Pharm-D Courses (Through Department of Pharmaceutics)

First Year					
1st Semester			2nd Semester		
Course No.	Title of Course	Cr. Hr.	Course No.	Title of Course	Cr. Hr.
PHT-301	Pharmaceutics- Fundamentals of Pharmacy Theory	3	PHT-302	Pharmaceutics- Pharmaceutical Dosage Forms Theory (I)	3
Second Year					
PHT-401	Pharmaceutical Dosage Forms (II)	3	PHT-402	Pharmaceutical Dosage Forms (Lab)	3
PHT-403	Pharmaceutical Microbiology (I)	3	PHT-404	Pharmaceutical Microbiology (II)	3
			PHT-414	Pharmaceutics Physical Pharmacy Theory	3
Third Year					
PHT-501	Pharmaceutics- Microbiology (Lab)	3	PHT-502	Physical Pharmacy Lab	3
PHT-513	Computer Application in Pharmacy (Lab)	2	PHT-504	Industrial Pharmacy-I Pharmaceutical Unit Operations	3
]	Fourth	Year		
PHT-603	Pharmaceutics- Industrial Pharmacy-II (Pharma. Eng.)	3	PHT-604	Pharmaceutics- Biopharmaceutics and Pharmacokinetics	3
PHT-605	Pharmaceutics-Industrial Pharmacy (Lab)	3	PHT-606	Pharmaceutics- Clinical Pharmacokinetics	3
PHT-613	Pharmaceutics- Pharmaceutical Technology	3	PHT-614	Pharmaceutics- Pharmaceutical Technology (Lab)	3
Fifth Year					
PHT-701	Pharmaceutics-Bio- Pharmaceutics & Pharmacokinetics Lab	3	PHT-702	Pharmaceutics- Prescription & Community Pharmacy	3
PHT-703	Forensic Pharmacy	3	PHT-704	Pharmaceutics- Pharmaceutical Management & Marketing	3
			PHT-706	Prescription Pharmacy (Lab)	3
-	-	_	PHT-708	Quality Control & Quality Assurance	3
	Total 22 Courses ma	king 68	8 Credit Hou	rs in five years	

FIRST SEMESTER

PHT-301

Fundamentals of Pharmacy (Theory)

Cr. Hrs. 3

1. Pharmacy Orientation

Introduction and orientation to the profession of pharmacy in relation to hospital pharmacy, retail pharmacy, industrial pharmacy, forensic pharmacy, pharmaceutical education and research etc.

2. History of Pharmacy

A survey of the history of pharmacy through ancient, Greek and Arab periods with special reference to contribution of Muslim scientists to pharmacy and allied sciences. Introduction to literature of pharmacy.

3. Literature of Pharmacy

Pharmacopocia, formularies, codices, abstracts, etc.

4. Physico-chemical Process

Precipitation, crystallization, evaporation, distillation, efflorescence deliquescence, lyophillization, elutrition, exication, descication, ignition, fusion, sublimation, calcination, decantation, adsorption, centrifugation, tirturation, levigation, dialysis, extraction, (maceration, percolation, infusion, decoction, digestion)

Books Recommended

- 1. Martin, P., Bustamante, P. and Chun, A.H.C Physical and Chemical Principles of Pharmaceutical Science, 4th Edition, New York (1999).
- 2. Aulton, M.E. Pharmaceutics: The Science of Dosage Form Design. 2nd Edition, Harcourt Publisher (2002).
- Rawlins E.A. (ed.). Berdley's Textbook of Pharmaceutics, 8th (or recent edition). Macmillan Publishing Co. Inc. New York (1977).
- 4. Banker G.S. and Rhodes C.T. Modern Pharmaceutics, 4th Edition (Revised and expanded), Marcel Dekker, Inc. New York (2002).
- Carstersen J.T. and Rhodes C.T. (ed.) Drug Stability: Principles and Practices, 3rd edition (revised and expanded), Mercel Dekker, New York (2000).

PHT-401 Pharmaceutical Dosage Forms (II) (Theory) Cr. Hrs. 3

Non – Galenicals – Solid Dosage Forms

- 1. Powders: Definition, properties, advantages, disadvantages, types and preparation etc.
- 2. Tablets: Definition, types, essentials, advantages, disadvantages, formulation, manufacture, evaluation etc.
- 3. Capsules: Definition, advantages, disadvantages, types etc.
- 4. Miscellaneous: Suppositories, surgical dressings, glycerogelatins, medicated pencils, cements etc.

Non-Galenical – Semi-solid Dosage Forms

- 1. Ointment: Definition, ointment bases, preparation, dispensing etc.
- 2. *Miscellaneous:* Creams, pastes, poultices, plasters etc.

New Dosage Forms

Introduction of new dosage forms, drug delivery system and cosmetology.

- 1. Anya M. Hellery, Andrew W. Lloyd, James Swarbrick. Drug Delivery and Targeting. For Pharmacist and Pharmaceutical Scientist. Taylor and Francis Publications. (2001).
- 2. Joseph R. Robinson. Controlled Drug Delivery. Marcel Dekker Publications. (1997)
- 3. Ramabhadran T.V. Pharmaceutical Design and Development.
- 4. Aulton ME. Pharmaceutics. The Science of Dosage Forms Design.. Harcourt Publications Second Edition (2002).
- 5. Gilbert S. Banker. Modern Pharmaceutics, Marcel Dekker Publishing, Fourth Edition, (2002).

6. Loyd V. Allen, Jr. Howard C. Ansel. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. 10th Edition. Lippincott Williams E Wilkins.

