Scheme of Evaluation (Choice Based Credit System)
Bachelor of Pharmacy (B. Pharm.)

SEVENTH SEMESTER

S. No.	Subject Code	Subject Name	L--T--P	T/P Marks (ESE)	Sessional	Total	Credit
Theory							
1.	*RPH-733/* *RPH-741*	Pharmaceutical Chemistry-VIII (Medicinal Chemistry-III)/ Pharmaceutics-XI Pharmaceutical Marketing & Management	3---0---0	70	30	100	3
2.	*RPH-734/* *RPH-740*	Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics)/ Pharmaceutics-X Pharmaceutical Biotechnology	3---0---0	70	30	100	3
3.	*RPH-735*	Pharmacology-III (Pharmacology & Pharmacovigilance)	3---0---0	70	30	100	3
4.	*RPH-736*	Pharmacognosy-IV	3---0---0	70	30	100	3
5.	*RPH-737*	Pharmaceutical Analysis-III (Pharmaceutical Analysis & Quality Assurance)	3---0---0	70	30	100	3
Practical/ Project							
6.	*RPH-734P/* *RPH-740P*	Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics) Practical/ Pharmaceutics-X (Pharmaceutical Biotechnology) Practical	0---0---4	50	50	100	2
7.	*RPH-735P*	Pharmacology-III (Pharmacology & Pharmacovigilance) Practical	0---0---4	50	50	100	2
8.	*RPH-736P*	Pharmacognosy-IV Practical	0---0---4	50	50	100	2
9.	*RPH-737P*	Pharmaceutical Analysis-III (Pharmaceutical Analysis & Quality Assurance) Practical	0---0---4	50	50	100	2
10.	*RPH-738P*	Hospital Training-II		50	50	100	1
TOTAL						**1000**	**24**

SEVENTH SEMESTER

RPH-733/RPH-833

PHARMACEUTICAL CHEMISTRY-VIII (MEDICINAL CHEMISTRY-III)

Classification, mode of action, uses, recent advances and structure activity relationship of the following classes of drugs (Synthetic procedures of individually mentioned drugs only).

Unit I

Steroidal drugs: Introduction, classification, nomenclature, and stereochemistry of-

Androgens and anabolic steroids: Testosterone, Stanazolol. ***Estrogens and progestogens:*** Progesterone, Estradiol. ***Adrenocorticoids:*** Prednisolone, Dexamethasone.

Unit II

Chemotherapy of microbial infections:

Antibiotics: Penicillin, Semi-synthetic Penicillins (Ampicillin), Cephalosporins (Cefepime), Chloramphenicol, Tetracyclines (Doxycycline), Aminoglycosides, Macrolides.

Antifungals: Ketoconazole and Clotrimazole.

Antiseptics & disinfectants: Chlorhexidine.

Unit III

Chemotherapy of microbial infections:

Synthetic antibacterials: Sulphonamides (Sulphamethoxazole, Sulphadiazine, Sulphacetamide), Quinolones/Fluoroquinolones (Nalidixic acid, Ofloxacin).

Antimycobacterial agents: PAS, Ethambutol, Isoniazid, Dapsone.

Unit IV

Chemotherapy of parasitic infections:

Antimalarials: Chloroquine, Primaquine, Pyrimethamine.

Antiamoebics: Ornidazole, Diloxanide.

Anthelmintics: Albendazole.

Unit V

Cancer chemotherapy: Alkylating agents (Chlorambucil, Carmustine), Antimetabolites

(Methotrexate, 5-Fluorouracil), Anticancer antibiotics (Doxorubicin).

Antiviral/Anti-HIV agents: Amantadine, Acyclovir, Zidovudine, Saquinavir, Raltegravir.

