   Introduction, Result from a Single-dose Study, Result from a Multiple-dose Study

6. **Designs with more than Two Formulations**
   Introduction, Williams Design, Example: Dose Linearity Study, Multiplicity

7. **Analysis of Pharmacokinetic Interactions**
   Introduction, Pharmacokinetic Drug-Drug Interaction Studies, Pharmacokinetic Food-Drug Interactions, Goal Posts for Pharmacokinetic Drug Interaction Studies including No Effect Boundaries, Labeling

8. **Population and Individual Bioequivalence**
   Introduction, Brief History, Study Designs and Statistical Models, Population Bioequivalence, Individual Bioequivalence, Disaggregate Criteria, Other Approaches, Average Bioequivalence in Replicate Designs, Example: The Antihypertensive Patch Dataset

9. **Equivalence Assessment for Clinical Endpoint**
   Introduction, Design, and testing Procedure, Power, and Sample Size Calculation

**Required Texts:**

1. Dieter Hauschke, Volker Steinijans, and Iris Pigeot: "Bioequivalence Studies in Drug Development – Method and Applications"

**Course code: PHT 805**
**Course title: Advanced Pharmaceutical Marketing**
**Course type: Optional**

1. **Marketing Management**
   Marketing function with emphasis on the procedures and techniques for analyzing, planning, and implementing marketing strategies and tactics related to pharmaceutical product, pricing, communication, and distribution decisions

2. **Marketing Research**
   Research methodology as applied to marketing problems; includes research problem definition, sample design, data collection procedures, valid and reliable measurement, data analysis techniques, and sales forecasting fundamentals

3. **Business Statistics**
   Number of multivariate analysis procedures such as discriminant analysis, analysis of variance, factor analysis, MDS (multi-dimensional scaling), conjoint analysis, choice models, etc

4. **Marketing Planning**
   Emerging paradigms and theory regarding the role of marketing within the firm and the effects of marketing mix variables on consumer behavior and firm performance. Tools and techniques for creating pharmaceutical marketing plans

5. **Customer Relationship Management and Data Mining**
   Techniques, procedures, and software applications for database marketing, managing customer

relations, and mining large databases

6. **Strategic Marketing**
   An integrative treatment of the role of pharmaceutical marketing in strategic problem solving

7. **Consumer Behavior**
   Concepts, theories, and techniques applicable to obtaining a sophisticated understanding of the pharmaceutical customer/consumer motives, attitudes, decision-making processes, and satisfaction determinants

8. **Product and Branding Policies**
   Pharmaceutical product line and portfolio planning, stage-gate approach to new product development, product launch and product life cycle management, and branding strategies and procedures

9. **Pharmaceutical Marketing Communications**
   Advertising, sales promotions, marketing-oriented public relations, event and sponsorship marketing, point-of-purchase communications, and other aspects of integrated marketing communications

10. **Sales and Sales Management**
    The role and activities of sales in pharmaceutical marketing, including concepts, practices, and procedures of sales force management

11. **Internet Marketing of Pharmaceutical Products**
    The Internet as both a marketing channel and communication medium, including E-commerce from a marketing perspective

12. **Managing Customer Satisfaction**
    This course explores the importance of customer satisfaction in today's marketplace and the challenges of designing and implementing an actual customer satisfaction measurement process

**Required Texts:**

1. Philip Kotler: Marketing Management, 14th Edition
2. Aaker, David A: Strategic Market Management. 6th ed., New York: John Wiley & Sons, 2001.
3. Kerin, Roger A. and Robert A. Peterson: Strategic Marketing Problems: Cases and Comments. 9th Edition, Boston: Allyn and Bacon, 2001.
4. Hartley, Robert F.: Marketing Mistakes. Wiley and Sons, 1998
5. Wooldridge, J.M.: Introductory Econometrics, Cengage Learning Emea, 2008
6. Anderson, S.P., de Palma A. and Thisse, J.F., Discrete Choice Theory of Product Differentiation, The MIT Press, 1992
7. Marketing Essentials, McGraw-Hill-Glencoe 2006
8. Wackerly, Mendenhall, and Schaeffer, Mathematical Statistics with Applications, 7th Edition, Duxbury Press, 2008
9. Harper W. Boyd, Ralph Westfall & Stanley F. Stasch: Marketing Research: Text and Cases; 7th Edition, published by Richard D Irwin, 1989
10. Naresh K Malhotra: Marketing Research: An Applied Orientation (6th Edition); Prentice-Hall Inc.
11. Leon Schiffman and Leslie Kanuk: Consumer Behavior (10th Edition)
12. Kevin Lane Keller: Strategic Brand Management (4th Edition), 2012

13. Supplementary Text: Meyer, Introductory Probability and Statistical Applications, 2nd Edition, Addison-Wesley Publishing, 1970.