PHT- 403 Pharmaceutical Microbiology (I) (Theory) Cr. Hrs. 3

1. General Microbiology

Historical introduction, scope of microbiology with special reference to pharmaceutical sciences. Nomenclature in classification of micro-organisms including virus, rickettsia, bacteria, fungi and protozoa.

2. Bacteria

Classification of bacteria, cell structure, morphology and functions, growth factors, growth characteristics and growth curve, nutritional requirement and nutritional factors effecting growth, Different type of media and staining procedures.

3. Immunology

Definitions, classifications and cellular basis of immune response, immunity, auto-immunity and tolerance. Antigen, antibody, antigen antibody reactions and their clinical and diagnostic applications. Hypersensitivity and allergy and drug allergy mechanisms. Graft reaction, autoimmune disease.

4. Infections

a. Study of infections caused by following bacterial genera:

Staphylococcus, Streptococcus, Salmonella, Cholera, Mycobacterium, Helicobacter.

Various viral and rickettsial infections including rabbies, hepititus, AIDS and other emerging patogens. Rickettsial infections including leishmania and protozoal infections including malaria and others. Normal flora of human body.

5. Microbiology of air, water and soil.

Books Recommended

- 1. Pommerville J.C., Alcamo's Fundamentals of Microbiology, Ninth Edition. Jonnes and Bartlett Publicatrions.
- 2. Jawetz, Melnick and Aldelberg's Medical Microbiology, McGraw Hill Lange Publication, 26th Edition.
- 3. Greenwood D, Barer M, Slack R, Irving W. Medical Microbiology. A Guide to microbial infections. Churchill Livingstone. Eighteenth Edition.
- 4. Tortora. G.J, Funke B.R, Case C.L. Microbiology an Introduction. Twelfth Edition. Pearson Education.

PHT-501 Pharmaceutical Microbiology (Practical) Cr. Hrs. 3

Practical Elaborating Theory Course

- 1. Sterilization of glassware and pharmaceutical products by various methods.
- 2. Preparation of general and selective media and culturing of microorganism.
- 3. Total and viable counts of microorganisms, morphological and selective biochemical characteristics of some species.
- 4. Staining of bacteria: Gram method, acid fast, Grams staining, capsule staining, flagella and spore staining.
- 5. Microbiological analysis of air, water and soil.
- 6. Microbial evaluation of pharmaceutical products.
- 7. Microbiological assays of antibiotics and vitamins.
- 8. Pyrogen test, sterility test, toxicity test

PHT-513 Computer Application in Pharmacy (Lab) Cr. Hrs. 2

- 1. Introduction to Microsoft Windows and its different packages like MS Word, Excel, PowerPoint and Access.
- 2. Internet and E-mail

Internet and Microsoft internet explorer 5, searching the internet, e-mail and news group, favorites, security and customizing explorer.

3. Web Page Development

Introduction to front page, creating a first web site, basic formatting technique, manipulating tables within front page, FrontPage, pictures and multimedia, hyperlinking, bookmarks and image maps, front page and frames, managing your web, good site design.

- 4. Complete Statistical Packages, Statistica®
- 5. Languages at least two prevailing languages will be taught.

Books Recommended

Introduction to computers, Windows 7, MS office XP.

PHT-603 Industrial Pharmacy (II) Pharmaceutical Engineering (Theory) Cr. Hrs. 3

1. Pharmaceutical Lay Out and Plant Designing

General layout and plant designing of the Pharmaceutical Industry Pharmaceutical plant construction, nature and properties of important materials employed in construction and erection of plant, convenience and storage of raw materials, semi finished and finished product.

2. Design of Sterile Area

Sterile area and its classification, ophthalmic ointments, preparation of parenterals (building, equipment), complete sterility (aseptic area), air control, (Laminar flow etc). Air locks, environmental monitoring' methods, sterilization. Filling/packaging (plastic and glass containers). Added substances (preservatives, antioxidants, solubilizer. suspending agents, buffers, stabilizers etc.)

3. Heat Transfer

4. Mass Transfer

Safety Methods in Pharmaceutical Industry Mechanical, chemical and fire hazards problems, inflammable gases and dusts.

5. Packaging Technology

Influence of packaging materials, stability, packaging lines, packaging area, and packaging equipment.

6. Equipments Used for

Patches, sprays, implants, sutures, plasters, sachet packing.

7. Study Tour

A visit of the pharmaceutical industry and training will be an integral part of syllabi

- 1. Martin, P., Bustamante, P. and Chun, A.H.C. Physical and Chemical Principles of Pharmaceutical Science, 4th Edition, New York (1999).
- 2. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- Rawlins E.A. (ed.) Berdley's Textbook of Pharmaceutics, 8th (or recent edition), Macmillan Publishing Co. Inc. New York (1977).
- 4. Banker G.S. and Rhodes C.T. Modern Pharmaceutics, 4th Edition (Revised and expanded), Marcel Dekker, Inc. New York (2002).

 Carstersen J.T. and Rhodes C.T. (ed.) Drug Stability: Principles and Practices, 3rd edition (revised and expanded), Marcel Dekker, New York (2000).

PHT-605 Industrial Pharmacy (Lab) Unit Operations Cr. Hrs. 3

1. Manufacture of Tablets by

- 2. Wet granulation method, manufacture of tablets by slugging, manufacture of tablets by direct compression method.
- 3. Coating of Tablets
- 4. Sugar coating, film coating, enteric coating.
- 5. Clarification of liquids by various processes.
- 6. Size reduction, homogenization.
- 7. Ampoule filling, sealing and sterilization clarity and leakage tests in injectable
- 8. Capsule filling by semi automatic machines.
- 9. Manufacture of sustained action drugs.
- 10. **Tablets tests**: Disintegration, dissolution, friability, hardness and thickness tests. Determination of weight variation in tablets. Density of powder. Particle size analysis.
- 11. Content uniformity test using HPLC technique, relative humidity and moisture content determination.

