**Evaluation Scheme**

**For**

**Ph.D Pharmacy**

(Effective from the Session: 2017-18)



**IIMT UNIVERSITY**

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**IIMT UNIVERSITY**

**IIMT University**

**COLLEGE OF PHARMACY**

Ph.D. (Pharmacy) Course Work

**EVALUATION SCHEME**

**SESSION 2017-18**

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| ***S.No.*** | ***Code*** | ***Subject*** | ***Scheme of Teaching*** | | ***Scheme of Examination*** | | ***Total Marks*** | ***Credits*** |
| ***L*** | ***T/P*** | ***TA*** | ***ESE*** |
| *1* | ***PHD-111*** | *Research Methodology and Biostatistics* | *3* | *2* | *30* | *70* | *100* | *4* |
| *2* | ***PHD-112***  ***PHD-112(A)***  ***PHD-112(B)*** | *Research Paper on Common course work*  *Pharmaceutics*  *Pharmaceutical Chemistry* | *3* | *2* | *30* | *70* | *100* | *4* |
| *3* | ***PHD-113***  ***PHD-113(A)***  ***PHD-113(B)***  ***PHD-113(C)*** | *Research Paper on core research area*    *Transdermal Drug Delivery System.*  *Controlled & Targeted Drug Delivery System.*  *Oral Drug Delivery System.* | *3* | *2* | *30* | *70* | *100* | *4* |

**IIMT University**

**COLLEGE OF PHARMACY**

Ph.D. (Pharmacy) Course Work

**SESSION 2017-18**

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| **Sr. No.** | **Reg. No.** | **Admission No.** | **Student Name** |
| 1 | IIMTU/A-2198 | 2117650020001 | ATUL PRATAP SINGH |
| 2 | IIMTU/A-2199 | 2117650020002 | VIVEK VERMA |
| 3 | IIMTU/A-2200 | 2117650020003 | PRANJAL KUMAR SINGH |