**Course code: PHT 806**
**Course title: Recent Trends in Food Technology and Cosmetology**
**Course type: Optional**

1. **Food Products Standardization**
   Sample Preparation methods in the analysis of pesticides residues in baby food with subsequent chromatographic determinations; Sample Preparation techniques for the determination of trace residues and contaminants in food; Use of compressed fluids for sample preparation: Food applications; Protein, Carbohydrate, Vitamins, Trace Elements, Heavy Metals, Pesticides Analysis

2. **Food Safety and Regulations**

3. **Food Processing Problems and Resolution**
   Vegetables, Fruits, Fish, Meats

4. **Food Contaminations and Health Hazards**
   Mechanism and Control of Food Allery, Microorganism Induced Food Contaminations

5. **Nutraceutical Processing Problems and Resolutions**

6. **Milk and Milk Product Processing Problems and Resolutions**

7. **Food Preparation and Processing**
   Food Properties, Food Safety and Hygiene Practice, Food Deterioration And Spoilage, Principles of Food Preservation and Storage, Reasons for cooking foods, Properties of food, Basic ingredients used in food preparation, Methods and equipment used in the preparation and processing of food, The role of technology in the preparation of food domestically and the social implications, Physical and nutritive effects of preparation and processing in domestic and industrial setting, Industrial food preparation levels of processing additives, environmental, social, health and economic effects, Presentation and service of food, Food packaging forms/materials

8. **Nutrition and Consumption**
   Nutritional components of food –food nutrient groups, The role of fiber in the diet, Foods which are developed to enhance health, Implications of under and over nutrition and diet-related disorders, Anorexia and restrained eating, food consumption in Australia and the impact this has on nutrient intake and health, Influences on food selection and the subsequent effects on health, National guidelines for healthy eating including the National Dietary Guidelines for children and adolescents, Nutrition, Nutritional requirements of different stages of the lifecycle, Selection of Nutritious Food, Changes in consumption patterns in relation to processed and unprocessed food

9. **Foods in Bangladesh**
   Use of foods native to Bangladesh, Multicultural influences, Influences on food selection, Factors affecting current consumption patterns, Development of food production and processing from both historical and contemporary perspectives

**10. Food Equity**

Circumstances that bring about food inequity, Groups that may experience food inequity in developed and developing countries, Influences on food availability and distribution, Physical and social cost of malnutrition, Provision of aid, Support networks for groups that may experience food inequities

**11. Food product development**

Reasons for developing food products, Impact of past and present food product innovations on society, Steps in food product development, Role of market research in product development, Promotion of new food products, Emerging technologies and new food products

**12. Food selection and health**

Function of food in the body, Digestion of food, Function and sources of food components, Nutritional needs, Factors that influence food habits, Nutritional implications of food consumption patterns –under and over nutrition, Response to general nutrition levels, Application of food guides for menu planning and food choices, Active non-nutrients such as phytochemicals and probiotics

**13. Food for special needs**

Circumstances which lead to special food needs, Support networks for individuals with special needs, Preparation and processing of foods for special needs such as low kilojoule, low salt, high fiber, high protein, low fat, Planning considerations for safe and nutritious foods for special needs, Specific circumstances which lead to special nutritional needs

**14. Food trends**

Trends in food, Trends in dining and food service, Trends in food presentation and food styling, Food styling and photography, Factors influencing acceptance of food trends, The relationship between marketing and food trends, Marketing of current food trends, Food styling and photography for marketing through print or electronic media

**Required Texts:**

1. J. Scott Smith and Y. H. Hui: "Food Processing: Principle and Application." Publisher: Blackwell Publishing Ltd.
2. James G. Brennan: "Food Processing Handbook." Publisher: Wiley-VCH Verley GmbH & Co.
3. Y. H. Hui: "Handbook of Food Product Manufacturing" Publisher: Wiley-Interscience.
4. H. D. Belitz, W. Grosch, P. Schieberle: "Food Chemistry." Publisher: Springer
5. Peter Zeuthen, Leif Bogh-Sorensen: "Food Preservation Technique." Publisher: Woodhead Publishing Limited
6. Rick Parker: "Introduction to Food Science." Publisher: Delmer, Thomson Learning Inc.
7. J P F D'Mello: "Food Safety: Contaminants and Toxins." Publisher: CABI Publishing