BOOKS RECOMMENDED

1. Abraham D.J., Burger's Medicinal Chemistry and Drug Discovery, John Wiley and Sons Inc., New York.
2. Block J.H. and Beale J.M., Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins, Philadelphia.
3. Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Foyes Principles of Medicinal Chemistry, Lippincott Williams and Wilkins, Philadelphia.
4. Vardanyan R.S. and Hruby V.J., Synthesis of Essential Drugs, Elsevier, Philadelphia.
5. Singh H. and Kapoor V.K., Medicinal and Pharmaceutical Chemistry, Vallabh Prakashan, Delhi.
6. Nogrady T., Medicinal Chemistry: A Biochemical Approach, Oxford University Press, New York.
7. Patrick G.L., An Introduction to Medicinal Chemistry, Oxford University Press, New York.
8. Hansch C., Comprehensive Medicinal Chemistry, Pergamon Press, U.K.
9. Dharuman J., Chemistry of Synthetic Drugs, AITBS Publishers, New Delhi.
10. Mann F.G. and Saunders B.C., Practical Organic Chemistry, Orient Longman Limited, New York.
11. Furniss B.S., Hannaford A.J., Smith P.W.G. and Tatchell A. R., Vogel's Textbook of Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.

RPH-734/RPH834

PHARMACEUTICS-IX (BIOPHARMACEUTICS & PHARMACOKINETICS)

Unit I

Introduction to biopharmaceutics and pharmacokinetics and their role in formulation development. Mechanism of absorption, physicochemical and pharmaceutical factors influencing absorption, drug distribution, volume of distribution and distribution coefficient. Plasma protein binding and its significance.

Unit II

Significance of plasma drug concentration measurement.

Compartment models and non-compartment models: Definition and scope.

Pharmacokinetics of drug absorption: Zero order and first order absorption rate constant. Determination of absorption rate constant using Wagner-Nelson and Loo-Reigelman method.

Unit III

Compartment kinetics: One compartment and preliminary information of multicompartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intra venous (I.V.) bolus and I.V. infusion.

Unit IV

Dosage adjustment in patients with renal and hepatic disease. Clinical Pharmacokinetics: Definition and scope.

Unit V

Brief introduction to bioavailability and bioequivalence: Definition and significance.

Measurement of bioavailability.

Introduction to i*n-vivo in-vitro* correlation (IVIVC) and its significance. Review of regulatory requirements for conduction of bioequivalence studies.

RPH-734P/RPH834P

PHARMACEUTICS-IX (BIOPHARMACEUTICS & PHARMACOKINETICS) PRACTICAL

Suggested Practicals

1. *In-vitro* drug release study of the any powder, uncoated tablet, capsule, film-coated tablet, sustained release tablet and fast release (M.D, Dispersible etc.) tablet using various dissolution media.
2. To determine the % protein binding of some drugs.
3. To determine the effect of protein binding on drug bioavailability.
4. To calculate various Pharmacokinetic parameters from zero order drug release data, first order drug release data, blood data of *I.V.* bolus injection (one compartment model) and urinary excretion data of *I.V.* bolus. Injection using both methods (Rate of elimination & sigma minus method one compartment model).
5. To study *in-vitro* drug- drug interactions.
6. To study the passive diffusion of a drug using cellophane membrane.
7. To study the passive diffusion of a drug using egg membrane.
8. To determine the various Pharmacokinetic parameters from the given blood data of oral administration of dosage form.
9. Determination of bioavailability by urinary method.
10. Determination of bioequivalence by dissolution method.

BOOKS RECOMMENDED

1. Notari, R.E, Biopharmaceutics and Pharmacokinetics-An introduction, Marcel Dekker Inc. New York.
2. Rowland M, and Tozer T.N. Clinical Pharmacokinetics, Lea and Febriger, New York.
3. Wagner J.G. Fundamentals of Clinical Pharmacokinetics, Drugs Intelligence Publishers, Hamilton.
4. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A.G. Basel, Switzerland.
5. Gibaldi, M., Biopharmaceutics & Clinical Pharmacokinetics, Pharma Book Syndicate, Hyderabad.
6. Robert, Rodriguezdiaz, Analytical Techniques for Biopharmaceuticals Development.
7. Curry, S. H., Drug Disposition & Pharmacokinetics, Pharma Book Syndicate, Hyderabad.

