



હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી

NAAC A (3.02) State University

પો.બો.નં.-૨૧, યુનિવર્સિટી રોડ, પાટણ (ઉ.ગુ.) ૩૮૪૨૬૫

ફોન:(૦૨૭૬૬) ૨૨૨૭૪૫, ૨૩૦૫૨૮, ૨૩૦૭૪૩, ૨૩૩૬૪૮

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પરિપત્ર ક્રમાંક - ૧૯૩ / ૨૦૧૮

વિષય:-એમ.વોક. ફાર્માસ્યુટીકલ કેમેસ્ટ્રી સેમેસ્ટર-૧ અને સેમેસ્ટર-૨ ના નવા અભ્યાસક્રમ અંગે...

યુનિવર્સિટી સંલગ્ન પ્રમુખ સ્વામી સાયન્સ એન્ડ એચ.ડી. પટેલ આર્ટ્સ કોલેજ, કડી ના આચાર્યશ્રીને જણાવવાનું કે, ફાર્માસ્યુટીકલ કેમેસ્ટ્રી ની અભ્યાસ સમિતિની તારીખ : ૨૮/૧૧/૨૦૧૮ ના રોજ મળેલ સભાએ ભલામણ કર્યાનુસાર સામેલ પરિશિષ્ટ મુજબનો એમ.વોક. ફાર્માસ્યુટીકલ કેમેસ્ટ્રી સેમેસ્ટર-૧ અને સેમેસ્ટર-૨ નો નવો અભ્યાસક્રમ / સ્કીમ શૈક્ષણિક વર્ષ: ૨૦૧૮-૧૯ થી ક્રમશઃ અમલમાં આવે તે રીતે એકેડેમિક કાઉન્સિલવતી માન. કુલપતિશ્રીએ મંજૂર કરેલ છે. જે સંબંધિત સર્વેની જાણ તથા અમલ સારૂ આ સાથે મોકલવામાં આવે છે.

આ બાબતની સંબંધિત અધ્યાપકો તથા વિદ્યાર્થીઓને આપના સ્તરેથી જાણ કરવા વિનંતી છે.

નોંધ :- (૧) વિદ્યાર્થીઓની જરૂરીયાત માટે પરિપત્રની એક નકલ કોલેજના ગ્રંથાલયમાં મૂકવાની રહેશે.

(૨) આ અભ્યાસક્રમ / સ્કીમ યુનિવર્સિટીની વેબ સાઈટ www.ngu.ac.in પર પણ ઉપલબ્ધ કરાવવામાં આવનાર છે.

બિડાણ : ઉપર મુજબ

કુલસચિવવતી

નં.-એ કે/અ× સ/ ૭૭૩૭ / ૨૦૧૮
તારીખ: ૨૦ / ૧૨ / ૨૦૧૮

પ્રતિ,

૧. આચાર્યશ્રી, પ્રમુખસ્વામી સાયન્સ એન્ડ એચ.ડી. પટેલ આર્ટ્સ કોલેજ, કડી
૨. પરીક્ષા નિયામકશ્રી, હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી, પાટણ. (પાંચ નકલ)
૩. ગ્રંથપાલશ્રી, હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી, પાટણ. (વિદ્યાર્થીઓના ઉપયોગ સારૂ રેકર્ડ ફાઈલ માટે)
૪. સિસ્ટમ એનાલીસ્ટશ્રી, કોમ્પ્યુટર (રીઝલ્ટ) સેન્ટર, હેમ.ઉ.ગુ.યુનિવર્સિટી, પાટણ. તરફ પરિણામ માટે તથા વેબસાઈટ પર મૂકવા સારૂ.
૫. માન.કુલપતિશ્રી/કુલસચિવશ્રીનું કાર્યાલય, હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી, પાટણ.
૬. અનુસ્નાતક પ્રશાખા (એકેડેમિક), હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી, પાટણ.
૭. મુખ્ય હિસાબી અધિકારીશ્રી (મહેકમ), હેમચંદ્રાચાર્ય ઉત્તર ગુજરાત યુનિવર્સિટી, પાટણ તરફ → પરિપત્રની ફાઈલ અર્થે
૮. સિલેક્ટ ફાઈલે.

