UNIVERSITY OF DHAKA

Department of Pharmaceutical Technology

Syllabus and Guidelines
for
Master of Pharmacy (M. Pharm.) Program

Effective from Session 2017-18 and onward
(Format approved by the Academic Committee on 05-04-2018,
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Department of Pharmaceutical Technology
Faculty of Pharmacy
University of Dhaka

Syllabus and Guidelines for Master of Pharmacy (M. Pharm.) Program Effective from Session 2017-18 and onward

● Preamble

The Master of Pharmacy (M. Pharm.) in Pharmaceutical Technology is a postgraduate program offered by the Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Dhaka, leading to specialization in the field of Pharmaceutical Technology. The program has been designed in view of the growing demand of highly trained manpower in the pharmaceutical sector, both home and abroad. The course is directed towards providing advanced academic knowledge and practical training to the graduate pharmacists in order to produce competent pharmacy professionals having necessary skill and proficiency in relevant areas of pharmaceutical sciences.

● Eligibility for admission

Graduates of the University of Dhaka who had successfully completed the B. Pharm. (Hons./ Prof.) program of the Faculty of Pharmacy are eligible to apply for admission in the M. Pharm. program of this Department. Foreign students are also allowed to get admission in the M. Pharm. program if their academic records are found acceptable by the equivalence committee of the university. The selection and admission process will be conducted as per existing rules of the institution. All decisions regarding admission of foreign students must be approved by the Academic Committee of the Department.

● Duration of the Program

The duration of the program will be of one academic year comprising of one session. The approximate time schedules for the different activities of the session are divided as

Theory and Practical Classes	30 weeks
Preparatory leave for Final Examination	4 weeks
Final Examination (Theory + Practical + Viva)	6 weeks
Total duration of the session	40 weeks

● Course structure, mark distribution and credit allocation

The entire M. Pharm. program of the Department is covered by a set of

(i) theoretical courses	(ii) practical courses	(iii) research work
(iv) presentation	(v) oral examination	(vi) report submission

Students of zze M. Pharm. (Pharm. Tech.) program will be divided into two groups - Thesis and Non-thesis, with courses having a total of 900 and 850 marks respectively. The students of the Non-thesis group will be required to take a total of 34 credits for completing the program whereas the requirement for the students of the Thesis group is 36 credits. Distribution of the marks and credits for the two groups are given below:

Non-thesis Group					
	Courses	**Marks Per Course**	**Total Marks**	**Credit Per Course**	**Total Credits**
Theory	6	100	600	4	24
Practical Course	6	25	150	1	6
Report submission on a particular topic	1	25	25	1	1
Presentation on the Report	1	25	25	1	1
Viva voce	1	50	50	2	2
		Total Marks	**850**	**Total Credits**	**34**

Thesis Group					
	Courses	**Marks Per Course**	**Total Marks**	**Credit Per Course**	**Total Credits**
Theory	6	100	600	4	24
Thesis	1	200	200	8	8
Thesis Presentation/Defense	1	50	50	2	2
Viva voce	1	50	50	2	2
		Total Marks	**900**	**Total Credits**	**36**

● Courses offered

***For Non-thesis Group*:**

There will be six (6) theoretical courses, all of which will be compulsory. Similarly, there will be six (6) practical courses all of which will be compulsory. Each student of this group will also be required to deliver one presentation and submit one report on a selected topic which will be decided by the M. Pharm. Examination Committee. Students will also be required to appear in an oral exam (v*iva voce*).

For Thesis Group:

There will be six (6) theoretical courses, all of which will be compulsory. There will be no practical course for this group. However, each student of thesis group will conduct a research work under the supervision of a Faculty Member of the Department and submit a dissertation within the stipulated period. Enrollment in the thesis group and distribution of thesis will be conducted as per decision of Academic Committee of the Department. Students will also be required to appear in thesis presentation and an oral exam (*viva voce*).

Courses offered by the Department along with details of mark distribution and credit allocation for the Non-thesis and Thesis groups are as follows:

Non-thesis group					
Course code	**Course title**	**Marks**			**Credit hours**
		In-course	**Final**	**Total**	
PHT 601	Advanced Pharmaceutical Manufacturing	20	80	100	4
PHT 602	Advanced Pharmaceutical Technology	20	80	100	4
PHT 603	Advanced Biopharmaceutics and Pharmacokinetics	20	80	100	4

PHT 604	Advanced Pharmaceutical Marketing and Industrial Management	20	80	100	4
PHT 605	Pharmaceutical Biotechnology and Food Technology	20	80	100	4
PHT 606	Research Methodology	20	80	100	4
PHT 601L	Advanced Pharmaceutical Manufacturing Practical			25	1
PHT 602L	Advanced Pharmaceutical Technology Practical			25	1
PHT 603L	Advanced Biopharmaceutics and Pharmacokinetics Practical			25	1
PHT 604L	Advanced Pharmaceutical Marketing and Industrial Management Practical			25	1
PHT 605L	Pharmaceutical Biotechnology and Food Technology Practical			25	1
PHT 606L	Research Methodology Practical			25	1
PHT 607	Report submission on particular topic			25	1
PHT 608	Presentation on the topic			25	1
PHT 609	Viva voce			50	2
			Total	**850**	**34**