RPH-735

PHARMACOLOGY-III (PHARMACOLOGY & PHARMACOVIGILANCE)

Unit I

Pharmacology of endocrine system: Hypothalamic and pituitary hormones, thyroid hormones and thyroid drugs. Parathormone, Calcitonin and Vitamin D, Insulin, oral hypoglycemic agents and Glucagon. Corticosteroids, androgens and anabolic steroids, Estrogens, Progesterone and oral contraceptives, drugs acting on the uterus.

Unit II

Chemotherapy: General principles of chemotherapy. Sulfonamides, Quinolones, Beta-lactam antibiotics, Chloramphenicol, Tetracyclines, Macrolides and Aminoglycosides.

Chemotherapy of parasitic infections: Tuberculosis, leprosy, malaria, fungal infections, viral diseases.

Unit III

Naturopathy: History, definitions, mechanism and its effect on various systems, hydrotherapy, mud therapy, chromotherapy, acupressure, aromatherapy and therapeutic massage.

Unit IV

Pharmacovigilance: Scope, definition and aims of pharmacovigilance and pharmacoepidemiology, therapeutic index- LD_{50} and ED_{50}, drug interactions.

Adverse drug reactions: Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADR, drug induced diseases affecting different organ systems.

Fixed dose drug combinations (FDDCs): Rational and irrational combinations, FDDCs in Indian scenario.

Unit V

Epidemiological methods: ***Case control study****:* Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study, advantages, disadvantages.

Cohort study*:* Concept, framework, combination of prospective and retrospective cohort study, relative risk, attributable risk, advantages, disadvantages.

RPH-735P

PHARMACOLOGY-III (PHARMACOLOGY & PHARMACOVIGILANCE) PRACTICAL

Suggested Practicals

1. To calculate the pA_2 value of Atropine and Chlorpheniramine.
2. Bioassay of Ach, Histamine and Oxytocin on suitable isolated preparations using matching assay, bracketing assay, interpolation, three point assay and four point assay.
3. Bioassay of histamine and acetylcholine using matching and interpolation method on rat and guinea pig.

The experiments should be conducted using software, wherever possible.

BOOKS RECOMMENDED:

1. Rang M.P., Dale MM, Riter JM, Pharmacology Churchill Livingstone, China.
2. Tripathi, K.D. Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.
3. Satoskar & Bhandarkar: Pharmacology & Pharmacotheropeutics, Popular Prakashan Pvt. Ltd., Bombay.
4. Ghosh M.N. Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta.
5. Katzung, B.G. Basic & Clinical Pharmacology, Prentice Hall International, New Delhi.
6. Ronald D. Mann & Elizabeth B. Andrews, Pharmacovigilance, John Wiley & Sons, West Sussex, England.
7. Waller and Patrick, An Introduction to Pharmacovigilance, John Wiley & Sons, West Sussex, England.
8. Mohanta G.P., Elementary Pharmacovigilance, PharmaMed Press, Hyderabad.
9. Mohanta G.P., Manna P.K., Textbook of Pharmacovigilance: Concept and Practice, PharmaMed Press, Hyderabad.
10. Grover J.K., Experiments in Pharmacy & Pharmacology, CBS Publishers, New Delhi.
11. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.
12. Barar F.S.K : Text Book of Pharmacology, Interprint, New Delhi.
13. Goodman & Gilman, The Pharmacological basis of Therapeutics, Eds: Hardman J.G., Limbird Le, Molinoss P.B., Ruddon R.W. & Gil A.G., Pergamon Press, U.K.
14. Laurene, D.R. & Bennet P.N.; Clinical Pharmacology, Churchill Livingstone, Harlow, England.
15. Paul L., Principles of Pharmacology, Chapman and Hall, New York.
16. Ravi Shanker K., Kiranmayi G.V.N., Pharmacology: A Companion Handbook with Illustrations, PharmaMed Press, Hyderabad.