સિદ્ધાંત
- સુપ્રિન્ટેન્ડન્ટ ડિપ્ટ
Head, Dept B
Pharmaceutical
Chemistry
R. S. V.

Received
R. S. V.

HEMCHANDRACHRAYA NORTH GUJARAT UNIVERSITY

PATAN – 384265



M.Voc.-Pharmaceutical Chemistry

Syllabus/Scheme

Semester - 1 To Semester - 2

Sem/ CBCS/Grading Patten

W.E.F. September . – 2018(and thereafter)

Date : 05 / 12 / 2018

TOTAL PAGE – 19

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CURRICULUM
Hemchandracharya
North Gujarat University, Patan.
General Information for
M.Voc. Pharmaceutical Chemistry
(With effect from September-2018)

1. M.Voc. Pharmaceutical Chemistry is a two-year (Four semester) program
2. The eligibility to enter this program is B.Voc. (Pharmaceutical Chemistry) and B. Pharm pass out from a recognized University.
3. There will be 30% internal marks and 70% external marks in each core compulsory course. These marks will comprise of book review, project work, seminar, internal and external theory and practical.
4. There will be following courses in first three semesters
 - a. Core – I (3 credits)
 - b. Core – II (3 credits)
 - c. Core – III (3 credits)
 - d. Core – IV (3 credits)
 - e. Practical (18 credits)
5. There will be following course in final semester
 - a. Industrial Training (15 credits)
 - b. Dissertation (15 credits)
6. Practical examinations will be conducted for Two days (six hours each day)
7. Total of 120 credits in 4 semesters.
8. The table on the next page (page number - MPC-2 OF 24) shows the overall pattern of marks, examination time, credit, teaching hours etc. for semester – I and semester – II.

M.Voc. Semester – I

Course	Name of the course	Code of the course	Exam Duration	Ext. marks	Int. marks	Total marks	Teaching hours / week	Credit
Paper I	Core I	MPC 101	2 : 30	50	50	100	3	3
Paper II	Core II	MPC 102	2 : 30	50	50	100	3	3
Paper III	Core III	MPC 103	2 : 30	50	50	100	3	3
Paper IV	Core IV	MPC 104	2 : 30	50	50	100	3	3
Practical Paper	Practical	MPC 105	3 / 4	200	500	700	18	18
				400	700	1100	30	30

M.Voc. Semester – II

Course	Name of the course	Code of the course	Exam Duration	Ext. marks	Int. marks	Total marks	Teaching hours / week	Credit
Paper V	Core V	MPC 201	2 : 30	50	50	100	3	3
Paper VI	Core VI	MPC 202	2 : 30	50	50	100	3	3
Paper VII	Core VII	MPC 203	2 : 30	50	50	100	3	3
Paper VIII	Core VIII	MPC 204	2 : 30	50	50	100	3	3
Practical Paper	Practical	MPC 205	3 / 4	200	500	700	18	18
				400	700	1100	30	30

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M.Voc. Semester - III

Course	Name of the course	Code of the course	Exam Duration	Ext. marks	Int. marks	Total marks	Teaching hours / week	Credit
Paper IX	Core IX	MPC 301	2 : 30	50	50	100	3	3
Paper X	Core X	MPC 302	2 : 30	50	50	100	3	3
Paper XI	Core XI	MPC 303	2 : 30	50	50	100	3	3
Paper XII	Core XII	MPC 304	2 : 30	50	50	100	3	3
Practical Paper	Practical	MPC 305	3 / 4	200	500	700	18	18
				400	700	1100	30	30

M.Voc. Semester - IV

Course	Name of the course	Code of the course	Exam Duration	Ext. marks	Int. marks	Total marks	Teaching hours / week	Credit
Practical Paper I	Industrial Training	MPC 401	---	200	500	700	15	15
Practical Paper II	Dissertation	MPC 402	---	200	500	700	15	15
				400	1000	1400	30	30