PHT-613 Pharmaceutical Technology (Theory) Cr. Hrs. 3

- 1. Barriers to Drug Delivery Systems (DDS)
 - a. Oral, IV, IM, Rectal, Pulmonary DDS
 - b. Reticulo-endothelial system
- 2. Principles of Non-Targeting/Conventional Pharmaceutical Formulations and Dosage Form Design
 - a. Need, product formulation and preformulation studies
 - b. Formulation development of Aerosols, Opthalmic and Parentral Preparations
 - c. Formulation development of Osmotic, Sustained-Release, Rapidly Disintegrating, Gastro-retentive drug delivery systems.
- 3. Concept of Targeting DDS
 - a. Active vs. Passive Targeting
 - b. Targeting Strategies
 - a. Environment and stimuli sensitive targeting: pH, temperature, ions, photo, magnetic, ultrasound, etc.
 - b. Regulated systems: enzyme complex etc
 - c. Ligand based targeting: Polymeric conjugates, biomacromolecular conjugates like antibody, affibody, aptamer and peptides etc
- 4. Introduction and Types of Various Dosage Forms and DDS
 - a. Nanoparticles, nanospheres, dendrimers, nanohydrogels, liposomes, niosomes, gold and iron oxide nanoparticles
 - b. Brief over view of theragnostic systems
- 5. Principles of Formulation of Novel Drug Delivery Systems
 - a. Introduction and brief overview of biomedical polymers, their physical and structure-property relationship.
 - b. Examples of bio-responsive and stimuli responsive polymers
 - c. Overview of methods to formulate polymeric nanoparticles, dendrimers, liposomes, niosomes, hydrogels and gold nanoparticles etc
 - d. Selection of ligands for delivery system with examples to targeting substrates
 - e. Formulation stability issues associated with novel DDS
- 6. Characterization Techniques for Novel DDS
 - a. Spectrophotometric (FT-IR, HPLC, UV, Fluorescence-spectroscopy, NMR etc)

- b. Partcles size characterization (SEM, TEM, DLS, Size-exclusion chromatography etc)
- c. Crystalline Structure (XRD etc)
- d. Miscellaneous techniques (AFM, Raman-spectroscopy etc)
- 7. Pharmacokinetic and pharmacological aspects of novel DDS
 - a. Clearance and in-vivo stability of novel DDS
 - b. Concept and strategies of designing long-circulating DDS
 - i. Phenomena of surface shape, charge, size and nature
 - ii. Effect of poly-ethylene glycol (PEG) and other long circulating polymers
 - c. Toxicity patterns of colloidal and novel drug delivery systems.
- 8. Drug and Disease Candidates for Novel DDS
 - a. Principles of selection of a disease
 - b. Principles of selection of drug(s) candidates for a disease
- 9. Commercial Benefits and Applications of Novel Drug Delivery Systems
 - a. Pharmaco-economic considerations
 - b. Advantages of novel DDS
 - c. Examples of commercialized novel DDS
- 10. Introduction to Pharmaceutical Bio-Technology
 - a. Introduction to basic science and application of biotechnologically derived pharmaceutical products (antibiotics, amino acids, insulin, enzymes and vaccines etc.), scope application new findings.
 - b. Role of Pharmaceutical Biotechnology in the new product development (NPD), challenges and opportunities.
- 11. Isolation and identification of suitable strains and their maintenance.
 - a. Genetic techniques for the strain improvement.
 - b. Effect of certain Bio-chemical parameters, media composition and process optimization
 - c. Isolation, extraction and purification techniques for the desired biopharmaceuticals.
 - d. Upstream and downstream processes.
 - e. Area design and quality requirements during manufacturing of biopharmaceutical.
 - f. Commercial implications of recombinant DNA technology.
 - g. The concept of gene therapy to cure genetic diseases.
- 12. Pharmaceutical Biotechnology and Health with special reference to treatment of cancer and possibly AIDS.

- 1. Gilbert S. Banker, Modern Pharmaceutics, Marcel and Dekker Publishing (20020
- 2. Pharmaceutical Biotechnology: Fundamentals and Applications October 22, 2013 by Daan J. A. Crommelin (Editor), Robert D. Sindelar (Editor), Bernd Meibohm (Editor).
- 3. Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications May 21, 2012, by Oliver Kayser (Editor), Heribert Warzecha (Editor).
- 4. Pharmaceutical Biotechnology: Concepts and Applications [Kindle Edition], Gary Walsh (Author).
- 5. Pharmaceutical Biotechnology: Concepts and Applications [Kindle Edition], Gary Walsh (Author).
- 6. "Drug Delivery: Engineering Principles for Drug Therapy" Edited by W. Mark Saltzman, Oxford University Press, Montreal Canada. (2001)
- 7. "Cellular Drug Delivery: Principles and Applications" Edited by D. Robert Lu and Svein Øie, Humana Press, Springer Science, New York, USA. (2004)
- "Biomaterials Science: An Introduction to Materials in Medicine", Third Edition by Buddy A. Ratner, Allan S. Hoffman, Frederick J. Schoen and Jack E. Lemons, Academic Press, Elsevier, Amsterdam, The Netherlands. (2013)
- 9. "Nanochemistry" by G. B. Sergeev, Elsevier Sceience, Amsterdam, The Netherlands. (2006)

10. Recent Review and tutorial articles published in high impact journals like Nature and Nature sister journals

PHT-701 Pharmaceutics-Biopharmaceutics & Cr. Hrs. 3 Pharmacokinetics Lab

- 1. To classify 4 Model drugs into respective classes of "Biopharmaceutics Classification System" according to FDA guidelines: (5 Practical to be performed)
 - a. Construction of standard curve of 4 model drugs by UV-visible spectroscopy
 - b. Construction of **pH-Solubility** profile of 4 model drugs at **pH 1.2, 4.5 and 6.8**
 - c. Calculation of **pKa** of 4 model drugs by **Handerson-Hasselbalch** equation
 - d. Determination of **log***P* values by **shake flask method** and calculation of **log***D* (**pH 1.2, 4.5 and 6.8**) values of 4 model drugs
 - e. Determination of "dissolution rate" of 4 model drugs in 30 mins by USP method I and II

Activity after 5 experiments

Finally students should discuss the results of 5 experiments and predict the Biopharmaceutics classes of the drugs their absorption site in GIT and formulation priority for the respective drugs.

