VALLABH VIDYANAGAR

SYLLABUS EFFECTIVE FROM: 2018-19
SYLLABUS FOR M.SC. (PHARMACEUTICAL CHEMISTRY)
Semester- IV

Paper Code : PS04CPCH 21	**Total Credits:4**
Title of paper: Novel Drug delivery	

Unit	Description In detail	Weightage (%)
I.	Fundamentals of controlled release drug delivery systems : Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.	25
II.	Oral drug delivery: Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery. TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREEFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technology, Egalet Technology, Buccal Mucoadhesives, Periochips.	25
III.	Parenteral controlled release system: Scope, Parenteral routes of administration: Intravenous Route, Intramuscular Route, Subcutaneous Route, Intradermal Route, Specialized Access, injectable controlled release, formulation. Injections, Types of Injections, Solvents and Vehicles for injections, Nonaqueous Vehicles, Sterilization of Parenteral Product: Steam, Dry Heat, Filtration, Gas, Ionizing Radiation. Implantable drug delivery, microspheres, liposomes & their quality control.	25
IV.	Site specific drug delivery system: Active & passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung & colon. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.	25

Basic Text & Reference Books:

1. Wiilliams and Willkins *Remington's pharmaceuticals sciences.* 21st Edition, Lippincott - Vol. I & II
2. Yie W. Chien, *Novel drug delivery system* – Marcel Dekker N.Y. Second Edition, Vol-50.
3. J. R. Robinson and Vincent H. L. Lee; *Controlled drug delivery system*; Marcel Dekker Second Edition, Revised and Expanded. Vol- 29.
4. N.K. Jain; *Novel and controlled drug delivery systems,* C.B.S. publishers and Distributors, New Delhi.
5. N.K. Jain; *Advances in Novel and Controlled Drug Delivery,* C.B.S. publishers and Distributors, New Delhi.
6. Robinson, J.R. & Lee, V.H.I., *Controlled and Novel Drug Delivery* Marcel Dekker, New York. Second Edition, Revised and Expanded Vol- 29.
7. Kim. C., *Controlled Release Dosage form Design,* Technomic Publishing Co, Basel.
8. J. Swarbrick, 2007. *Encyclopedia of Pharmaceutical Technology*, Third Edition, Volume 1-6, Informa Healthcare.
9. R. Williams, D. Taft and J. McConville, "*Advanced formulation design to optimize therapeutic outcomes*" Marcel Dekker, Inc.
10. L. Xiaoling, B. R. Jasti, "*Design of Controlled Release Drug Delivery Systems*" McGraw-Hill.

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Semester: IV
Syllabus Effective From: June 2018

Paper Code : PS04CPCH 22	**Total Credits: 4**
Title of paper : Validation and cGMP	

Unit	Content	Weightage (%)
I.	Definition, Government regulation, scope and advantage of validation, relationship between validation and qualification, validation master plan, FDA 21 CFR Part 11, qualifications of utilities and process equipments (protocols & reports for DQ, IQ, OQ, PQ).	25
II.	Validation of medical devices, biotechnology processes, pharmaceutical ingredients, air handling and HVAC systems, sterile and non sterile areas, aseptic processes and sterilization methods, purified water system, distilled water and water for injection.	25
III.	Concepts and Philosophy of cGMP in manufacturing, processing, packaging, and holding of Drugs. Organization and Personnel: Responsibilities, qualification, experience, training, personal hygiene and clothing.	25
IV.	Buildings and Facilities: Location, design, plant layout, maintenance and sanitation, environmental control, utilities and services like gas, water, control of contamination and maintenance of sterile areas. Raw materials: Purchase specifications, selection of vendors, control on raw materials and finished dosage forms.	25

Basic Text & Reference Books:

1. Robert A. Nash, Alfred H. Wachter, *Pharmaceutical Process Validation*, Vol. 129, Marcel Dekker Inc.
2. Sidney H. Willing and Murray M. Tuckerman, *Good Manufacturing Practices for Pharmaceuticals*, Vol. 16, Marcel Dekker Inc.
3. James Swarbrick, James C. Boylan, *Encyclopedia by pharmaceutical technology,* Marcel Dekker Inc.gtg
4. Sharma PP, *How to practice GMPs,* 3rd Ed., Vandana Publication.
5. *Drug and Cosmetic Act and Rules* (Governent of India).
6. Potdar MA, *Current Good Manufacturing Practices* Pharma-Med Press, Hyderabad.
7. Potdar MA, *Pharmaceutical Quality Assurance*, Nirali Prakashan, Pune.