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North Gujarat University, Patan.
M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – I

(With effect from September-2018)

MPC 101 : ANALYTICAL INSTRUMENTAL TECHNIQUES

(3 CREDITS)

Unit-I: UV-Visible spectrophotometry

Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effect, applications of UV-Visible spectroscopy, Woodward – Fischer rules for calculating absorption maximum, photometric titrations and its applications

Unit-II: Infra-red spectrophotometry

Absorption in the infrared region, factors influencing molecular vibrations, Calculation of vibrational frequencies, applications, interpretation of infra-red spectra, FTIR- Theory, Instrumentation, Attenuated Total reflectance spectroscopy (ATR)

Unit-III: Nuclear Magnetic Resonance Spectroscopy

Basic principles, theory of PMR spectroscopy, Instrumentation, applications, Chemical shift, spin-spin coupling, factors affecting chemical shift and spin coupling, ^{13}C NMR spectroscopy, interpretation of NMR spectra, 2D NMR spectroscopy

Unit-IV: Mass spectroscopy:

Basic principles, ion formation and types, Fragmentation rules, recognition of molecular ion peak, Tandem mass spectroscopy.

Applications of spectral studies

(UV, IR, NMR and Mass spectroscopy) to identification of drug metabolites and related substances, degradation products and standard impurities.

Unit-V

A. Molecular Luminescence Spectrometry:

Theory of fluorescence and phosphorescence, factors affecting the intensity of chemiluminescence 's, instrumentation and analytical applications and recent advancement

B. Molecular Absorption Spectrometry:

Theory, aspects, basic instrumentation, elements of interpretation of spectra, and applications of Absorption Spectroscopy

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Recommended books:

1. Elementary Organic Spectroscopy, Y R Sharma.
2. Spectroscopy of Organic Compounds, P S Kalsi, New Age International Publishers.
3. G.R. Chatwaal, Analytical spectroscopy, 1st, Himalaya publishing house, Mumbai, 1996.
4. K.Bansal, Analytical spectroscopy, 1st Ed., Campus books, New Delhi, 2000.

Reference Books

1. Applications of Absorption Spectroscopy of Organic compounds J. R. Dyer, Prentice Hall, London.
2. Organic Spectroscopy, W. Kemp, 3rd ed, ELBS publication, NY, 1991.
3. Spectroscopic identification of organic compounds. R.M. Silverstein, G.C. Bassler, T.C. Morrill Pub: John Wiley and Sons, NY.

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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – I

(With effect from September-2018)

MPC 102: ADVANCED PHARMACOLOGY-I

(3 CREDITS)

Unit-I: Neurotransmission

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
- d. Non-adrenergic non cholinergic transmission (NANC). Transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

Unit-II: Central nervous system Pharmacology

General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.

Unit-III: Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

Unit-IV: Autocoid Pharmacology

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

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Recommended Books:

1. Pharmacological Basis Of Therapeutics By Goodman & Gillman.
2. Pharmacology And Pharmacotherapeutics By Satoshkar & Bhandarkar.
3. Essentials Of Pharmacotherapeutics By F.S.K. Barar.
4. Essentials Of Medical Pharmacology By K.D. Tripathi.
5. Pharmacology By Rang & Dale.

Reference Books

1. Fundamentals Of Experimental Pharmacology By M.N. Ghosh.
2. Handbook Of Experimental Pharmacology By S.K. Kulkarni.
3. Pharmacology by V. J. Sharma.
4. Lippincot's Pharmacology by Heavy & Champ.
5. General P^tology : Basic Consept by H.L. Sharma.
6. Practicals in Pharmacology by Dr. Goyal.
7. Medical Pharmacology By Goth.
8. Pharmacology By Gaddum.
9. Principles Of Drug Action By Goldstein Aronow & Kalaman.
10. Lewis Pharmacology By Crossland.
11. Elements Of Pharmacology By Dr. Derasari & Dr. Gandhi.
12. Drug Interactions By Hansten.
13. Pharmacological Experiments On Isolated Preparations By Perry.