**Course code: PHT 807**
**Course title: Advances in Herbal and Traditional Medicine Research and Development**
**Course type: Optional**

**1. Different Systems of Traditional Medicine**

Role of Traditional System of Medicine in Primary Health Care, World Situation on Traditional Medicine, WHO's Policy on the Traditional Medicine

2. **Natural Products as Leads for New Pharmaceuticals**
   Example of Some Drug Derived from Natural Sources as New Pharmaceuticals

3. **Phyto-constituents and Their Analysis**
   Importance of phyto-constituents in Therapy, Qualitative Analysis of Crude Extracts, Fractions and Isolated Compounds, Alkaloids, Volatile Oils, Fixed Oils, Phenols, Flavonoids, Resins, Tannins, Terpenoids, Glycosides, Steroids ect and their Analysis

4. **Qualitative Assurance and Control of Herbal Medicine**
   Factors Affecting Herbal Quality, Quality Standards of Herbal Products, Factors Relating to Quality of Herbal Drugs, Sampling Procedures, Morphological Examination, Microscopical Evaluation, Development and Standardization Parameters (Determination of Ash Value, Acid Insoluble Ash, Water Soluble Ash, Total Solid, Moisture Content, Lose on Drying, Essential Oil etc), Maximum Limits of Pesticides Residues for Herbal Drugs, Methods Determination of Pesticide Residues, Specific Test or Criteria for Evaluation of Quality

5. **Ethnobotany and Ethnopharmacology**
   Ethnobotany in Herbal Drug Evaluation, Impact of Ethnobotany in Traditional Medicine, Ethnopharmacology in Drug Evaluation, Impact of Ethnopharmacology in Modern Medicine

6. **Herbal Drug Regulation in Bangladesh**
   Herbal Drug Technical Advisory Committee/Board, Constitution of the Board, Functions of the Committee, Consultative Committee

**Required Texts:**

1. Lesley Bremness: "The Complete Book of Herbs: A Practical Guide to Growing and Using Herbs."
2. Matthew Wood: "The Book of Herbal Wisdom: Using Plants as Medicines."
3. David Hoffman: "Holistic Herbal: A Safe and Practical Guide to Making and Using Herbal Remedies."

**Course code: PHT 808**
**Course title: Drug Discovery and Bioorganic Medicinal Chemistry**
**Course type: Optional**

1. **Recent Trends in Quantitative Structure-Activity Relationships**
   Introduction, Multiple Descriptors of Molecular Structures, QSAR Modeling Approaches, Validation of QSAR Models, QSAR Models as Virtual Screening Tools

2. **Molecular Modeling in Drug Design**
   Introduction, Background and Methods, Statistical Mechanics Foundation, Molecular Dynamics, Known Receptors, Unknown Receptors

3. **Combinatorial Library Design, Molecular Similarity, and Diversity Applications**
   Introduction, Molecular Similarity/Diversity, Virtual Screening by Molecular Similarity, Combinatorial Library Design, Example Approaches

4. **Docking and Scoring Functions/Virtual Screening**
   Introduction, General Concepts and Physical Background, Docking, Scoring Functions, Virtual Screening

5. **Bioinformatics: Its Role in Drug Discovery**
   Introduction, Bioinformatics in Drug Discovery, What is Bioinformatics, Bioinformatics and Target Discovery, Databases, Tools and Application, The Bioinformatics Knowledge Model, Structural Genomics

**Required Texts:**

1. Donald J. Abraham, David P. Rotella: Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set

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**Department of Pharmaceutical Technology**
**Faculty of Pharmacy**
**University of Dhaka**

**Syllabus and Guidelines for**
**Master of Philosophy (M. Phil.) in Pharmaceutical Technology Program**
**Effective from 2014 and onwards**