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Semester: IV Syllabus Effective From: June 2018

Paper Code: PS04CPCH 23	**Total Credits:4**
Title Of Paper: Quality Assurance of Pharmaceuticals	

Unit	Descri	Weightage
I.	Introduction of Quality Control: Main Principal of Pharmaceutical products, quality Management in drug industry, Philosophy, and essential elements, Active Ingredient, Pharmaceutical Excipients, specific Pharmaceutical Products, Hazards and Risk analysis in pharmaceutical products	25
II.	Water Treatment & Sterilization Process: Techniques and maintenance– RO, DM, ultra– filtration, WFI. Sterilization andsterility testing: Principle, validation ofdifferent sterilization processes, methods, industrialsterilizer, airhandlingunit and sterilitytestingofdifferent	25
III.	Pilotplantdesign and Largescalesynthesis: Basicrequirements fordesign, facility,equipment selection fortablets,capsules,liquid orals, parenteralsand semisolid preparations. Large-scaleSynthesis:Introduction, scale-up: syntheticstrategy,	25
IV.	Quality Assurance: Basicconcept ofqualityassurance, functions, sourceofvariation, control of quality– Rawmaterials,APIs, Packingmaterials,finished products and environment.Formaterials, production, facilities &equipment, packaging & labeling. In-process quality control – importance, inspection, IPQC tests.	25

Basic Text & Reference Books:

1. P. D. Sethi, *Quality assurance of Drugs in Pharmaceuticals*, Vandana Publ, New Delhi.
2. S. B. Bolton, *Pharmaceutical statistics,* Vol 80, Marcel Dekker, Inc.
3. D. A. Berry, *Statistical Methodology in Pharmaceutical Science,* Marcel Dekker,Inc.
4. P. D. Sethi, *Howto Practice GLP*, Vandana Publ, New Delhi.
5. G C Cole, *Pharmaceutical Production facilities, design and applications*, Publisher: Taylor andFrancis.
6. LachmanL.; *The Theory and Practice Of Industrial Pharmacy, Spl Indian Ed, 2009*,ISBN: 8123916973,ISBN-13: 9788123916972, 978-8123916972, Publisher: CBSPublishers &Distributors.

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Paper Code: PS04CPCH024	**Total Credits: 4**
Title Of Paper : Practical-I	

	Description in detail	Weightage (%)
I.	Group – A: Calibration and validation of UV-Visible, Calibration and validation of dissolution apparatus, Determination of 'Sodium' in Sodium chloride injection, Assay of injections IP.	50
II.	Group – B: Quantitative Analysis of drugs in the following 'Multicomponent dosage form' - Ibuprofen & Paracetamol Tablet, Paracetamol and Nimesulide Tablet, Assay of the following official formulations : a) Metformin Tablet b) Chloroquine Tablet	50

Basic Text & Reference Books:

1. Longman;*Organic Qualitative analysis byVogel's*,ISBN-13: 9780582442504;ISBN: 0582442508.
2. V. K. Ahuluwalia, *Comprehensive Practical Organic Chemistry: Volume–I&II;* Universities Press (India) Pvt. Ltd; ISBN: 8173712735.
3. Vogel's : Textbook of quantitative chemical analysis revised by G. H. Jeffery, J. Bassett, J. Mendham, R. C. Denney, 6th Edition, Pearson Education Publishers - New Delhi, 1989, India..
4. H. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol. I and Vol. II, 4thEdition CBS Publishers, 1997, New Delhi.
5. Indian Pharmacopoeia, Vol. I & II, 1996. The Controller of Publications, Government of India.
6. Higuchi, Bechmman and Hassan : Pharmaceutical Analysis, 2nd Edition, John Wiley and Sons, New York.
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi.
8. P. D. Sethi, *Quantitative Analysis of Drugs in Pharmaceutical Formulation*, 3rd Edition.
9. J. W. Munson, *Pharmaceutical Analysis - Modern Methods, Part - A & B*, 2001.

