

Scheme of Studies for M. Phil in Pharmacy

M. Phil Course work: 24 Credit Hours

1st Semester: 12 Credit hours

2nd Semester: 12 Credit hours

M. Phil Thesis: 12 Credit Hours

1st Semester

Specialty Courses

Course Code	Course Title	Credit Hours
PMY 701	Pharmaceutics-I	2 + 1
PMY 702	Pharmacokinetics and Biopharmaceutics	2 + 1
PMY 703	Research Methodology	2 + 0

Compulsory Courses

Course Code	Course Title	Credit Hours
BMS 704	Bio safety & One health	1 + 1

Elective Courses

Course Code	Course Title	Credit Hours
PMY 704	Transdermal drug delivery system (TDDS)	2 + 0
PMY 705	Stability of Pharmaceutical Products	2 + 0

2nd Semester

Specialty Courses

Course Code	Course Title	Credit Hours
PMY 706	Pharmaceutics-II	2 + 1
PMY 707	Formulation Design and Product Development	2 + 1
PMY 708	Smart Drug Delivery Systems	2 + 0

Compulsory Course

Course Code	Course Title	Credit Hours
PMY 709	Pharmaceutical Biostatistics	2 + 0

Elective Courses

Course Code	Course Title	Credit Hours
BMS 740	Research Techniques Basic instrumentation	1 + 1
PMY 710	Pharmaceutical Microbiology	2 + 0

Thesis

BMS 799	Thesis	12
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PMY 701 (Cr 2+1, Specialty)

PHARMACEUTICS-I

Course Objectives:

- To provide students with a broad perspective on the emerging field of pharmaceuticals.
- To enable graduates to formulate and assess experimental design for solving theoretical and experimental problems in pharmaceuticals.
- To provide in-depth understanding in a particular research specialty/interest.
- To provide students with the knowledge to design target specific delivery systems.

Course Outlines:

1. Advances in pharmaceutical tablet formulations; multilayered tablets, ODT and FDT technologies, mucoadhesive tablets, fixed dose combinations.
2. Pharmaceutical Incompatibilities.
3. Polymers used in advanced drug delivery systems and different approaches to alter the properties of these polymers.
4. New approaches for Colon targeted drug delivery;
 - a. Primary approaches
 - pH dependent drug delivery system
 - Delayed or time-controlled drug delivery system
 - Microflora activated drug delivery system
 - Prodrug approach
 - Polysaccharide based system
 - b. New approaches for colon targeted drug delivery
 - Pressure controlled drug delivery system (PCDDS)
 - CODE
 - Osmotic controlled drug delivery system (OROS-CT)
 - Pulsatile

- Pulsincap system
 - Port system
 - Hydrogels
 - Multiparticulate system-based drug delivery
5. Surfactants: Classification and their applications in Pharmaceutical Dosage Forms.
 6. Radiopharmaceuticals.

Recommended Books

- Taylor, K. M., & Aulton, M. E. (Eds.). (2021). Aulton's pharmaceuticals E-Book: The design and manufacture of medicines. Elsevier Health Sciences.
- Mannhold, R., Buschmann, H., & Holenz, J. (2019). Innovative Dosage Forms: Design and Development at Early Stage (Vol. 76). John Wiley & Sons.
- Denton, P., & Rostron, C. (Eds.). (2013). Pharmaceuticals: the science of medicine design. Integrated Foundations of Phar.
- Jain, S. K., Soni, V., & Rawlins, E. A. (2012). Textbook of pharmaceuticals. Reed Elsevier India Private Limited.
- Nickerson, B. (Ed.). (2011). Sample Preparation of Pharmaceutical Dosage Forms: challenges and strategies for sample preparation and extraction. Springer Science & Business Media.
- James Swarbrick (2002), Encyclopedia of pharmaceutical technology. 2nd ed., Marcel Dekker Publishing, New York, USA.
- Banker, G. S., Siepmann, J., & Rhodes, C. (Eds.). (2002). Modern pharmaceuticals. CRC Press.
- AK, Ø. G. (2001). Introduction of Pharmaceuticals-1. CBS Publishers & Distributors, New Delhi, India.