## ● Preamble

The Master of Philosophy (M. Phil.) in Pharmaceutical Technology is a specialized research oriented academic program offered by the Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Dhaka, leading to various fields of specialization in the field of Pharmaceutical Technology. The program has been designed to prepare highly educated and skilled professionals for careers in Pharmacy teaching and industry. The vast number of Pharmacy educational institutions commissioned in our country during the recent years faces a crucial demand of highly educated and expert teachers in the discipline of Pharmaceutical Technology. Moreover, the changing scenario of the pharmaceutical industries has opened new and competent career opportunities in product development, hi-tech production, regulatory affairs, international marketing, drug administration and similar areas. Realizing the present academic and industry requirements for generating skilled manpower, the Department of Pharmaceutical Technology has reorganized its M. Phil. program to cope with the current demands. Inclusion of dedicated modern laboratory facilities as well as supervision by expert Faculties for conducting the M. Phil. program, will, no doubt, contribute to the expansion of higher studies and research of this country.

## ● Eligibility for admission

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II. Candidates who have obtained B. Pharm. (Hons.) and M. Pharm. from any private university and secured a CGPA of at least 3.50 (on a scale of 4.00) are also eligible to apply provided (i) they have minimum 3 years of working experience in teaching, research or industry and (ii) at least one research publication. The final decision about the admission of such a candidate will depend on the report of the Academic and Equivalence Committees.

III. Candidates having post-graduate degree from non-Pharmacy disciplines, such as medicine, public health, nutrition, food science and technology, biochemistry, microbiology, health economics, population sciences, veterinary science or any other relevant subjects and may also apply for admission in the M. Phil. program. The final decision about the admission of such a candidate will depend on the report of the Academic and Equivalence Committees. After successful completion of the program, students from non-Pharmacy disciplines will be awarded a generalized M. Phil. degree and not a professional M. Phil. degree in Pharmaceutical Technology.

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**● Course activities**

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| (iv) | Viva voce | The M. Phil. student will also be required to appear in an oral exam conducted by the M. Phil. examination committee after submission of the dissertation. |

**● Assessment of activities and conferring of award**

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**● Regulations regarding thesis work**

I. A student of the program will be required to conduct a research on a relevant field of Pharmaceutical interest under the supervision of a Faculty member recommended / approved by the Academic Committee.
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III. A supervisor may even recommend to the Academic Committee to cancel admission of a student in the M. Phil. program if his / her performance is unsatisfactory for doing research work or for involving in any sort of unlawful or illegal activity.
IV. A thesis student must abide by the rules and regulations of the laboratories including Good Laboratory Practices (GLP) and should strictly follow the instructions of Laboratory Coordinators / Officers.
V. A thesis student must get clearance from all concerned authorities including the Department and pay all dues, if any, after completion of the research work. Publication of the final result may be halted in such cases.
VI. In addition to the abovementioned guidelines, the general rules and regulations endorsed for the Ph. D. / M. Phil. programs of the University shall also be applicable to the students.
VII. Under any circumstance which is not covered by the abovementioned guidelines, the decision made by the Examination Committee, Academic Committee or University Authority, whichever is appropriate to that situation, will be considered as final.

● **Research areas and courses offerings**

| Course code | Course title | Type |
|---|---|---|
| PHT 701 | Research Methodology in Pharmaceutical Sciences | Compulsory |
| PHT 702 | Recent Developments in Pharmaceutical Technology | Optional |
| PHT 703 | Product Development and Formulation Technology | Optional |
| PHT 704 | Advanced Research in Biopharmaceutics and Pharmacokinetics | Optional |
| PHT 705 | Advanced Pharmaceutical Marketing | Optional |

## DETAIL SYLLABUS OF THE THEORETICAL COURSES

**Course code: PHT 701**
**Course title: Research Methodology in Pharmaceutical Sciences**
**Course type: Compulsory**

1. **Introduction to Research**
   Definitions and characteristics of research; types of research (Qualitative, Quantitative, Exploratory); main components of any research work

2. **Research Methods**
   Required for Choosing a Basic Method of Research

3. **Research Design Formulation**
   Literature Review, Topic Selection (Problem Identification); Analysis and Statement of the Problem (analyzing the problem and formulating the problem statement), Objectives of a Research, Measurement & Scaling, Questionnaire Design

4. **Data Collection, Preparation, Analysis & Reporting**
   Basic Methods of Collecting Data, Sampling Techniques, Fieldwork & Data Preparation, Application of one or more statistical packages (SPSS)

5. **Research Trends in Different Pharmaceutical Areas**
   Product Development, Natural Product Chemistry, Bioorganic Chemistry, Public Health, Rational Use of Drug, Analytical Method Development, Food and Cosmetics

6. **Selected Applications of Marketing Research**
   Identifying Pharmaceutical Market Segments; Pharmaceutical Product Research, Pharmaceutical Market, & Sales Analysis

**Required Texts:**

1. Harper W. Boyd, Ralph Westfall & Stanley F. Stasch; Marketing Research: Text and Cases; 7th edition, published by Richard D Irwin; February 1989
2. Naresh K Malhotra; Marketing Research: An Applied Orientation (6th Edition); Prentice-Hall Inc.