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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – I

(With effect from September-2018)

MPC 103: GMP AND PHARMACEUTICAL PROCESS VALIDATION (3 CREDITS)

Unit-I: GOOD MANUFACTURING PRACTICES

(i) GMP in manufacturing, processing and packaging of drugs (ii) GMP practices in finished products, organization, personnel, buildings and facilities, equipment, production and packaging (iii) Brief introduction of GLP (iv) Third party GMP certification

Unit-II: PHARMACEUTICAL PROCESS VALIDATION

(i) Pharmaceutical ingredients (ii) Solid dosage forms (iii) Sterilization processes and sterile products (iv) Computer system validation (v) Analytical Method validation Change controls and SUPAC guidelines for IR, MR and SS dosage forms.

Unit-III: PREPARATION OF QUALITATIVE AND QUANTITATIVE DEPARTMENTAL LAYOUTS

Preparation of qualitative and quantitative departmental layouts with equipment required for different dosage forms- solids, liquids, semisolids and sterile formulations, Detailed study of the equipment's required in the manufacture of different dosage forms as per Schedule, Preparations of documents like batch manufacturing record and batch packaging record, Preparation of standard operative procedures for equipment, manufacturing and processing steps, Pharmaceutical process Scale up for tablets, parenteral, non-parenteral liquids and semi-solids

Unit- IV: METHOD VALIDATION AND IMPURITY PROFILE

Method development and validation parameters: sensitivity, selectivity, accuracy and precision, linearity (calibration curves), recovery matrix effect and stability, robustness, ruggedness and impurity profile (based on ICH Guidelines), Concept of QBD, Risk based Guideline



Recommended Books

1. Gary D. Christian, Analytical chemistry, John Wiley & Sons N.Y., 5th Ed., 1994.
2. Indian Pharmacopoeia 2007, Volume-I, II and III.
3. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Laboratory Practice.

Reference Books

1. J.A. Dean, Analytical chemistry handbook, McGraw hill Inc., 1st Ed., 1995.
2. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
3. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – I

(With effect from September-2018)

MPC 104: NEW DRUG DEVELOPMENT AND TOXICOLOGY (3 CREDITS)

Unit-I: PRECLINICAL SAFETY AND LABORATORY ANIMALS

Common laboratory animals in pharmacology research, regulations for the care and use of laboratory animals.

Preclinical safety evaluation of new chemical agent: Concept of LD50, Determination of LD50, acute, sub-chronic and chronic toxicity studies.

Unit-II: CLINICAL EVALUATION OF NEW CHEMICAL ENTITY

Placebo, clinical trial study designs, phase of clinical trials.

Bio assays: Basic principles of bio-assays, types of bioassays and application.

- RIA: Principles of RIA and application.

- ELISA: Principles and application.

Unit-III: TOXICOLOGY

General principles of management of poisoning. Diagnosis and Management of toxicity due to atropine, barbiturates, Morphine & Alcohol

Unit-IV: EXPERIMENTAL MODELS FOR SCREENING THE DRUG

Analgesics, Anti-inflammatory agents, Anti- psychotics, Anti- depressants, Anti-anxiety agents, Anti-ulcer drugs, Anti-diabetics, ICH Guideline for Safety and Efficacy.

Recommended Books

1. Essentials Of Pharmacotherapeutics By F.S.K. Barar.
2. Essentials Of Medical Pharmacology By K.D. Tripathi.
3. Pharmacology By Rang & Dale

Reference Books:

1. F.C.Lu, Basic Toxicology : Fundamentals, Target Organs and Risk Assessment , 3rd edition, Taylor and Francis, Washington, U.S.A. 1996
2. D.R. Laurence and A.L. Bachrach, (eds.) Evaluation of Drug activities Pharmacometrics Vol. I, Academic Press, London, U.K. 1964
3. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd edition , Scientific Book Agency, Calcutta, India, 1984.
4. H.G. Vogel and W.H. Vogel (eds.) , Drug Discovery and Evaluation- Pharmacological Assays, Springer Verlag, Berlin, Germany,1997