Journals:

- Pharmaceuticals
- International Journal of Pharmaceuticals
- Drug Delivery
- Carbohydrates
- Cellulose
- Journal of Drug Delivery Science and Technology
- Frontiers in Drug Delivery
- International Journal of Biological Macromolecules

PMY 702 (Cr 2+1, Specialty)

PHARMACOKINETICS AND BIOPHARMACEUTICS

Course Objectives:

- To provide an in-depth understanding of the pharmacokinetic principles and biopharmaceutical concepts.
- To understand how the pharmacokinetic principles affect drug absorption, distribution, metabolism and elimination.
- To know how to apply mathematical models to predict drug behavior in the body.
- To have knowledge about how to optimize dosage regimens and understand the impact of physiological factors on drug disposition.

Course Outlines:

1. Introduction to Pharmacokinetic and Biopharmaceutics
2. Factors influencing drug's Absorption, distribution, metabolism and elimination.
3. Compartmental pharmacokinetic models
4. Linear and non-linear Pharmacokinetics
5. Pharmacokinetic modeling and dose optimization
6. Drug-drug interactions and their implications
7. Pharmacokinetic considerations in special populations
8. In vitro-in vivo correlation (IVIVC) and bioavailability/bioequivalence studies
9. Pharmacogenetics

Recommended Books

- Shargel L (2015), Applied Pharmacokinetics and Biopharmaceutics (7th Ed.), McGraw Hill / Medical.
- Sinko, P. J. (2023). Martin's physical pharmacy and pharmaceutical sciences. Lippincott Williams & Wilkins.
- Allen, L., & Ansel, H. C. (2013). Ansel's pharmaceutical dosage forms and drug delivery systems. Lippincott Williams & Wilkins.
- Shargel L, Yu A, Wu-Pong S (2012), Applied Biopharmaceutics & Pharmacokinetics, (6th Edition), McGraw-Hill Education / Medical.
- Curry SH (2010), Drug disposition and pharmacokinetics, Black Well Scientific Publishing, Oxford, UK.
- Tipnis H.P and Bajaj A, (2019), Principles and Applications of Biopharmaceutics and Pharmacokinetics, Pharma Career Publications.
- Li AP (2004), In vitro Approaches for Evaluation of Drug Efficacy and Toxicity, CRC Press, Boca Raton, Florida, USA.

Journals:

- Journal of Pharmacokinetics and Pharmacodynamics
- Biopharmaceutics and Drug Disposition
- Drug Metabolism and Pharmacokinetics
- Molecular Pharmaceutics
- Pakistan Journal of Pharmaceutical Sciences
- Pharmaceutics
- International Journal of Pharmaceutics
- European Journal of Pharmaceutics and Biopharmaceutics

PMY 703 (Cr 2+0, Specialty)

RESEARCH METHODOLOGY

Course Objectives:

- To have a better understanding of doing scientific research, provide practical advice, and insight into the field.
- To enable students to formulate hypothesis, construct theories, learn data collection techniques and ethical issues in research and design.
- To enable the students to distinguish among different types of research, tools used and their relative roles and reliability.

- To enable the students how to write interpret and publish the data.