**Course code: PHT 702**
**Course title: Recent Developments in Pharmaceutical Technology**
**Course type: Optional**

1. **21 CFR Part 11**
   Introduction, Regulatory Background, Implementation in Industry, Contents, Selected articles

2. **Controlled Release Dosage Forms**
   Rationale, General Design Principle for Controlled - Release Drug Delivery Systems, Physicochemical and Biological Factors Influencing Design and Performance of Controlled - Release Formulations, Physicochemical Factors, Biological Factors, Controlled - Release Oral Dosage Forms, Design and Fabrication of Controlled – Release Dosage Forms, Technologies for Developing Transdermal Dosage Forms, Ocular Controlled - Release Dosage Forms, Vaginal and Uterine Controlled - Release Dosage Forms, Release of Drugs from Controlled - Release Dosage Forms, Time - Controlled - Release Dosage Forms, Stimuli - Induced Controlled - Release Systems

3. **Microencapsulation Technology**
   Introduction, Microencapsulation techniques and description, Achievment and limitations, Recent advances in Microencapsulation Technology, recent applications of microparticle systems

4. **Liposomes And Drug Delivery**
   Introduction, Liposome Structure and Characteristics, Phospholipids: Structure Stability and Characterization of Lipid Membranes, Physicochemical Properties of Liposomes, Preparation of Liposomes, Functionalization of Liposomes, In Vivo Distribution, Conventional Liposomes, Long - Circulating or PEGylated Liposomes, Other Routes of Administration, Applications of Liposomes in Therapeutics, Anticancer Drug Delivery

5. **Isolators For Pharmaceutical Application**
   Introduction, Technical Guidelines and standards, Applications, Design considerations, Construction, Cleaning and sanitization

6. **Radiopharmaceutical Manufacturing**
   Introduction, Radiopharmacy, Ideal Characteristics, Radioactive Decay, Principles of Radiation Protection, Product Development, Radionuclides, Carrier Molecules/Active Ingredients, Manufacturing Aspects, Design of Manufacturing Sites, Design of Production Processes, Design of Production Equipment, Cleaning and Sanitation, Environmental Control, Sterilization of Radiopharmaceutical, Labeling and Packaging, Production of Radionuclides, Production of Radiopharmaceuticals, Quality Considerations, Documentation, Qualification of Personnel, Quality Control, Validation and Control of Equipment and Procedures, Stability Aspects of Radiopharmaceuticals, Extemporaneous Preparation of Radiopharmaceuticals

7. **Automation in Pharmaceutical Technology**
   Introduction, Computer application, Data and Information Management Systems, Material inventory system, Formulation information system, Stability information systems, Analytical information systems, Document Management and Publishing Systems Quality assurance information system, Expiry Date Prediction, Laboratory Automation, Process Control and Automation, Building Automation

**Required Texts:**

1. Pharmaceutical manufacturing handbook: Production and process, by Shayne Cox GAD, John Wiley & Sons, Inc., USA, 2008
2. Encyclopedia of Pharmaceutical Technology, by James Swarbrick, 3rd edition, Informa Healthcare, USA, 2007
3. Modern Pharmaceutics, by Banker and Rhodes, 4th edition, Marcel Dekker, USA, 2007

**Course code: PHT 703**
**Course title: Product Development and Formulation Technology**
**Course type: Optional**

1. **Preformulation Predictions:**
   Initial Physicochemical Characterization, Initial Solubility, Initial Stability Investigations, Crystallinity, Crystal Morphology, Hygroscopicity, Salt Selection

2. **Biopharmaceutical Support in Candidate Drug Selection**
   Drug Dissolution and Solubility, Luminal Interactions, Absorption/Uptake over the GI Membranes, Models for Studying the Absorption Potential of Drugs, Permeability Coefficients versus Fa, In Vivo Techniques for Studies in Man, Vehicles for Absorption Studies, Functional Use of Absorption Models, In Vitro Dissolution, Bioavailability Studies, In Vitro/In Vivo Correlations, Animal Models, Imaging Studies