17. Singh S. J., History and Philosophy of Naturopathy, Nature Cure Council of Medical Research, Lucknow.
18. Bakhru H. K., Complete Handbook of Nature Cure, Jaico Publishing House, New Delhi.
19. Pizzorno J. E., Murray M. T., The Encyclopedia of Natural Medicine, Simon & Schuster, New York, USA.
20. Sheffield Bioscience Programs, U.K. ISBN. 1-8747558-02-6.

RPH-736

PHARMACOGNOSY-III

Unit I

Systematic study of source, cultivation, collection, processing, commercial varieties, chemical constituents, substitutes/adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following alkaloid containing drugs-

Pyridine-piperidine: Tobacco, Areca and Lobelia.

Tropane: Belladona, Hyoscyamus, Datura, Coca and Withania. **Quinoline and isoquinoline:** Cinchona, Ipecac and Opium. **Indole:** Ergot, Rauwolfia, Catharanthus and Nux-vomica.

Unit II

Imidazole: Pilocarpus.

Steroidal: Veratrum and Kurchi.

Alkaloidal amine: Ephedra and Colchicum.

Glycoalkaloid: Solanum. **Purines:** Coffee and Tea **Quinazoline:** Vasaka.

Unit III

Production and utilization of phytoconstituents: Calcium sennosides, Diosgenin, Solasodine, Podophyllotoxins, Tropane alkaloids, Isoquinoline alkaloids and Quinoline alkaloids.

Unit IV

Plant tissue culture: Historical development of plant tissue culture, type of culture, nutritional requirements, growth and maintenance, factors affecting plant tissue culture. Applications of plant tissue culture in pharmacy.

Unit V

Introduction to herbal fingerprinting using HPTLC technique. Introduction to herbal drug interactions.

Introduction to bioactive compounds enhancing bioavailability such as- Piperine, Vitamin K.

RPH736-P

PHAMACOGNOSY-IV PRACTICAL

Suggested Practicals

1. To study the morphology and microscopy of Datura and Withania.
2. To study the morphology and microscopy of Ipecac and Rauwolfia.
3. To study the morphology and microscopy of Catharanthus and Nux-vomica.
4. To study the morphology and microscopy of Ephedra and Kurchi.
5. To study the morphology and microscopy of Solanum and Vasaka.
6. a) Morphology of Areca, Colchicum.
   b) Transverse section of Catharanthus leaf and Kurchi bark.
7. To study the TLC profile of Catharanthus leaf.
8. To study the TLC profile of Withania root.
9. Chemical test of Tea, Tobacco, Datura and Withania.
10. Chemical test of Nux-vomica, Ephedra and Kurchi.
11. Preparation of different callus cultures using various parts of plants.
12. Study of micopropogation using callus culture.
13. Effect of various plant hormones on micropropogation.

BOOKS RECOMMENDED

1. Trease, G.E., and Evans, W.C., Pharmacognosy, Bailliere Tindall East Baorne, U.K.
2. Wallis. T.E. "Text Book of Pharmacognosy" J&A Churchill Ltd., London.
3. Kokate C.K., Gokhale A.S., Gokhale S.B., Cultivation of Medicinal Plants, Nirali Prakashan.
4. Tyler V.E., Lynnr B. and Robbers J.E., Pharmacognosy, 8th Edition, Lea & Febiger, Philadelphia.
5. Harborne J.B., Phytochemical Methods, Chapman & Hall International Edition, London.
6. Medicinal Plants of India, Vol. I & II, Indian Council of Medical Research, New Delhi.
7. Nadkarni A.K., Indian Materia Medica, Vol- 1&2, Popular Prakashan (P) Ltd., Bombay.
8. Sukh Dev, A Selection of Prime Ayurvedic Plant Drugs, Anamaya Publisher New Delhi.
9. Indian Herbal Pharmacopoeia, Vol. I & II, ICMR & RRL, Jammu.
10. Indian Ayurvedic Pharmacopoeia, Govt. of India.
11. The Wealth of India, Raw Materials (All volumes), Council of Scientific & Industrial Research, New Delhi.