2. To estimate pharmacokinetic parameters using plasma drug concentration vs time curve on semi-log graphs (manually) and comparison with parametric values obtained through data plotting and estimation by PK solver. [Each practical shall involve manual as well as software based PK calculations and then comparative assessment of parameters obtained from two methods]

(Total of 8 Experiments)

a. IV bolus administration

- i. Non-compartment
- ii. One-compartment
- iii. Two-compartments
- iv. Three-compartments
- b. Oral administration
 - i. Non-compartment
 - ii. One compartment
- c. IV infusion
- d. Urinary Excretion Data
- 3. To estimate oral pharmacokinetic parameters using plasma drug concentration vs time curve after oral administration by **Wagner-Nelson method**.
- 4. To perform **IVIVC** determination of **2 model drugs data** (dissolution and in-vivo)
 - a. By Convolution method
 - b. By De-convolution method
- 5. To prepare **plasma samples** for HPLC based analysis of 2 model drugs (high soluble and low soluble).
- 6. Introduction and performance on WinNonLin using PK data of 2 model drugs
- 7. To determine 'plasma protein binding' of 2 model drugs by
 - a. Gravimetric Method
 - b. Spectrophotometric Method
 - c. Other Relevant Method
- 8. To perform **Clinical Pharmacokinetics** based "**Therapeutic Drug Monitoring**" of models drugs according to established relevant clinical guidelines
 - a. Manual calculations based studies.
 - b. Software based (JKPD) development of "user defined model" and application
 - i. Vancomycin
 - ii. Gentamicin
 - iii. Cyclosporin

- iv. Digoxin
- v. Phenytoin
- vi. Theophylline
- vii. Carbamazepine

- 1. Bauer, L. 2008 Applied Clinical Pharmacokinetics, 2nd ed., McGraw-Hill, ISBN #0071476288
- Birkett, D.J. 2002. Pharmacokinetics Made Easy, McGraw-Hill Australia, North Ryde NSW Australia, ISBN 0 074 71072 9
- Bonate, P.L. 2011 Pharmacokinetic-Pharmacodynamic Modeling and Simulation, 2nd ed, Springer, New York, NY ISBN-13 978-1441994844
- 4. Bonate, P.L. and Howard, D.R., ed. 2004 Pharmacokinetics in Drug Development: Regulatory and Development Paradigms, Volume 2, AAPS Press, Arlington, VA ISBN 0-9711767-3-6
- 5. Boroujerdi. M. 2002 Pharmacokinetics: Principles and Applications, McGraw-Hill Professional Publishing, ISBN: 0-07135-164-7
- 6. Bourne, D.W.A. 1995 Mathematical Modeling of Pharmacokinetic Data, Technomic Publishing Company, Lancaster, PA ISBN 1-56676-204-9
- Burton, M.E., Shaw, L.M., Schentag, J.J., and Evans, W.E. (editors) 2006. Applied Pharmacokinetics & Pharmacodynamics, Principles of Therapeutic Drug Monitoring, Lippincott Williams & Wilkins, Baltimore, MD ISBN 0-7817-4431-8
- Carstensen, J.T. 1996. Modeling and Data Treatment in the Pharmaceutical Sciences, Technomic Publishing Co., Inc., Lancaster, PA ISBN 1-56676-440-8
- 9. Crommelin, D. J. A. and Sindelar, R. D., 2007 Pharmaceutical Biotechnology, 3rd ed., Taylor & Francis, Philadelphia, PA ISBN 0415285011
- 10. Crommelin, D. J. A., Sindelar, R. D., Meibohm, B., 2007 Pharmaceutical Biotechnology:
- 11. D.Argneio, D.Z. 2004 Advanced Methods of Pharmacokietic and Pharmacodynamic Sys-tems Analysis Vol.3, Kluwer Academic Publishers, Norwell, MA ISBN 1-4020-7804-8
- 12. Florence A.T. and Attwood, D. 2006 Physicochemical Principles of Pharmacy, 4th ed., Pharmaceuitcal Press, London, UK. ISBN 0 85369 608 X
- 13. Gabrielsson, J and Hjorth, S. 2012 Quantitative Pharmacology, An Introduction to Integrative Pharmacokinetic-Pharmacodynamic Analysis Swedish Pharmaceutical Press, Stockholm, Sweden ISBN 9789197945233
- 14. Gabrielsson, J. and Weiner, D. 2007 Pharmacokinetic and Pharmacodynamic Data Analysis, Concepts and Applications, 4th ed., CRC Press, Baco Raton, FL ISBN 978-9-1976-5100-4
- Gibaldi. M. and Perrier, D. 1982 Pharmacokinetics, 2nd edition, Marcel Dekker, New York. ISBN 0-8247-1042-8-6
- 16. Hedaya, M.A. 2007 Basic Pharmacokinetics, CRC Press, Baco Raton, FL ISBN 978-1-4200-4671-7
- 17. Humma, L.M., Ellingrod, V.L. and Kolesar, J.M. 2003 Lexi-Comp's Pharmacogenomics Handbook, Lexi-Comp, Hudson, OH ISBN 1-59195-060-0
- 18. Kallen, A. 2007 Computational Pharmacokinetics, CRC Press, Baco Raton, FL ISBN 978-1-4200-6065-2
- Karch, S.B. 2007 Pharmacokinetics and Pharmacodynamics of Abused Drugs, CRC Press, Boca Raton, FL ISBN 978-1-4200-5458-3
- 20. Kimko, H. and Duffull, S.B. 2002 Simulation for Designing Clinical Trials, A Pharmacokinetic-Pharmacodynamic Modeling Perspective, Marcel Dekker, New York, NY ISBN 0-8247-0862-8
- 21. Krishna, R. 2004 Applications of Pharmacokinetic Principles in Drug Development, Kluwer Academic/Plenum Publishers, New York, NY ISBN 0-306-47766-1
- 22. Krishna R. 2006 Dose Optimization in Drug Development Taylor and Francis/Informa Healthcare ISBN: 1574448080
- 23. Krishna, R. and Yu, L., 2008 Biopharmaceutics Applications in Drug Development, Springer ISBN: 978-0-387-72378-5
- 24. Kwon, Y. 2001 Handbook of Essential Pharmacokinetics, Pharmacodynamics, and Drug Metabolism for Industrial Scientists, Kluwer Academic/Plenum Publishers, New York, NY ISBN 0-306-46234-6
- Meibohm, B., 2006 Pharmacokinetics and Pharmacodynamics of Biotech Drugs: Principles and Case Studies in Drug Development, Wiley-VCH, Weinheim, Germany. ISBN 3-527-31408-3
- 26. Murphy J.E. 2001 Clinical Pharmacokinetics, 2nd ed., American Society of Health-System Pharmacists, Bethesda, MD ISBN 1-879907-98-4