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| **Common paper course work for pharmaceutics students in pharmacy** | | | | | |
| **Course Code PHD - 112 (A)** | | **Theory Course** | **L-P-C** | **4-0-4** | |
| **Course Contents** | | | | | **HOURS** |
| **Unit I** | **A) Pre formulation Studies:**  (i)Physiochemical aspects: pKa, Partition coefficient, Reaction kinetics & Mechanism.  (ii)Biological aspects: Reaction Kinetics & Mechanism  **B) Drug solubility studies**  (i) General principle definition, the phase rule solubility expression, determination of solubility  (ii) Solvent solute interaction polar solvent non-polar solvent and semi-polar solvent, Solubility calculations  (iii) Types of solution, the solubility of gases in liquids, effect of pressure, temperature, salt and chemical reactions. | | | | **8** |
| **Unit II** | **Topical Drug Delivery Systems:** Factors affecting percutaneous absorption of drugs, sorption promoters, absorption enhancement by energy input - iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin permeation, Design, formulation, development, characterization, advantages and limitation of hydrogel, organogel, insitugel, gel using thixotropic behavior. | | | | **8** |
| **Unit III** | **A) Concepts and system design for rate controlled delivery:-**  Rate programmed, Activation Modulated & feedback regulated drug delivery system, effect of system parameters on controlled release drug delivery.  **B) Sustained Release (SR) and Controlled Release (CR) formulations:**  Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. | | | | **8** |
| **Unit IV** | **Parentral drug delivery system:**  Major routes of parentral administration, selection, design & development. Biopharmaceutics of sustained/controlled release pattern of drug products, polymer microspheres and their biocompatibility and dispersed DDS. | | | | **8** |
| **Unit V** | **Brief study of targeted drug delivery system**:  Different levels of targeting-first order, second order and third order targeting, active and passive targeting, EPReffect, receptor mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting, active and passive targeting, Monoclonal antibodies, Carrier systems- Microspheres, nanoparticles, liposomes, Released erythrocytes etc. | | | | **8** |
| **Unit VI** | **Stability studies:** Drug development cycles and stability testing, Stress testing, Stability-indicating methods, Role of kinetics studies, Stability testing protocols, Retest period/shelf life determination, Photostability, Stability testing of biotechnological products,. Stability testing of phytopharmaceuticals, Post-approval changes, reduced stability-testing plans, ICH guidelines. | | | | **8** |
| **Unit VII** | **Regulatory Considerations**: Bioavailability enhancement methods.  Introduction to i*n-vivo in-vitro* correlation (IVIVC) and its significance. Review of regulatory requirements for conduction of bioequivalence studies. Design of single dose bioequivalence study.  **B) Biopharmaceutical & Pharmacokinetic aspects of CRDDS**: Strategies and design, diffusion and dissolution controlled release, ion-exchange resins, pH-independent formulations, osmotically controlled release, Pharmacokinetics of drugs following zero/one/ two compartment open models with first order elimination kinetics.Absorption rate constant determination using Wagner-Nelson and Loo-Reigelman method.  **C) Release mechanism and interpretation of Kinetic data.** | | | | **8** |
| **Books Recommended** | 1. Notari, R.E, Biopharmaceutics and Pharmacokinetics-An introduction, Marcel Dekker Inc. New York. 4rth edition 1987. 2. 4. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A.G. Basel, Switzerland.2011. 3. 5. Gibaldi, M., Biopharmaceutics & Clinical Pharmacokinetics, Pharma Book Syndicate, Hyderabad. 2005. 4. 6. Robert, Rodriguezdiaz, Analytical Techniques for Biopharmaceuticals Development. 2005 5. 7. Curry, S. H., Drug Disposition & Pharmacokinetics, Pharma Book Syndicate, Hyderabad. 2017. 6. Bentley S Textbook of Pharmaceuticals, 8Th Edition by E. A. Rawlins, Elsevier India, 2010. 7. Khar R K, Vyas S.P, Targeted & Controlled Drug Delivery -Novel CarrierSystems2012. 8. Jain N K, Advance in controlled and novel drug delivery, CBS Publications 1st Edition 2011. 9. Rawlins E A, Bentley’s Textbook of pharmaceutics, Elsevier 8th edition 2015. 10. Carstensen J T, Rhodes C T, Drug Stability: Principles And Practices, 3rd Revised Edition 2000. 11. Bankar u v, pharmaceutical dissolution testing vol. 49 edition 1991, Taylor & Francis India Pvt Ltd - New Delhi 12. Raymond R C, Handbook of Pharmaceutical Excipients 6th Revised Edition 2009 13. Bauer E.J, Pharmaceutical Packaging Handbook, informa healthcare 2009 14. Naizi S K, Handbook of preformulation chemical, biological & botanical drugs, CRC press 2006. 15. Rathbone MJ, Hadgrapt J, modified release drug delivery technology, 2nd edition informa healthcare 2008. | | | | |