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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – I

(With effect from September-2018)

MPC 105: PRACTICAL

(18 CREDITS)

1. Determination of iron in iron tablets.
2. Preparation of SOP.
3. Calibration of glassware's.
4. Titration of HCl with NaOH using potentiometer.
5. Standardization of an acid with a standard solution of base using pH-meter.
6. Determination of water content of salt hydrate.
7. Spectrophotometric (UV/VIS) Estimations
Amino acids, Protein, Carbohydrates, Cholesterol, Ascorbic acids, Aspirin, Caffeine
8. Spectroscopic Measurement of Plasma drug Concentration.
9. Dissolution of tablets and capsules.
10. Determination of total hardness of tablets.
11. Determination of water content by moisture balance and by Karl Fischer method.
12. Volumetric analysis of ibuprofen in tablets.
13. Analysis of ascorbic acid in given tablets.
14. Spectrophotometric determination of aspirin content in soluble aspirin tablets.
15. Spectrophotometric determination of Paracetamol in tablets.
16. Determination of Vitamin B1 and B2 in given tablets.
17. Determination of ephedrine hydrochloride in given syrup.
18. Determination of tetracycline in given capsules.
19. Determination of phenobarbitone in given cough syrup.
20. Determination of chloramphenicol in given capsules.
21. Monograph of Different drugs.

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CURRICULUM
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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – II

(With effect from September-2018)

MPC 201: ADVANCED INSTRUMENTAL TECHNIQUES (3 CREDITS)

Unit-I: COLUMN AND TLC

Fundamentals of chromatography, Definition of resolution, capacity factor, selectivity factor, dead time and dead volume. Types of chromatography depending upon mobile phase, instrumentation and principle of separation Principle, Working, Apparatus, Rf values, Applications

Unit-II: HPLC UPLC CHROMATOGRAPHY

Introduction, Fundamental Principle, Types of HPLC / UPLC, Working mechanism, Apparatus and construction, Detectors and Applications

Unit-III: GAS CHROMATOGRAPHY, LIQUID CHROMATOGRAPHY

Principle, Types of GC and LC, Working, Apparatus and construction, Applications

Unit-IV: INTREGRATION OF CHROMATOGRAPHIC TECHNIQUES WITH SPECTROSCOPY.

Principle, Types of LC-MS, Working of GC-MS & LC-MS, Construction of equipment, Applications

Recommended Books

1. Gary D. Christian, Analytical chemistry, John Wiley & Sons N.Y., 5th Ed., 1994.
2. J.A. Dean, Analytical chemistry handbook, McGraw hill Inc., 1st Ed., 1995.

References Books:

1. Thin Layer chromatography, E. Stahi
2. Chromatography, Heptman
3. HPTLC, Dr. P.D. Sethi
4. High performance liquid chromatography, Dr. P. D. Sethi
5. Principles of Instrumental Analysis, D. A. Skoog and J. L. Loary, W. B. Saunders.
6. Fundamentals of Analytical Chemistry, D.A. Skoog, D. M. West and F. J. Holler, W. B. Saunders.
7. Principles of Instrumental analysis, D. A. Skoog and W. B. Saunders
8. Analytical Chemistry by G. D. Christian

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M.Voc. Pharmaceutical Chemistry
M.Voc. Semester – II

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(With effect from September-2018)

MPC 202: ADVANCED PHARMACOLOGY II

(3 CREDITS)

Unit-I: Drug Action at Receptors

Structure and classification of receptors, general mode of operation, Superfamily Type 1, 2, 3, 4, Ligand-receptor relationships, The chemical nature of the binding of ligands to receptors, Neurotransmitters, signaling process, Ion channels and their control, Membrane-bound enzymes-activation/deactivation, conformational changes in receptor, Binding groups, Position of binding, Size and shape, ligand concentration-response curves (Agonist concentration-response relationships, Antagonist concentration-receptor relationships), Ligand-receptor theories (Clark's occupancy theory, rate theory, two-state model), Citalopram, an antagonist antidepressant -case study, α -Blockers