- 27. Notari, R.E. 1987 Biopharmaceutics and Clinical Pharmacokinetics, 4th edition, Dekker. New York, NY ISBN 0-8247-7523-6
- 28. Peters, S.A. 2012 Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations Principles, Methods, and Applications in the Pharmaceutical Industry, Wiley, ISBN 978-0-470-48406-7
- 29. Reddy, M.B., Yang, R.S.H., Clewell, H.J. and Andersen, M.E. 2005 Physiologically Based Pharmacokinetic Modeling, Wiley, Hoboken, NJ ISBN 0-471-47814-8
- 30. Ritschel, W.A. and Kearns, G.L. 2004 Handbook of Basic Pharmacokinetics ... including Clinical Applications, 6th ed., American Pharmaceutical Association, Washington, DC ISBN 1-58212-054-4
- 31. Rowe, P. 2012 Pharmacokinetics, Free at bookboon.com ISBN 978-87-403-0090-1
- 32. Schoenwald, R.D. 2002 Pharmacokinetics in Drug Discovery and Development, CRC Press, Boca Raton, FL ISBN 1-56676-973-6
- 33. Semla, T.P., Beizer, J.L. and Higbee, M.D. 2003 Lexi-Comp's Geriatric Dosage Handbook, 9th ed., Lexi-Comp, Hudson, OH ISBN 1-59195-067-8
- 34. Shargel, L., Wu-Pong, S. and Yu, A.B.C. 2012 Applied Biopharmaceutics and Pharmacokinetics, 6th ed., McGraw-Hill, New York, NY ISBN 978-0-07-160393-5
- 35. Testa, B., van de Waterbeemd, H., Folkers, G., and Guy, R. (ed) 2001 Pharmacokinetic Optimization in Drug Research, Verlag Helvetica Chimica Acta, Zurich, ISBN 3-906390-225
- Tozer, T.N. and Rowland, M. 2006 Introduction to Pharmacokinetics and Pharmacodynamic: The Quantitative Basis of Drug Therapy, Lippincott Williams & Wilkins, Baltimore, MD ISBN 0-7817-5149-7
- 37. Wagner, J.G. 1975 Fundamentals of Clinical Pharmacokinetics, Drug Intelligence
- 38. Wagner, J.G. 1993. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing Company, Lancaster, PA ISBN 1-56676-032-1
- 39. Washington, N., Washington C. and Wilson, C.G. 2001 Physiological Pharmaceutics, Barriers to Drug Absorption, Taylor and Francis, Inc., New York, NY ISBN 0-748-40562-3
- Winter, M.E. 2004 Basic Clinical Pharmacokinetics, 4th ed., Lippincott Williams & Wilkins, Baltimore, MD ISBN 0-7817-4147-5

PHT-703

Forensic Pharmacy

Cr. Hrs. 3

- Study of Drug Laws
 The Drugs Act 1976 and rules framed there under. Provincial drug rules (Respective Drug Rules will be taught in the relevant province). Advertisement rules. Other related rules and Legal aspects.
- 2. The Pharmacy Act 1967 and Amendate Pharmacy Act of 1971
- 3. The Dangerous Drugs Act, 1930
- 4. The Factory Law 1934
- 5. Shops and Establishment Ordinance, 1969 with rules
- 6. The Poisons Act 1919
- 7. Control of narcotics substances Act 1997

Books Recommended

- 1. The Manual of Drug Laws in Pakistan.
- 2. The Factory Law (1934).
- 3. Shop and Establishment Ordinance (1969).
- 4. Control of Narcotics Substances Act (1997).