Thesis group

Course code	**Course title**	**Marks**			**Credit hours**
		In-course	**Final**	**Total**	
PHT 601	Advanced Pharmaceutical Manufacturing	20	80	100	4
PHT 602	Advanced Pharmaceutical Technology	20	80	100	4
PHT 603	Advanced Biopharmaceutics and Pharmacokinetics	20	80	100	4
PHT 604	Advanced Pharmaceutical Marketing and Industrial Management	20	80	100	4
PHT 605	Pharmaceutical Biotechnology and Food Technology	20	80	100	4
PHT 606	Research Methodology	20	80	100	4
PHT 610	Thesis work			200	8
PHT 611	Thesis Defense			50	2
PHT 612	Viva voce			50	2
			Total	**900**	**36**

● Assessment of students' performances and examination policy

A. Assessment of theoretical courses: For theory courses, the assessment of students' performances is made through in-course and final examinations. The distribution of marks for a theory course will be as follows:

(i) In-course examination **20** (ii) Year-final examination **80**

In-course examination

(i) There will be two in-course exams for each course. The average of the marks will be taken as the final mark of that in-course exam.
(ii) The duration of in-course exam will be 1 hour.
(iii) It is mandatory for a student to appear in both the in-course exams. A student failing to appear in any in-course test(s) will not be given a second chance.
(iv) Schedules for in-course examinations will be prepared by the Chairman of the Department through consultation with the Course Teachers within one month of commencement of the classes.
(v) The course content and format for each of the in-course examinations will be decided by the assigned Course Teacher(s).
(vi) Students having unacceptable attendances in the classes beyond the university set limits may not be allowed to sit for the in-course exams if decided by the Academic Committee of the Department.

Year final examination

i) The year-final examination will be conducted by the Controller of Examinations in collaboration with the Department as per existing rules and regulations of the institution.
ii) The duration of year-final examination will be 4 hours.

B. Assessment of practical courses (*for Non-thesis group*)**:**

i) Practical courses will be conducted based on laboratory experiments, field work, surveys and / or assignments as decided by the assigned course teachers.
ii) The assessment of practical courses will be made through in course activities and final examination which include observation of the student at work, table viva, homework, evaluation of practical reports, quizzes and exam performance.
iii) Methods of evaluation of practical examination will be decided by the respective examiner.

C. Viva-voce / Oral examination: Viva-voce / Oral examination will be taken by the Examination Committee.

D. Thesis work (*for Thesis group*)**:**

(i) A student of the Thesis group will be required to conduct a research on a relevant field of Pharmaceutical interest under the supervision of a Teacher assigned by the Academic Committee.
(ii) A Thesis group 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 transfer a student to the Non-thesis group if his / her performance is unsatisfactory for doing research work at the postgraduate level 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) The thesis must be submitted within four (4) months after the end of theory examination. If a student fails to submit his / her thesis within the stipulated period of time, the result will be finalized by showing him / her absent in the Thesis course. However, the defaulter will be allowed to submit his / her thesis with the next batch. In such a case, the numbers of the theoretical courses obtained by the defaulter will remain valid. However, such a student will not be eligible to get a grade better than B+ (grade point 3.25) in the thesis.

E. Presentation:

For non-thesis group

(i) Each student of the Non-thesis group will be required to deliver a presentation on a selected topic. The examination committee will select topics of relevant pharmaceutical interest and assign them to the students.
(ii) Students may also be asked to propose the presentation topics by themselves but the final decision will be made by the Examination Committee.
iii) The duration of a presentation will be 15 minutes followed by 5 minutes of question-answer session.

For thesis group

(i) Each student of the Thesis group will be required to deliver a presentation on the topic of research he / she has conducted.
(ii) The duration of a presentation will be 20 minutes followed by 10 minutes of question-answer session.
(iii) One or more practice presentations may be arranged for the thesis group students during the course of their research work to evaluate the progress of the dissertation and to provide additional guidelines and suggestions for the betterment of their thesis work.

● Results and grades:

A. Grading system

The letter grading system and numerical grading scale (4.00), as directed by the UGC and approved by Academic Council of the University on 21.03.2006 will be followed for publishing the results of the students. The following letter grades and corresponding grade-points will be used to determine the students grade point average (GPA):

Numerical Marks	Letter Grade	Grade Points
80 and above	A+	4.00
75 to less than 80	A	3.75
70 to less than 75	A−	3.50
65 to less than 70	B+	3.25
60 to less than 65	B	3.00
55 to less than 60	B−	2.75
50 to less than 55	C+	2.50
45 to less than 50	C	2.25
40 to less than 45	D	2.00

Less than 40	F	0
	I*	Incomplete
	W*	Withdrawn

B. **Grade Description**

The grades (with numeric values) are described as follows:

Grade A – Exceptional performance:
All course objectives achieved; objectives met in a consistently outstanding manner.