Course Outlines:

1. Introduction
 - a. Concept of Research
 - b. The nature of the research process.
 - c. Ethics in research.
2. Types Of Research, Tools of research (library, statistics, computer technology & measurement)
3. Starting A Research Project / Research Proposal
 - a. Choosing research topics and developing the research.
 - b. Questions and hypotheses.
 - c. Writing a Research Proposal.
4. Writing Styles For Publication Purposes
 - a. Critique
 - b. Literature Review
 - c. Research Ethics.
5. Research Design
 - a. Reliability
 - b. Validity
 - c. Generalizability
 - d. Control
 - e. Reflexivity
 - f. Triangulation
 - g. Tradeoffs in design decisions.
6. Origins Of Research Questions
 - a. Creativity
 - b. Literature review
 - c. Secondary analysis.
7. Questionnaire design
 - a. Codebooks
 - b. Reliability
 - c. Types of scales
 - d. Validity of scales
 - e. Indices
8. Building the oral presentation of the research proposal
 - a. Visual aids and information system tools
 - b. Organizing the presentation.
9. Building the written presentation of the research results
 - a. Methods of keeping notes
 - b. Journal-writing
 - c. Thesis.
10. Fundamentals of experimental and Quasi-Experimental designs
 - a. Threats to internal and external validity.
11. Qualitative Research Designs
 - a. Focus groups
 - b. In-depth interviews.
12. Sampling, Generalizability & Causality
 - a. Effects on statistical inference
 - b. Block designs

- c. Expanded designs
- d. Single subject research designs
- 13. Survey Methods
 - a. Special Topics in Survey Research
 - b. Social Network Analysis
 - c. Time-use Analysis
 - d. Special Issues in Research.
- 14. Conferences
 - a. Publishing
 - b. Life as a Student in Academia (Research)
- 15. Plagiarism
 - a. Intellectual Property Right
 - b. Plagiarism
 - c. Avoiding Plagiarism
- 16. Bibliography
 - Bibliography
 - In-Text citation
 - Modern Language Association (MLA) system of Bibliography
 - Harvard system of Bibliography
 - American Psychological Association (APA) system of Bibliography

Recommended Books

- Zina, O. (2021). The essential guide to doing your research project. Sage.
- OâÂ Â²Leary, Z. (2017). The Essential Guide to Doing Your Research Project. The Essential Guide to Doing Your Research Project, 1-415.
- Merriam, S. B., & Tisdell, E. J. (2015). Qualitative research: A guide to design and implementation. John Wiley & Sons.
- Creswell, J. W., & Creswell, J. D. (2017). Research design: Qualitative, quantitative, and mixed methods approaches. Sage publications.
- Booth, W. C., Colomb, G. G., & Williams, J. M. (2003). The craft of research. University of Chicago press.
- Robson C (2002), Real World Research: A Resource for Social Scientists and Practitioners (2nd Ed.), Blackwell Publishers, Oxford, UK.
- Rudestam KE, Newton RR (2000) Surviving Your Dissertation: A Comprehensive Guide to Content and Process (2nd Ed.), SAGE Publications, Los Angeles, USA.

Journals:

- BMC Medical Research Methodology
- Research Methods & Evaluation
- Methodological Innovations
- International Journal of Social Research Methodology

BMS 704 (Cr 1+1, Compulsory)

BIOSAFETY AND ONE HEALTH

i. Biosafety

Course Objectives:

- To empower students with the skills, tools, and confidence on sustainable bio-risk management.
- To enable them to apply principles of biosafety and biosecurity in facilities.
- To reduce/eliminate the risk of infection in laboratory setting.
- Comprehend basics of research in light of modern ethics.
- Comprehend basic knowledge of the ethical issues in biomedical research.
- Select and design research project and critically analyze and communicate scientific data.
- Analyze literature critically and comprehend the foundations of Bioethics theories.
- how to deal with patients within the boundaries of biomedical ethics.
- how to improve the basic health care services on ethical grounds.