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| **Syllabus for Core Research Area**  **Transdermal Drug Delivery system (Mr. Atul Pratap Singh)** | | | | | |
| **Course Code PHD – 113 - (A)** | | **Theory Course** | **L-P-C** | **4-0-4** | |
| **Course Contents** | | | | | **HOURS** |
| **Unit I** | **Percutaneous Drug Absorption:** Definition, diagram, percutaneous absorption, advantages, limitation, types of transdermal patch, formulation development and evaluation test for conventional and modified transdermal drug delivery system. | | | | **8** |
| **Unit II** | **Transdermal Drug Delivery System-:** Skin, structure, factor affecting percutaneous absorption, Design, formulation development, characterization, advantages and limitation of hydrogel, organogel, insitugel, gel using thixotropic behavior, Stimuli Response Gel.  **Regulatory affairs:**Regulatory requirement for TDDS. | | | | **8** |
| **Unit III** | **Nano systems for Pharmaceuticals:** [Definition](https://en.wikipedia.org/wiki/Nanoparticle#Definition),[Classification](https://en.wikipedia.org/wiki/Nanoparticle#Classification),[Background](https://en.wikipedia.org/wiki/Nanoparticle#Background),[Properties](https://en.wikipedia.org/wiki/Nanoparticle#Properties), [Synthesis](https://en.wikipedia.org/wiki/Nanoparticle#Synthesis), [Colloids](https://en.wikipedia.org/wiki/Nanoparticle#Colloids), [Morphology](https://en.wikipedia.org/wiki/Nanoparticle#Morphology)[Characterization](https://en.wikipedia.org/wiki/Nanoparticle#Characterization) ,Evaluation parameters, [Functionalization](https://en.wikipedia.org/wiki/Nanoparticle#Functionalization)[Health and safety](https://en.wikipedia.org/wiki/Nanoparticle#Health_and_safety), [Medicinal applications](https://en.wikipedia.org/wiki/Nanoparticle#Medicinal_applications). | | | | **8** |
| **Unit IV** | **Specialized nanosystems:**[Introduction, Use for drug delivery](https://en.wikipedia.org/wiki/Solid_lipid_nanoparticle" \l "Use_for_drug_delivery), Types of specialized Nano particle, [Characteristics and production](https://en.wikipedia.org/wiki/Solid_lipid_nanoparticle#Characteristics_and_production), Methods of preparations, [Advantages](https://en.wikipedia.org/wiki/Solid_lipid_nanoparticle#Advantages) and application. | | | | **8** |
| **Unit V** | **Stability studies:**  Drug development cycles and stability testing, Stress testing, Stability-indicating methods, Role of kinetics studies, Stability testing protocols, Retest period/shelf life determination, Photostability,Stability testing of biotechnological products, Stability testing of phytopharmaceuticals, Post-approval changes, Reduced stability-testing plans, ICH guidelines. | | | | **8** |
| **Unit VI** | **Psoriasis:**History, Signs, [Causes](https://en.wikipedia.org/wiki/Psoriasis#Causes), [Mechanism](https://en.wikipedia.org/wiki/Psoriasis#Mechanism), [Diagnosis](https://en.wikipedia.org/wiki/Psoriasis#Diagnosis), [Management](https://en.wikipedia.org/wiki/Psoriasis#Management), [Prognosis](https://en.wikipedia.org/wiki/Psoriasis#Prognosis), [Epidemiology](https://en.wikipedia.org/wiki/Psoriasis#Epidemiology), Socioeconomic impact, psoriasis information data base. | | | | **8** |
| **Unit VII** | **Alternative medicines:** Role of alternative medicine and treatment of psoriasis in different medical system (allopathy, Ayurveda, Unani, siddha). | | | | **8** |
| **Books Recommended** | 1. Jain. N.K., Advance in controlled and novel drug delivery, CBS publishers 1st edition 2011. 2. Khar. RoopK.Vyas.S.P.,The theory and practice of industrial pharmacy CBS publishers 4rth edition 2013.(Lachman/Lieberman) 3. Maffat C Antony,Osselten David M Clarke’s, Analysis of drug and poison 3rd edition PHP Pharmaceutical Press 2004. 4. Subrahmanyam. C.V.S.,Textbook of Physical Pharmaceutics,Vallabh Prakashan,3rd edition 2015. 5. Rawlins E.A, Bemtley’s Textbook of pharmaceutics Elsevier 8rth edition 2015. 6. Aulton .M.E The science of dosage form Design Elsevier 2nd edition 2004. | | | | |