Grade B – Very good performance:
Significantly more than the majority (at least two-thirds) of the course objectives achieved; objectives met in a consistently through manner.

Grade C – Satisfactory performance:
At least majority of the course objectives achieved; objectives met satisfactory.

Grade D – Minimally acceptable performance:
Less than the majority but more than the minimum required course objectives achieved; objectives achieved at a minimally acceptable level.

Grade F – Unacceptable performance:
Minimum required course objectives not met; objectives not met at a minimally acceptable level; no credit earned.

Grade I and Grade W – Not applicable for Master of Pharmacy curriculum.

C. Earned Credits

A course in which a student has obtained `D' or a higher grade will be counted as credits earned by him/her. Any course in which a student has obtained `F' grade will not be counted towards his earned credits, but will be used for GPA calculation.

D. Calculation of GPA and CGPA

Grade Point Average (GPA) is the weighted average of the grade point obtained in all the courses passed/completed by a student. The Grade Point Average (GPA) is computed in the following manner:

$$GPA = \frac{\sum (\text{Grade Point} \times \text{Credits})}{\sum \text{Credits offered}}$$

The Cumulative Grade Point Average (CGPA) will be same as that of GPA as there is only one session in one-year program.

E. Other regulations

(i) There will be no provision of grade or result improvement examination in the M. Pharm. Program.

(ii) The M. Pharm. Program must be completed within three (3) academic years.
(iii) Irregular examinees will have to appear in the exam with the students of the next batch after taking readmission as per rules. No separate supplementary exam will be taken for any irregularity.
(iv) In addition to the abovementioned guidelines, the general rules and regulations endorsed for the master's courses of the University shall also be applicable to the students.
(v) 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.

SYLLABUS OF M. PHARM. IN PHARMACEUTICAL TECHNOLOGY PROGRAM

Course code: PHT 601
Course Name: Advanced Pharmaceutical Manufacturing
Credit hours: 4 No. of Lectures: 60

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.

Course code: PHT 602
Course Name: Advanced Pharmaceutical Technology
Credit hours: 4 No. of Lectures: 60

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:**

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

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

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

7. **Pharmaceutical process validation:**

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:**

***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 BaillereTindall.
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.

Course code: PHT 603
Course Name: Advanced Biopharmaceutics and Pharmacokinetics
Credit hours: 4 No. of Lectures: 60

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 In-vivo 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, Drug-Receptor theory relating pharmacologic effect and dose, Pharmacodynamic models, Maximum effect (E_{max}) 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.

Course code: PHT 604
Course Name: Advanced Pharmaceutical Marketing and Industrial Management
Credit hours: 4 No. of Lectures: 60

Part A: 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.

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.

Part B: Industrial Management

1. **Total Quality Management (TQM) and Productivity:**
   (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, in-process 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.

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.

Course code: PHT 605
Course Name: Pharmaceutical Biotechnology and Food Technology
Credit hours: 4 No. of Lectures: 60

Part A: 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

Part B: Food Technology

1. **Introduction to Food Science:**
   Functions of food, different categories of food products, role of pharmacists in food sector, food industries through worldwide, responsiveness to change in food products.

2. **Food Additives:**
   Different types of food additives, food additives and their roles in food processing, food additives intake assessment, risk and benefits of food additives, laws and regulation regarding food additives.

3. **Food Processing:**
   Preparation of Food Products**.** Principle of food processing, effects of various processes on food quality, conserving energy in food processing, new process in food industry.

4. **Food Packaging and Storage.** Types of packaging, packaging materials for food and food products, package testing, environmental consideration, innovations in packaging.

5. **Quality Factors in Food Products:**
(i) Food Spoilage - Types of food spoilage, factors affecting food spoilage – microbial and nonmicrobial factors, measures for preventing food spoilage.
(ii) Food Preservation **-** Principle of food preservation, methods of food preservation – dehydration, temperature, preservatives, quality control and specifications of food products.

6. **Food Safety:**
Principle of food safety, food related hazards and their control, HACCP and food safety factors-GAP, GMP, and ISO.

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.

Course code: PHT 606
Course Name: Research Methodology
Credit hours: 4 No. of Lectures: 60

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.

Practical courses

Course code	Course title	Credit hours	Description
PHT 601L	Advanced Pharmaceutical Manufacturing Practical	1	Practical courses will be designed and conducted on the basis of laboratory experiments, field work, surveys and / or assignments or report submission as decided by the assigned course teachers.
PHT 602L	Advanced Pharmaceutical Technology Practical	1	
PHT 603L	Advanced Biopharmaceutics and Pharmacokinetics Practical	1	
PHT 604L	Advanced Pharmaceutical Marketing and Industrial Management Practical	1	
PHT 605L	Pharmaceutical Biotechnology and Food Technology Practical	1	
PHT 606L	Research Methodology Practical	1	

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