Unit-II: ADME

Scheme of fate of dosage form after its administration, definition and introduction to concept of absorption, distribution, biotransformation and elimination of drug, Introduction to bioavailability and various equivalence referring plasma time profile of drug, significance of metabolisms involved in the absorption and bio transformation of drugs, effects of physico-chemical, pharmaceutical and biological factors on ADME, renal and non-renal excretion, Concept of clearance, disintegration and dissolution studies

Unit-III: Barriers to Drug Exposure in Living Systems

Introduction to Barriers, drug dosing, barriers in the mouth, stomach, gastrointestinal tract, kidney, permeation of the gastrointestinal cellular membrane, metabolism in the Intestine, enzymatic hydrolysis in the intestine, absorption enhancement in the Intestine, barriers in the blood stream, plasma enzyme hydrolysis, plasma protein binding, red blood cell binding, blood brain barrier

Unit-IV: Chemotherapy

General principle of chemotherapy (various targets of chemotherapy covering pathology of infection and mechanism of actions of drugs, concept of resistance), Sulphonamides and co-trimoxazole, Antibiotics-Penicillins, Cephalosporins, Chloramphenicol, Macrolides, Quinolones and Fluoroquinolones, Quinolones, Tetracyclines, Aminoglycosides and miscellaneous antibiotics; Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, AIDS, protozoal diseases, worm infections, urinary tract infections and sexually transmitted diseases.

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Recommended Books:

1. Pharmacological Basis Of Therapeutics By Goodman & Gillman.
2. Pharmacology And Pharmacotherapeutics By Satoshkar & Bhandarkar.
3. Essentials Of Pharmacotherapeutics By F.S.K. Barar.
4. Essentials Of Medical Pharmacology By K.D. Tripathi.
5. Pharmacology By Rang & Dale.

Reference Books

1. Fundamentals Of Experimental Pharmacology By M.N. Ghosh.
2. Handbook Of Experimental Pharmacology By S.K. Kulkarni.
3. Pharmacology by V. J. Sharma.
4. Lippincot's Pharmacology by Heavy & Champ.
5. General P^cology : Basic Consept by H.L. Sharma.
6. Practicals in Pharmacology by Dr. Goyal.
7. Medical Pharmacology By Goth.
8. Pharmacology By Gaddum.
9. Principles Of Drug Action By Goldstein Aronow & Kalaman.
10. Lewis Pharmacology By Crossland.
11. Elements Of Pharmacology By Dr. Derasari & Dr. Gandhi.
12. Drug Interactions By Hansten.
13. Pharmacological Experiments On Isolated Preparations By Perry.

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MPC 203: DOSAGE FORM DESIGN

(3 CREDITS)

Unit-I: Pharmaceutical Pre-formulation

Perspective & Concepts, Preformulation methodology : Selection of Drug candidate and type of formulation, Physical, Chemical and Pharmaceutical Factors influencing formulation of drugs, Analytical Methods for characterization of Drug & Excipients, Drug – Excipient compatibility study

Unit-II: Tablet Formulation and Design

Introduction, Preformulation Studies, A Systematic and Modern Approach to Tablet Product Design, Tablet Components and Additives, Regulatory Requirements for Excipients in the United States

Unit-III: Capsule Formulation and Design

Introduction, Innovation and Type of Capsule, A Systematic and Modern Approach to Capsule Product Design, Capsule Components and Additives,

Unit-IV: Liquid Dosage form

Introduction, types, Rheological properties,
Emulsion and Suspension Formulation: Theory, Principle, Method of Preparation, Evaluation parameter and Stability Study
Brief Introduction about different dosage form: Syrup, Elixir-linctus, Pills, Effervescent Granules and Mixture

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Recommended Book:

1. Mehta, R. M: Dispensing and General Pharmacy.
2. Lachman, Leon and H.A. Lieberman. The theory and industrial pharmacy, 3rd edition. Varghese publishing Co