Course Contents:

1. Biorisk management (BRM) introduction, scope & importance
2. Terminology
3. Assessment, Mitigation, and Performance (AMP) Model – brief introduction
4. Biorisk assessment
 - a. Hazards & threat identification & analysis (frequency and magnitude)
 - b. Levels of biological risks
 - c. Likelihood & consequences evaluation
5. Biorisk mitigation – introduction/ brief account of a-e
 - a. Elimination & substitution
 - b. Engineering control
 - c. Administrative control
 - d. Practices & procedures
 - e. PPE
6. Performance – introduction
 - a. Key elements of performance
 - b. Control (monitoring protocols)
 - c. Assurance
 - d. Improvement
7. **Biosafety** – Introduction, purpose, requirement
 - a. Biosafety Levels – brief description of levels 1 – 4
 - b. BSL-1
 - c. BSL-2
 - d. BSL-3
 - e. BSL-4
 - f. Laboratory Design & Facilities
8. GLWPs - importance
 - a. Responsibility for enforcing GLWPs
 - b. Barriers to glwps
 - c. Lab equipment calibration & validation
9. PPE, **Biosecurity** – introduction, principles, history, objective
 - a. Key pillars of biosecurity
 - Physical security
 - Personal management
 - Information security
 - Transport security
 - Material control & accountability

- b. Incident Management: Scope
- c. Incident response system
- d. Incident reporting
- 10. Waste management: Collection, segregation, transportation, storage & disposal
- 11. Decontamination
- 12. Introduction to medical/bioethics
- 13. Ethical Theories
- 14. Historic perspective of bioethics in the development of vaccines and medicine and clinical trials, The Four Basic Principles of bioethics and their importance in research, Ethical justification and scientific validity of biomedical research involving human subjects
- 15. Ethical review committees. Ethical review of externally sponsored research,
- 16. Obtaining informed consent: Essential information for prospective research subjects, Inducement to participate in research, Benefits and risks of study participation.
- 17. Ethical justification of research involving individuals who are not capable of giving informed consent, Children, mentally retarded, behavioural disorders, Choice of control in clinical trials, and Research involving vulnerable persons, children, women and pregnant women.
- 18. Safeguarding confidentiality, Bioethical research involving animals and research misconduct.

Recommended Readings:

- Uzochukwu, S. V. A. (Ed.). (2022). Biosafety and Bioethics in Biotechnology: Policy, Advocacy, and Capacity Building. CRC Press.
- Beauchamp, T., & Childress, J. (2019). Principles of biomedical ethics: marking its fortieth anniversary. *The American Journal of Bioethics*, 19(11), 9-12.
- Council, G. M. (2013). Good medical practice. London: GMC.
- Kuhse, H., Sch, U., & Singer, P. (Eds.). (2015). *Bioethics: an anthology*. John Wiley & Sons.
- Sateesh, M. K. (2013). *Bioethics and biosafety*. IK International Pvt Ltd.
- Montanari Vergallo, G., Busardò, F. P., Zaami, S., & Marinelli, E. (2016). The static evolution of the new Italian code of medical ethics. *European Review for Medical & Pharmacological Sciences*, 20(3).
- National Treatment Agency for Substance Misuse. (2006). Models of care for treatment of adult drug misusers: Update 2006. NTA.

Journals:

- Biosafety and Health
- BMC Medical Ethics
- Journal of Bioethical inquiry
- Journal of Biosafety and Biosecurity
- Bioethics
- Applied biosafety
- Journal of Biosafety
- Cambridge Quarterly of Healthcare Ethics
- Hastings Center Report
- Journal of Clinical Ethics
- Journal of Medical Ethics

- The American Journal of Ethics
- Journal of Medicine and Philosophy
- Medicolegal and Bioethics

ii. One Health

This course is an introduction to the One Health approach of cross-disciplinary problem solving. Students will be introduced to the disciplines of infectious disease prevention and control through partnerships between human health, animal health, and environmental health. Through the cross-disciplinary One Health approach professionals are tackling public health's most difficult problems such as epidemics of zoonotic diseases and international food safety. The course will introduce students to infectious disease surveillance, diagnostic tools, outbreak investigations, vaccine trials, public health interventions, food safety, biodefense, emerging infectious diseases, and analytical approaches pertaining to infectious disease prevention and control.