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| **Syllabus for Core Research Area**  **CONTROLED AND TARGETTED DRUG DELIVERY SYSTEM (Mr. Vivek Verma)** | | | | | |
| **Course Code PHD – 113 (B)** | | **Theory Course** | **L-P-C** | **4-0-4** | |
| **Course Contents** | | | | | **HOURS** |
| **Unit I** | **Drug solubility studies:**   1. General principle definition, the phase rule solubility expression, determination of solubility 2. Solvent solute interaction polar solvent non-polar solvent and semi-polar solvent 3. Types of solution, the solubility of gases in liquids, effect of pressure, temperature, salt and chemical reactions 4. Solubility calculations | | | | **8** |
| **Unit II** | **Pharmaceutical Excipients:**  Types of Polymer,General Mechanism of Drug Release from Polymer, Application of Polymers in formulation of Controlled drug delivery system, compatibility-studies. | | | | **8** |
| **Unit III** | **Concepts and system design for rate controlled delivery:-**  Rate programmed, Activation Modulated & feedback regulated drug delivery system, effect of system parameters on controlled release drug delivery. | | | | **8** |
| **Unit IV** | **Brief study of targeted drug delivery system**:  Active and passive targeting, Monoclonal antibodies, Carrier systems- Microspheres, nanoparticles, liposomes, Released erythrocytes etc. | | | | **8** |
| **Unit V** | **Microspheres:**  Introduction, classification, Use for drug delivery, Formulation techniques, Mechanism of Drug Release, characterization, applications. | | | | **8** |
| **Unit VI** | **Microspheres:**  Introduction, classification, Use for drug delivery, Formulation techniques, Mechanism of Drug Release, characterization, applications.  **Packaging development:**  Development of package that ensures stability of products and are transport worthy, Evaluation of package E.G. G.S.M of paper, Bursting strength of paper and corrugated boxes, drop height test for final package. | | | | **8** |
| **Unit VII** | **Product Stability:**  Physical stability testing of pharmaceutical dosage form. Accelerated stability testing and shelf life assignment influence of packaging components on dosage form stability.  Chemical stability   1. Kinetics of rate process involving simple & complex reactions 2. Influence of temperature solvent ionic strength, dielectric constant, salt, pH catalysis & light on the reaction rate. 3. Chemical stability prediction of pharmaceutical dosage forms | | | | **8** |
| **Books Recommended** | 1. Bentley S Textbook of Pharmaceuticals, 8Th Edition by E. A. Rawlins, Elsevier India, 2010. 2. Khar R K, Vyas S.P, Targeted & Controlled Drug Delivery -Novel CarrierSystems2012. 3. Jain N K, Advance in controlled and novel drug delivery, CBS Publications 1st Edition 2011. 4. Rawlins E A, Bentley’s Textbook of pharmaceutics, Elsevier 8th edition 2015. 5. Carstensen J T, Rhodes C T, Drug Stability: Principles And Practices, 3rd Revised Edition 2000. 6. Bankar u v, pharmaceutical dissolution testing vol. 49 edition 1991, Taylor & Francis India Pvt Ltd - New Delhi 7. Raymond R C, Handbook of Pharmaceutical Excipients 6th Revised Edition 2009 8. Bauer E.J, Pharmaceutical Packaging Handbook, informa healthcare 2009 | | | | |

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| **Syllabus for Core Research Area**  **ORAL DRUG DELIVERY SYSTEM (Mr. Pranjal Kumar Singh)** | | | | | |
| **Course Code PHD – 113 (C)** | | **Theory Course** | **L-P-C** | **4-0-4** | |
| **Course Contents** | | | | | **HOURS** |
| **Unit I** | **Stomach**  Anatomy of stomach, drug absorption from stomach | | | | **8** |
| **Unit II** | **Oral Drug delivery**  **Tablets:** Classification, granulation technology on large-scale, physics of tablets making, different types of tablet compression machinery and the equipment, evaluation of tablets. Coating of tablets: Types of coating, film forming materials, formulation of coating solution, equipment for coating process, evaluation of coated tablet.  **Sustained Release (SR) and Controlled Release (CR) formulations:**  Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. | | | | **8** |
| **Unit III** | **Gastro-Retentative Drug Delivery Systems:**  Principle, concepts advantages and disadvantages, modulation of GI transit time approaches to extend GI transit. Formulation and evaluation of floating tablets. | | | | **8** |
| **Unit IV** | **Mucosal drug delivery systems:** Principle of mucoadhesion, various mucosal routes, advantages and disadvantages, mechanism of drug permeation through rectal and buccal cavity, formulation and evaluation of buccal gel. | | | | **8** |
| **Unit V** | **Pharmaceutical polymers:** Classification of polymers, synonyms, storage and pharmaceutical applications of polymers. | | | | **8** |
| **Unit VI** | **Stability studies:** Stability studies pertaining to tablets as per ICH guidelines. | | | | **8** |
| **Unit VII** | **Regulatory requirements:** Regulatory requirementspertaining to sustained release and controlled release drug delivery systems as per guideline of different countries. | | | | **8** |
| **Books Recommended** | 1. Jain. N.K., Advance in controlled and novel drug delivery, CBS publishers 1st edition 2011. 2. Khar. RoopK.Vyas.S.P.,The theory and practice of industrial pharmacy CBS publishers 4rth edition 2013.(Lachman/Lieberman) 3. Maffat C Antony,Osselten David M Clarke’s, Analysis of drug and poison 3rd edition PHP Pharmaceutical Press 2004. 4. Subrahmanyam. C.V.S.,Textbook of Physical Pharmaceutics,Vallabh Prakashan,3rd edition 2015. 5. Rawlins E.A, Bemtley’s Textbook of pharmaceutics Elsevier 8rth edition 2015. 6. Aulton .M.E The science of dosage form Design Elsevier 2nd edition 2004. | | | | |