3. **Product Design**
   The Importance of Product Design, Product Design Considerations

4. **Product Optimization**
   Product Optimization Purpose and Scope, Excipient and Pack Optimization Considerations, Sources of Information, Expert Systems, Experimental Design, Stability Testing, Developing Specifications, Process Design, Process Optimization and Scale-Up, Validation and Launch

5. **Parenteral Dosage Forms**
   Guiding Principles for Simple Parenteral Solutions, Choice of Excipients, Sterility Considerations, Strategies for Formulating Poorly Soluble Drugs, Strategies for Formulating Unstable Molecules, Strategies for the Formulation of Macromolecules, Liposomal Delivery Systems, Sustained-Release Parenteral Formulations, In Vitro and In Vivo Testing Methods, Packaging of Parenteral Products, Manufacturing of parenteral Products, Administration of Parenteral Products, Parenteral Products and the Regulatory Environment

6. **Inhalation Dosage Forms**
   Lung Deposition, Particle Sizing, Dry Powder Inhalers, Metered Dose Inhalers, Nebulisers, Standards, Future

7. **Oral Solid Dosage Forms**
   Powder Technology, Powder Flow, Mixing, Compaction, Solid Dosage Forms, Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules

8. **Ophthalmic Dosage Forms**
   Ocular Topical Drug Delivery Issues and Challenges, Drug Candidate Selection, Product Design Considerations, Product Optimisation Considerations, Processing Considerations

9. **Aqueous Nasal Dosage Forms**
   Nasal Anatomy and Physiology, Formulation Selection Considerations, Device Selection Considerations, Regulatory Aspects, Special Considerations for Peptide Nasal Delivery

10. **Topical and Transdermal Delivery**
    The Skin and Percutaneous Absorption, Drug Candidate Selection and Preformulation, Formulation

**Required Texts:**

1. Pharmaceutical preformulation and Formulation, by Mark Gibson, CRC Press, USA, 2004
2. Pharmaceutical dosage form: Tablets, by Liebarman, Lachman and Schwartz; Vol: 1, 2 & 3, 2nd edition, Marcel Dekker, USA, 1990
3. Modern Pharmaceutics, by Banker and Rhodes, 4th edition, Marcel Dekker, USA, 2007
4. Ansel's Pharmaceutical dosage forms and drug delivery systems, by Allen, Popovich and Ansel, 8th edition, Lippincott Williams & Wilkins, USA, 2005
5. Handbook of Preformulation: Chemical, Biological, and Botanical Drugs, by Sarfaraz K. Niazi, Informa Healthcare, USA, 2007

**Course code: PHT 704**
**Course title: Advanced Research in Biopharmaceutics and Pharmacokinetics**
**Course type: Optional**

1. **Pharmacokinetic Characteristics for Bioequivalence Studies (Single- and Multiple-dose)**
   Introduction, Pharmacokinetic Characteristics (Metrics) for Single Dose Studies, Pharmacokinetic rate and Extent Characteristics (Metrics) for Multiple-Dose Studies

2. **Basic Statistical Considerations**
   Introduction, Additive and Multiplicative Model, Hypotheses Testing, the RT/TR Crossover Design Assuming an Additive Model

3. **Assessment of Average Bioequivalence in the RT/TR Design**
   Introduction, the RT/TR Crossover Design Assuming a Multiplicative Model, Test Procedures for Bioequivalence Assessment

4. **Power and Sample Size Determination for Testing Average Bioequivalence in the RT/TR Design**
   Introduction, Challenging the Classical Approach, Exact Power, and Sample Size Calculation, Modified Acceptance Ranges, Approximate Formulas for Sample Size Calculation, Exact Power, and Sample Size Calculation by nQuery®

5. **Presentation of Bioequivalence Studies**
   Introduction, Result from a Single-dose Study, Result from a Multiple-dose Study

6. **Designs with more than Two Formulations**
   Introduction, Williams Design, Example: Dose Linearity Study, Multiplicity

7. **Analysis of Pharmacokinetic Interactions**
   Introduction, Pharmacokinetic Drug-Drug Interaction Studies, Pharmacokinetic Food-Drug Interactions, Goal Posts for Pharmacokinetic Drug Interaction Studies including No Effect Boundaries, Labeling