Course Objectives:

The course is designed with under-mentioned objectives:

- Understand the value of the One Health approach in tackling difficult public health problems.
- Understand the etiologic, environmental, and host factors important to infectious disease epidemiology.
- Understand the value of epidemiological principles and methods in the identification and control of infectious disease.
- Develop skills needed to apply epidemiological principles and methods in solving problems related to infectious diseases and including identifying surveillance and control measures given a specific infectious disease outbreak.

Course Contents:

1. One Health: Introduction to the One Health Approach – To introduce students to the principles of employing the One Health approach in preventing and controlling infectious diseases. It includes a practical overview of host factors, environmental factors, and microbiological factors that influence this dynamic field of study. Through lectures and exercises, students will be introduced to infectious disease surveillance, diagnostic tools, outbreak investigations, vaccine trials, public health interventions, biodefense, emerging infectious diseases and analytical approaches as they pertain to infectious disease prevention and control.
2. One Health: Public Health Laboratory Techniques – To introduce students to public health laboratory methods. A special emphasis will be placed upon respiratory virus work, especially influenza.
3. One Health: An Introduction to Entomology, Zoonotic Diseases, and Food Safety – To introduce students to the epidemiology and control of entomological, zoonotic, and food-borne diseases. Each day there will be 3 hours of lecture and 3 or more hours of field activity. The course is comprised of readings, lectures, field studies, laboratory exercises, and a term paper. Zoonoses endemic to the Southeastern United States are emphasized.
4. One Health: An Introduction to Environmental Health – To examine sources, routes, media, and health outcomes associated with biological, chemical, and physical agents in the environment. Effects of agents on a disease, water quality, air quality, food

safety, and land resources are reviewed, as well as legal frameworks, policies, and practices associated with environmental health and intended to improve public health.

5. Advantages of a closer cooperation between human and animal health
6. Trans-disciplinary processes that can solve an everyday One Health problem
7. Shortfalls resulting from poor communication between human doctors and veterinarians
8. Social-ecological perspectives for the improvement of human and animal well-being
9. Fundamental principles of cross-sector human and animal health economics
10. Environmental policy and law that supports food safety
11. Prevention of diseases from livestock to human via food
12. Matrix calculations to describe growth rates of populations
13. Principles of disease transmission dynamics between humans and animals
14. Collection of vaccination coverage data
15. Interpretation of vaccination coverage data

Recommended Readings:

- World Health Organization. (2022). Ending the neglect to attain the sustainable development goals: One health: approach for action against neglected tropical diseases 2021-2030.
- Prata, J. C., Ribeiro, A. I., & Rocha-Santos, T. (Eds.). (2022). One Health: Integrated Approach to 21st Century Challenges to Health. Academic Press.
- Mehlhorn, H., & Heukelbach, J. (Eds.). (2022). Infectious Tropical Diseases and One Health in Latin America. Springer.
- Abed, Y., Dobe, M., Eliakimu, E., Goletic, R., Hokama, T., Laaser, U., ... & Sahu, M. (2023). Special Volume No. 1, 2021: The Global One Health Environment. South Eastern European Journal of Public Health.
- Cork, S., Hall, D., & Liljebjelke, K. (2016). One Health case studies: Addressing complex problems in a changing world. 5m Books Ltd.
- Stadtländer, C. T. H. (2015). One Health: People, animals, and the environment. Infection ecology & epidemiology, 5(1), 30514.

Journals:

- International Journal of One Health
- One Health
- One Health & Implementation Research

One health bulletin

PMY 704 (Cr 2+0, Elective)

TRANSDERMAL DRUG DELIVERY SYSTEM (TDDS)

Course Objectives:

At the end of this course the candidate will be able

- To have a deep understanding about the TDDS.
- To know about the advantages of this route of administration over other routes.