References Books

1. Drug like properties: concepts, structure design and methods, from ADME to toxicity optimization, by Edward H. Kerns and Li Di, Elsevier publications, ISBN: 978-0-1236-9520-8
2. Formulation Tools for Pharmaceutical Development (English, Hardcover, Aguilar Aguilar)
3. Formulation Development of Extended Released Rifaximin Micro-Particles by Bhise Kiran (Author), Karanje Rohan (Author)
4. Lachman, Leon and H.A. Lieberman. The theory and industrial pharmacy, 3rd edition. Varghese publishing Co.
5. Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics. Marcel Decker.
6. Barnard T.L. and Robert A. Narth, Pharmaceutical process validation volume 23, Marcel Decker.
7. Norman A. Hodges and Stephen P. Denyer, hand book of Microbiology Quality Control Tayler and francies, London.
8. Horth Tonneson, Photostability of Drugs and Drugs formulations, Taylor and Frances, London.
10. Formulation tools for Pharmaceutical Development by J E Aguilar

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MPC 204: PHARMACEUTICAL QUALITY ASSURANCE

(3 CREDITS)

Unit-I: Concepts and Philosophy of TQM, GMP, ISO-9001-14001-45001.

Organization and personnel, responsibilities, training, hygiene. Raw Materials: Purchase specifications, Maintenance of stores, Selection of vendors, Controls on Raw materials. Standard operating procedures for various manufacturing steps, for the operation of equipment

Unit-II: Packaging and labeling controls

line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners

Unit-III: Finished product release

Quality review, Quality audits, Batch release document. Warehousing: Good warehousing practice, Materials, Managements. Waste disposal, Scrap disposal procedure and records, Concept of In process quality control

Unit- IV: Errors, Statistics and Sampling

Accuracy and precision, Error, types of error, systematic and random errors, minimisation of errors, mean and standard deviations, reliability of results, confidence interval, comparison of results, student T test, F test, Comparison of two samples (Paired T test), correlation and regression, correlation coefficient and liner regression, Sampling, the basis of sampling, sampling procedure, sampling statistics

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Recommended Books

1. Indian Pharmacopoeia Voll , II & III 2007, 2010, 2014.
2. Methods of sampling and microbiological examination of water, first revision, BIS
3. ICH Guidelines for impurity profiles and stability studies.
4. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.

Reference Books:

1. D. A. Skoog and D. M. West, Fundamental of Analytical Chemistry, 7th Edition (1996), Saunders College Publishing, Philadelphia, Holt, London.
2. R. L. Pecsok, L. D. Shields, T. Cairns and L.C. McWilliam, Modern Methods of Chemical Analysis, (1976), John Wiley & Sons, New York.
3. Lachman, Leon and H.A. Lieberman, The theory and practices of industrial pharmacy, 3rd edition, Varghese publishing Co.
4. Gilberts S. Banker and C.T. Rhodes, Modern Pharmaceutics Marcel Decker.
5. Kennerth Harburn, Quality control of packaging material in the Pharmaceutical Industry.
6. Sidney H. Willing, Good Manufacturing Practice for Pharmaceuticals Marcel Decker Inc.

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MPC 205: PRACTICAL

(18 CREDITS)

1. Determination of % purity of drug.
 2. Determination of λ_{max} of $KMnO_4$
 3. Determination of log P of Drug Component.
 4. Preparation and standardization of iodine solution
 5. Assay of norfloxacin tablets and chlorpromazine tablets
 6. Experiment related to sampling of drugs from formulations
 7. Experiment related to sampling of drugs from biological fluids
 8. Formulation and evaluation of creams.
 9. Formulation and evaluation of gels.
 10. Demonstration of column chromatography
 11. Assay of paracetamol tablets and syrup
 12. Estimation of effect of solvent, concentration on absorption of compounds
 13. Demonstration of bathochromic shift and hypsochromic shift
 14. Comparison of methods of assay of aspirin using titrimetry and spectroscopy
 15. Formulation and evaluation of floating beads.
 16. Formulation and evaluation of buccal gel.
 17. Separation of amino acids by TLC.
 18. Separation of drugs by TLC.
 19. Separation of dyes by TLC.
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