SECOND SEMESTER

PHT-302 Pharmaceutical Dosage Forms Theory (I) Cr. Hr. 3

1. Classification of Pharmaceutical Dosage Forms

Significance of classification, different classifications based on the following; methods of preparation. Galenicals and non-galenicals preparations, sterile and non-sterile preparations. Physical classification,

pharmacological classification, classification according to mode of application, Pharmaceutical classification according to release of drug, conventional dosage forms, time release products, repeat action products, prolonged action products, sustained released products, classification according to name of manufactures.

2. Pharmaceutical Dosage Forms

Galenical liquid aqueous dosage forms

Infusions, decoctions, galenical liquid non-aqueous dosage forms, alcoholic dosage forms (tinctures, fluidextracts), oleagenous dosage forms (oleoresins, infused oils), galenical solid dosage forms. Extracts, resins.

Non galenical aqueous liquid dosage forms

Aqueous dosage forms, waters, diluted acids solutions, douches, enemas, gargles, washes, juices, ophthalmic solutions. Sweet viscid aqueous dosage forms, syrups, honeys, mucilages, jellies, aqueous suspensions, suspensions, mixtures, magmas, gels, lotions.

Non-glaenical non-aqueous dosage forms

Alcoholic solutions, spirits, elixirs, dental liniments, etherial solutions (collodions), glycerine solution (glycerites), oleagenous dosage forms (oleovitamins, toothache drops, inhalations, sprays, liniments, emulsions.

3. Parenterals

Definition, history, types, advantages, disadvantages uses, parenteral production area, containers and closures vehicles, pyrogens, requirements, manufacturing, testing etc.

Books Recommended

- 1. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- Rawlins E.A. (ed.). Bentley's Textbook of Pharmaceutics, 8th (or recent edition). Macmillan Publishing Co. Inc. New York (1985).
- 3. Alfonso R Gennaro. Remington The Science and Practice of Pharmacy 20th Edition. Mack Publishing Company. (2002).
- 4. Winfield J. and Richards RME. Pharmaceutical Practice. Second Edition. Prentice Hall Publishing. (2004).

PHT-402 Pharmaceutical Dosage Forms (Lab) Cr. Hrs. 3

Practical Elaborating Theory Course

Preparation of simple syrups, emulsions. Ointments, lotions, throat paints, glycerites, linimints, sprits, poultices, granules.

Books Recommended

- 1. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- Rawlins E.A. (ed.). Bentley's Textbook of Pharmaceutics, 8th (or recent edition). Macmillan Publishing Co. Inc. New York (1985).

PHT-404 Pharmaceutical Microbiology (II) (Theory) Cr. Hrs. 3

1. Sterilization and Disinfection

Methods of sterilization and disinfection, mechanism of killing. Kinetics of death of micro-organism, evaluation of sterilization and disinfection procedures.

2. Fermentation

Fermentation and respiration, ranges of fermentation, parameters of fermentation. Production of pharmacologically active fermentation products, selection of a suitable medium, isolation and recovery, kinetics of microbial growth, continuous culture application in fermentation, engineering aspect of fermentation.

3. Biologicals

Vaccines, classification of vaccines, production of vaccines and antisera. DNA recombinant technology for preparing vaccines Hormones and other biologicals. Pyrogen, sterility and toxicity tests.

4. Antibiotics

Definitions, classification of antibiotics, mode of actions, antimicrobial spectrum and side effects of different groups of antibiotics.

5. Factory and Hospital Hygiene

Introduction, control of microbial contamination during manufacturing, manufacturing of sterile products.

Books Recommended

- 1. Hugo W.B. and Russell A.D. Pharmaceutical Microbiology.
- 2. Presscot and Dunn Industrial Microbiology.
- 3. Daan JA Crommelin, Robert D Sindelar. Pharmaceutical Bio-technology. An Introduction for Pharmacist and Pharmaceutical Scientist. Harwood Academic Publishers. (1997).
- 4. Pelczar and Chan Microbiology.
- 5. Meckallee M. Microbiology Essentials and Applications by Collen and Lynes. Microbiology Methods.

PHT-414 Physical Pharmacy Cr. Hrs. 3

1. **Physico-chemical Principles**

Solutions: Introduction, types, concentration expressions ideal and real solution, colligative properties, their mathematical derivations and application in Pharmacy, molecular weight determinations, distribution co-efficient and its applications in Pharmacy solubilization, solubility factor affecting solubility. HLB-value, surfactants, their properties and types. Micelles, their formulation and types, ionization. pH, pH indicators, pK_a, buffer's equation. Isotonic solutions and their applications in pharmacy.

2. Micromeritics

Particle size and shapes, distribution of particles methods of determination of particle size and importance of particle size in pharmacy.

3. Dispersion

Colloids: Types, methods of preparation, properties (optional, kinetic, electrical). Dialysis and artificial kidney, stability of colloids, protection and sensitization phenomenon and application of colloids in Pharmacy. *Emulsions:* Types, theories of emulsification, emulsifying agents their classification and stability of emulsion.

Suspensions: Types, methods of preparation, properties, suspending agents, their classification and stability. *Adsorption:* Techniques and processes of adsorption in detail.

4. Rheology

Definition and fundamental concept. Properties contributing to rheological behaviour. Graphic presentation of rheological data.

5. Rate and order of reactions.

6. Kinetic Principles and Stability Testing, Theoretical Considerations

Degradation, physical factors, influence of pH, temperature, ionic strength, acid base catalysis, UV light. Chemical factors. Complex chemical reactions, oxidation-reduction hydrolysis.