- To identify best drug candidates that could be administered via transdermal route to enhance their therapeutic effectiveness.
- Explore new approaches/methods and devices for crossing skin barriers.
- To develop new painless therapeutic niches for various diseases.

Course Outlines:

1. Transdermal drug delivery system (TDDS) and recent advances.
2. Types of transdermal drug delivery system i.e., monolithic systems and membrane-controlled delivery systems.
3. Strategies development and important parameters of drug selection for TDDS.
4. Characteristics, evaluation, and stability studies of TDDS.
5. Permeation enhancers, payload delivery, devices used and nanocarriers in TDDS, Iontophoresis, Sonophoresis and Phonophoresis.

Recommended Books

- Tapash K. Ghosh (2019), "Dermal Drug Delivery" From Innovation to Production" 1st edition. CRC Press Publishers
- Kewal K. Jain (2018), Drug Delivery Systems (MIMB, volume 437), Humana Press.
- Richard H. Guy, Jonathan Hadgraft (2019), Transdermal Drug Delivery Systems, Revised and Expanded (2nd Ed.), CRC Press.
- Kochhar, J.S., Tan, J.J.Y., Kwang, Y.C., Kang, L. (2019), Microneedles for Transdermal Drug Delivery. Springer.
- Ryan F. Donnelly, Thakur Raghu Raj Singh (2015), Novel Delivery Systems for Transdermal and Intradermal Drug Delivery. WILEY.

Journals:

- Research and Reports in Transdermal Drug Delivery
- Drug Delivery
- JAMA Dermatology
- Journal of advanced Scientific research
- International Journal of Pharmaceutics

PMY 705 (Cr 2+0, Elective)

STABILITY OF PHARMACEUTICAL PRODUCTS

Course Objectives:

At the end of the course the student will be able to understand:

- About rationale and significance of stability testing of a pharmaceutical product
- Various protocols and guidelines about stability testing
- Various analytical techniques used for stability testing of a pharmaceutical product

Course Outlines:

1. Stability as an essential quality attribute for pharmaceuticals.
 - a. Rationale for stability testing
 - b. Significance of stability testing

2. Stability testing and determination of shelf life of pharmaceutical products.
3. Stability studies at the pre-formulation and formulation stages of drug development
4. Essential elements of a stability study program
5. Stability indicating assay methods.
 - a. High Performance Liquid Chromatography (HPLC)
 - b. Liquid Chromatography with Mass Spectrometry (LC-MS)
6. Regulatory aspects of stability testing (FDA and ICH guidelines)
7. Stability testing Protocols.
8. Examples of stability studies of some drug substances.

Recommended Books

- Lachman L. (2017), The Theory and Practice of Industrial Pharmacy” (4th Ed), Lea and Febiger, Philadelphia.
- Huynh-Ba K, (2008) Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, (2009th Ed), Springer.
- Alexander T. F., David A., (2006) Physicochemical principles of Pharmacy, (4th Ed), Pharmaceutical Press, London, Scicago.

Journals:

- Drug Stability and Stabilization Techniques
- Drug Stability
- European Journal of Hospital Pharmacy

PMY 706 (Cr 2+1, Specialty)

PHARMACEUTICS-II

Course Objectives:

By the end of the course, student will be able to;

- Understand the chemical, biophysical and biological factors that impact on targeted and controlled drug delivery systems.
- Specially emphasis on colloidal systems and systems that provide a regulated controlled release.
- Understand the pharmacokinetic and dynamic factors that impact drug delivery.
- Learn how to target tissue specific diseases using nano-systems and intelligent materials.

Course Contents:

1. Liposomes and niosomes: Preparation, delivery and challenges.
2. Microparticles: Preparation, delivery and challenges.
3. Nanoparticles: Preparation, delivery and challenges.
4. Pellets: Preparation, delivery and challenges.
5. *In vitro* and *in vivo* characterization of liposomes and niosomes, microparticles, nanoparticles and pellets

Recommended Books