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Paper Code: PS04EPCH 21	**TotalCredits:4**
Title of paper : Advanced Pharmaceutical Chemistry	

Unit	Description in details	Weightage (%)
I.	Combinatorial Chemistry Introduction, Combinatorial synthesis for drug optimization, Combinatorial chemistry for drug discovery, Combichem – solid phase techniques, Methods of parallel synthesis, Methods in mixed combinatorial synthesis: General principles, The mix and split method, Mix and split in the production of positional scanning libraries, Isolation of active component in a mixture – DE convolution, Structure determination of Active compound, Limitation of Combinatorial synthesis	25
II.	Chiral Technology: Introduction to Chirality and Techniques used asymmetric synthesis of Diltiazem, Timolol, Vitamin C, Ampicillin, Dextrapropoxyphen, Thienamycin, Citrenalol, Propranolol, Atenolol, and Naproxen.	25
III.	Biopharmaceuticsls from Blood: Whole blood, Platelets and red blood cells. Blood substitutes: Dextrans, Albumin, Gelatin, Oxygen-carrying blood substitutes. Blood clotting: Factor VIII and haemophilia, Production of factor VIII, Factors IX, VIIa and XIII. Anticoagulants, Antithrombin, Thrombolytic agents, Tissue plasminogen activator (tPA), Enzymes of therapeutic value, Digestive aids. Liposome mediated drug delivery. Drug delivery methods for therapeutic proteins.	25
IV.	Agents used in Neurodegenerative diseases: Alzheimer's and Parkinsonism. Agents used in treatment of AIDS: Life cycle of HIV and Drugs used. Proteins and Peptide drugs: Chemistry, structure and stability, Reactivity of proteins and peptides. Different ways to synthesize these drugs - study of Insulin, Relaxin, Somatostatin, DNAse Interferon.	25

Basic Text & Reference Books:

1. Burger: *Medicinal Chemistry* (John Wiley & Sons N.Y.)
2. Foye: *Principles of Medicinal Chemistry* (Varghese & Co.)

3. Ledinicer: *Organic Drug synthesis* Vol. 1,2,3,4 (John Wiley &. Sons N.Y.)
4. Ariens : *Medicinal Chemistry Series*
5. Wilson and Gisvold: *Text book of Medicinal Chemistry* (J.B. Lippinc off cam)
6. G.L. Patrick: *An Introduction to medicinal Chemistry* (Oxford University Press).
7. Arup Mukherjee, *Combinatorial Chemistry.*
8. Biopharmaceuticals Biochemistry and biotechnology Second Edition Gary Walsh.

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Paper Code: PS04EPCH 22	**Total Credits:4**
Title Of Paper : Industrial Hygiene and Safety	

Unit	Description in detail	Weightage (%)
I.	Hazards:Classification Hazardous chemical, transportation of Hazardous chemicals, Storage, Handling and control measures for hazardous chemicals. Hazards and controls in Unit process and Unit Operations. Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring &prevention systems, industrial effluent testing&treatment. Control of environmental pollution.	25
II.	Fire and safety : Fire: Chemistry of fire, Personal protective equipments, Fire extinguishers, type of fire extinguishers, and useof fire extinguishers. Safety: Safety work permits, safety of pipelines, safety industrial equipments, safest art up and shut down procedures, emergency shutdown.	25
III.	Concept of Industrial Safety: Accidents investigation and Analysis, Statutoryprovisions, Types ofchemical hazards and control, control techniques, process flow chartand its importance forsafetyinspection, interpretation, use and training of MSDS, UN,HAZCHEM. Safety in chemical industry:General introduction, typeofchemical hazards, Safetyand risk phrases,Storagehazards andcontrol, Prevention ofoverflow-pressure-temperature andprocess flow, Types ofguards and valves forthe vessel, its inlet and out let, need ofremote and auto control valves, Process hazards and controls.	25
IV.	House-keeping and Firstaid: House-keeping and toxicology, First aid training, First aid measures.	25

Basic Text & Reference Books:

1. Dr. K. U. Mistry, *Supervising safety for hazardous Processes*, Safety Health and Environment Association, 1st edition.
2. J.J. Keller; *Safety managers Handbook*, J.J. Keller and Associates Inc, USA
3. *Accident prevention manual for industrial operations*, National safety council, Chicago, 10^{th}edition.
4. Howard H., *Safety and Accident prevention in chemical operation*, 2 nd edition
5. S. Lawrence, *Handbook of occupational safety and Health*
6. MSDS –your guide to chemical safety
7. A. Richard; *Engineering design for control of work place hazards*.