Books Recommended

- 1. Martin, P., Bustamante, P. and Chun, A.H.C. Physical and Chemical Principles of Pharmaceutical Science, 4th Edition; New York (1999).
- 2. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- Rawlins E.A. (ed.) Bentley's Textbook of Pharmaceutics, 8th (or recent edition). Macmillan Publishing Co. Inc. New York (1977).
- 4. Banker G.S. and Rhodes C.T. Modern Pharmaceutics, 4th Edition (Revised and expanded), Marcel Dekker, Inc. New York (2002).
- 5. Carstensen J.T. and Rhodes C.T. (ed.) Drug Stability: Principles and Practices, 3rd edition (revised and expanded), Marcel Dekker, New York (2000).

PHT-502

Physical Pharmacy (Lab)

Cr. Hrs. 3

Practical Elaborating Theory Course

Experiments to demonstrate some of physico-chemical processes, like simple distillation, steam distillation, crystallization, Dialysis.

Determination of emulsion systems. Practicals based on rheological and structural character of emulsions stabilized by mixed films of emulsifier.

Determination of particle size, angle of repose of powders. Preparation of buffer solutions and isotonic solution.

Determination of percentage composition of solutions by specific gravity method.

Partition-coefficient, surface tensions, viscosity.

Determination of various pH by acidic and alkaline buffers.

Drug stability experiments, preparation of stock solution (dilution method).

Determination of critical micelle concentration (CMC) of a surface active agents. Flocculation and deflocculation of Kaolin Suspensions.

Books Recommended

- 1. Martin, P., Bustamante, P. and Chun, A.H.C. Physical and Chemical Principles of Pharmaceutical Science, 4th Edition, New York (1999).
- 2. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- Rawlins E.A. (ed.) Berdley's Textbook of Pharmaceutics, 8th (or recent edition), Macmillan Publishing Co. Inc. New York (1977).
- 4. Banker G.S. and Rhodes C.T. Modern Pharmaceutics, 4th Edition (Revised and expanded), Marcel Dekker, Inc. New York (2002).
- 5. Carstersen J.T. and Rhodes C.T. (ed.) Drug Stability: Principles and Practices, 3rd edition (revised and expanded), Marcel Dekker, New York (2000).

PHT-504 Industrial Pharmacy (I) Pharmaceutical Unit Operations (Theory) Cr. Hrs. 3

Mixing

Fundamentals, mechanism. Mixing equipment used in liquid/liquid, liquid/solid and solid/solid mixing. Comminution (size reduction), Reasons for size reduction. Factors affecting size reduction, size analysis. Sieving, energy mills (Ball mill, edrunner, edge runner mill disintegrant, colloid mill, hammer mill, cutter mill, fluid energy mill etc.).

Drying

Theories of drying, drying of solids, classification of dryers, general methods, fluidized bed systems, pneumatic systems, spray dryer, freeze drying

Clarification and Filtration

Theory, filler media, filter aids, filter selection, equipment used for filtration.

Evaporation

General principles of evaporation, evaporators, evaporation under reduced pressure.

Compression and Compaction

The solid-air interface, angle of repose, flow rates, mass volume relationship, density, Heckel plots, consolidation, granulation, friability, compression (dry method, wet method, slugging), physics of tableting. Tableting machines and other equipment required, problems involved in tableting, tablet coating.

Encapsulation

Capsulation hard and soft gelatin capsules.

Books Recommended

- 1. Aulton M.E. Pharmaceutics. The Science of Dosage Form Design. Harcourt Publishers. Second Edition (2002).
- 2. Leon Lachman, Lea and Febiger. Theory and Practice of Industrial Pharmacy (1986).
- 3. James Swarbrick. Encyclopedia of Pharmaceutical Technology, Marcel and Dekker Publishing (2002).

PHT-604 Bio-Pharmaceutics and Pharmacokinetics (I) Cr. Hrs. 3 (Theory)

1. Biopharmaceutics

Definition and concept, bioavailability, physiology of the G.I.T. Physiologic factor affecting the physiochemical. Formulation factor. Dissolution, factor effecting the dissolution for the absorption of the drug. Physiology of the skin. Physiological factor effect the absorption of the drug through the skin. Parenteral release dosage form. Route

of administration, physiological factor effecting the absorption of the drug. Bio-pharmaceutics of other dosage form.

2. Pharmacokinetics

Review of mechanical fundamentals, rate and order of reaction. Definition and concept of pharmacokinetics. Determination through plasma level.

Books Recommended

- 1. Leon Shargel. Biopharmaceutics and Pharmacokinetics. Fourth Edition (2002).
- 2. Ronald D. Schoenwald. Pharmacokinetics Principles of Dosing Adjustment. (2002).
- 3. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Fourth Edition (1991).

PHT-606 Clinical Pharmacokinetics (II) Cr. Hrs. 3

Compartment models. One compartment model. Two compartment models. Three compartment models. Noncompartmental models. Biological half-life in vitamin. Clearance, elevation. Protein bounding. Multiple dosage Application of pharmacokinetics in clinical situation. Application in dosage sites. Bioavailability and bioequivalence testing.

Pharmacokinetics of intravenous infusion.