8. **Population and Individual Bioequivalence**
   Introduction, Brief History, Study Designs and Statistical Models, Population Bioequivalence, Individual Bioequivalence, Disaggregate Criteria, Other Approaches, Average Bioequivalence in Replicate Designs, Example: The Antihypertensive Patch Dataset

9. **Equivalence Assessment for Clinical Endpoint**
   Introduction, Design, and testing Procedure, Power, and Sample Size Calculation

**Required Texts:**

1. Dieter Hauschke, Volker Steinijans, and Iris Pigeot: "Bioequivalence Studies in Drug Development – Method and Applications"

**Course code: PHT 705**
**Course title: Advanced Pharmaceutical Marketing**
**Course type: Optional**

1. **Marketing Management**
   Marketing function with emphasis on the procedures and techniques for analyzing, planning, and implementing marketing strategies and tactics related to pharmaceutical product, pricing, communication, and distribution decisions

2. **Marketing Research**
   Research methodology as applied to marketing problems; includes research problem definition, sample design, data collection procedures, valid and reliable measurement, data analysis techniques, and sales forecasting fundamentals

3. **Business Statistics**
   Number of multivariate analysis procedures such as discriminant analysis, analysis of variance, factor analysis, MDS (multi-dimensional scaling), conjoint analysis, choice models, etc

4. **Marketing Planning**
   Emerging paradigms and theory regarding the role of marketing within the firm and the effects of marketing mix variables on consumer behavior and firm performance. Tools and techniques for creating pharmaceutical marketing plans

5. **Customer Relationship Management and Data Mining**
   Techniques, procedures, and software applications for database marketing, managing customer relations, and mining large databases

6. **Strategic Marketing**
   An integrative treatment of the role of pharmaceutical marketing in strategic problem solving

7. **Consumer Behavior**
   Concepts, theories, and techniques applicable to obtaining a sophisticated understanding of the pharmaceutical customer/consumer motives, attitudes, decision-making processes, and satisfaction determinants

8. **Product and Branding Policies**
   Pharmaceutical product line and portfolio planning, stage-gate approach to new product development, product launch and product life cycle management, and branding strategies and procedures

9. **Pharmaceutical Marketing Communications**
   Advertising, sales promotions, marketing-oriented public relations, event and sponsorship marketing, point-of-purchase communications, and other aspects of integrated marketing communications

10. **Sales and Sales Management**
    The role and activities of sales in pharmaceutical marketing, including concepts, practices, and procedures of sales force management

11. **Internet Marketing of Pharmaceutical Products**
    The Internet as both a marketing channel and communication medium, including E-commerce from a marketing perspective

12. **Managing Customer Satisfaction**
    This course explores the importance of customer satisfaction in today's marketplace and the challenges of designing and implementing an actual customer satisfaction measurement process

**Required Texts:**

1. Philip Kotler: Marketing Management, 14th Edition
2. Aaker, David A: Strategic Market Management. 6th ed., New York: John Wiley & Sons, 2001.
3. Kerin, Roger A. and Robert A. Peterson: Strategic Marketing Problems: Cases and Comments. 9th Edition, Boston: Allyn and Bacon, 2001.
4. Hartley, Robert F.: Marketing Mistakes. Wiley and Sons, 1998
5. Wooldridge, J.M.: Introductory Econometrics, Cengage Learning Emea, 2008
6. Anderson, S.P., de Palma A. and Thisse, J.F., Discrete Choice Theory of Product Differentiation, The MIT Press, 1992
7. Marketing Essentials, McGraw-Hill-Glencoe 2006
8. Wackerly, Mendenhall, and Schaeffer, Mathematical Statistics with Applications, 7th Edition, Duxbury Press, 2008
9. Harper W. Boyd, Ralph Westfall & Stanley F. Stasch: Marketing Research: Text and Cases; 7th Edition, published by Richard D Irwin, 1989
10. Naresh K Malhotra: Marketing Research: An Applied Orientation (6th Edition); Prentice-Hall Inc.
11. Leon Schiffman and Leslie Kanuk: Consumer Behavior (10th Edition)
12. Kevin Lane Keller: Strategic Brand Management (4th Edition), 2012
13. Supplementary Text: Meyer, Introductory Probability and Statistical Applications, 2nd Edition, Addison-Wesley Publishing, 1970.

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