PHT-614 Pharmaceutical Technology (Lab) Cr. Hrs. 3

- 1. To prepare matrix tablet of drugs by single-punch machine
 - a. Preparation of matrix tablet for less water soluble drug
 - b. Preparation of matrix tablet for highly water soluble drug
 - c. Perform dissolution testing by USP method I and II
- 2. Formulation of 2 Model Drugs (highly soluble and less soluble) in Nano particles/Micro particles
 - a. To prepare polymeric Nano/Micro particles by single / double emulsion / nanoprecipitation method(s)
 - i. Hydrophilic drugs by double emulsion method
 - ii. Hydrophobic drugs by single emulsion method
 - iii. Hydrophobic drugs by nanoprecipitation method
 - b. To visualize the nano/microparticles under stereromicroscope
 - c. To perform the release testing of 2 model drugs from nanoparticles stirring method (UV-visible spectroscopy)
- 3. To prepare the oral formulation of drugs by extrusion/spheronization method
 - a. Matrix based pellets
 - b. Coated pellets (perform coating)
 - c. Pellitization to form immediate release, controlled/extended release and enteric coated pellets.
- 4. To observe the geometry and surface of spheronized formulation (pellets) by stereomicroscope
- 5. To perform the release testing of drugs from spheronized (pellets) particles by USP method I and II
- 6. To compare and study the swelling and disintegration profile (physical deformation) of expired vs. valid film, enteric coated tablets and hard gelatin capsules [the experiment involves the physical phenomena that happens to expired tablets specially the coating of polymers since they tend to be oxidized or cured over the period of time and may hamper the disintegration of tablets and capsules.
- 7. To develop transdermal patches of suitable active pharmaceutical excipients.
- 8. To develop bilayer-tablet formulations of different active pharmaceutical ingredients.
- 9. Fast dispersible tablet formulations different NSAIDs.
- 10. To develop osmotically-controlled tablet formulations for control over extended period of time.
- 11. To preparation pharmaceutical hydrogels
- 12. To prepare liposomal formulations of 2 model drugs (highly soluble and low soluble)

PHT-702 Prescription Pharmacy and Community Cr. Hrs. 3 Pharmacy

1. Basic Principles of Compounding and Dispensing

Weights and measures. Calculations for compounding and dispensing. Fundamental preparations in compounding. Containers and closures for different products. Prescription handing, Parts of prescription, filling, labelling, pricing of dispensed medication.

- 2. Extemporaneous Dispensing
- 3. **Pharmaceutical Incompatibilities** Types of incompatibilities. Manifestations, correction and prevention with reference to typical examples.
- 4. I. V. admixtures
- 5. Dispensing of radio pharmaceuticals
- 6. Definitions and background of community pharmacy
- 7. Epidemiology and its control. Prevents Health (EPI & CDC). Family planning. Health policy and National drug policy.
- 8. Patient assessment.
- 9. Medical compilation of drug administration (General & Socio-economic Aspects).
- 10. Patient pharmacist communication.
- 11. Patient education and counseling.
- 12. Control of drug abuse and misuse.
- 13. Role of pharmacist as Public Health Educator in the community for drug monitoring and drug information

Books Recommended

- 1. Carter SJ. Cooper and Guns. Dispensing for Pharmaceutical Students (1997).
- 2. Roy Robertson. Management of Drug Users in the Community: A practical Handbook edited.
- 3. Alfonso R Gennaro. Remington The Science and Practice of Pharmacy 20th Edition. Mack Publishing Company (2002).
- 4. Martindale's Extra Pharmacopoeia. 32nd edition. (2002).

PHT-704 Pharmaceutical Management and Marketing Cr. Hrs.3 (Theory)

Management

Nature and principles of management, types and functions of managers.

Planning

Purpose and types of planning, steps in planning. Organizing, management control systems. Purpose, steps in the control process. Forms of operations control. Requirements for adequate control. Critical control points and standards. Motivation, innovation and creativity, communication.

Production Management

Material management, supply chain, demand management, regulatory control.

Marketing Management

Marketing channels, promotion, advertising and salesmanship. Promotion marketing.

Sales Management

Personnel, buying, receiving and pricing, Sales promotion and customer services.

Pharmacy Layout Design

Objectives of layout design. Types of community pharmacies. Pharmaceutical centre, prescription-oriented pharmacies, traditional pharmacies, the super drug store.

Consumer goods and purchases. Classes of layout designs. Principles and characteristics of layout design. Traffic flow analysis.

- 1. Patrick Tharp C. and Pedro J. Lecca. Pharmacy Management for students and practitioners.
- 2. Harry A. Smith. Principles and Methods of Pharmacy Management.

- 3. Dalton E. McFarland. Management Foundations and Practices.
- 4. Kreitner. Management.
- 5. Newman and Summer. The Process of Management.

PHT-706 Prescription Pharmacy (Lab) Cr. Hrs. 3

Practicals Elaborating Theory Course

Preparation and dispensing of:

Syrups, Mixtures, Ointments, Creams, Lotions, Pastes, Ear drops, Glycerite, Mouth wash, Nasal drops etc.

PHT-708 Pharmaceutical Quality Control and Quality Cr. Hrs. 3

Assurance (Theory)

1. Validation of Pharmaceutical Process

Control of components and drug product containers and doses. Production and process controls. Packaging and labelling controls. Holding and distribution. Repackaging and relabelling. Regulating basis for person validation, sterilization validation of sterile products. Sterile product validation. Validation of solid dosage form. Process validation and quality assurance. Prospective process validation, validation for water system for sterile and non-sterile products, cleaning validation, equipment validation, process validation of raw materials. Analytical method validation, computer system validation, validation of diluted aerosole

2. **Different Quality Control tests** of liquids, emulsion, solid state and time release product. Biological assays. Biological methods. Bioassay of antibiotics. Standard preparation and unit of activity. Assay of vitamins, hormones miscellaneous tests. Toxicity tests and identification test, ash contents etc. General knowledge of B.P, B.P.C. USP, N. etc. Statistical interpretation of quality controls data. Quality control and assurance of hospital and clinical pharmacy.

- 1. Sydney H. Willig. Good Manufacturing Practices for Pharmaceuticals. Marcel Dekker Publishing.
- 2. Pharmaceutical Process Validation. Marcel Dekker Publishing (1999)
- 3. Joseph. T. Dipiro. Encyclopedia of Pharmaceutical Technology. Marcel Dekker Publishing (2003).