12. Rastogi R. P. and Mehrotra B.N., Compendium of Indian Medicinal Plants I-IV, Publications & Information Directorate/Central Drug Research Institute, New Delhi.
13. Wallis T.E., Analytical Microscopy, J&A Churchill Ltd., London.
14. Kokate C.K., Practical Pharmacognosy, Vallabh Prakashan, New Delhi.
15. Iyengar M.A., Pharmacognosy of Powdered Crude Drugs, PharmaMed Press, Hyderabad.
16. Iyengar, M.A. and Nayak S.C.K., Anatomy of Powdered Crude Drugs, PharmaMed Press, Hyderabad.

RPH-737

PHARMACEUTICAL ANALYSIS-III

(PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE)

Unit I

Ultra violet and visible spectroscopy: Principle and origin of spectra, quantitative laws, chromophores and auxochromes, factors affecting absorption, instrumentation- single and double beam spectrophotometer, Woodward-Fieser rule, applications.

Infra-red spectroscopy: Principle, effect of hydrogen bonding and conjugation on absorption band, instrumentation, interpretation of IR spectra of simple compounds (Ethanol, Benzaldehyde). FTIR, applications of IR spectroscopy in pharmaceutical analysis.

Unit II

NMR spectroscopy: Principle of ^{1}H-NMR, chemical shift and factors affecting it, shielding and desheilding, spin-spin coupling and coupling constant, spin-spin splitting, instrumentation, NMR active compounds and study of ^{1}H-NMR spectra of- Ethanol, Benzaldehyde. Introduction to ^{13}C-NMR.

Unit III

Mass spectrometry: Principle, fragmentation pattern in relation to molecular structure and functional groups including McLafferty rearrangement, ionization techniques (CI, FAB, ESI, MALDI), instrumentation, applications, mass spectra of some simple compounds (Ethanol, Benzaldehyde).

Unit IV

Miscellaneous techniques: Principle, instrumentation and applications of atomic absorption spectroscopy, fluorimetry and flame photometry.

Introduction to gel electrophoresis, scanning electron microscopy (SEM) and transmission electron microscopy (TEM).

Unit V

Quality Assurance: Basic concept of quality, difference between QC and QA, quality audit, types of quality audits, concept of TQM, ISO 9000 series. Elementary study of WHO guidelines. Different documents prepared by QA department (batch manufacturing record, master formula record, validation master plan). Basic concept of validation, types of validation, different validation parameters, protocols for process validation.

RPH-737P

PHARMACEUTICAL ANALYSIS-III

(PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE) PRACTICAL

1. Determination of λ_{max} of different compounds by UV-visible spectrophotometry.
2. Verification of Beer's law.
3. Determination of unknown concentration of some drugs by UV-visible spectrophotometry.
4. Simultaneous estimation of multi-component drugs by UV-visible spectrophotometry.
5. Determination of factors which affect λ_{max} by UV-visible spectrophotometry.
6. Interpretation of IR, Mass and NMR spectra.
7. Assay of official formulations containing single and more active ingredients using instrumental techniques.
8. Assay of pharmaceutical substances by flame spectrophotometry (NaCl, KCl oral sachet).
9. Separation of a protein mixture using gel electrophoresis.
10. Formation and maintenance of different documents/records formed by QA department.

BOOKS RECOMMENDED

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Becket A. H. and Stenlake J. B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
3. Chatten L. G., A text book of Pharmaceutical Chemistry, Vol. I & II, Marcel Dekker, New York.
4. Willard H.H.,Merrit L.L., Dean J.A.,Settle P.A., Instrumental Methods of analysis, Van Nostrand Renhold, New York.
5. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York, 1970.
6. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.
7. Silverstein R.M.,and Webster F.X., Spectrometric Identification of Organic Compounds, John Wiley & Sons.
8. Skoog V., Principles of Instrumental Analysis, Holler-Neimen.
9. Kemp W., Organic spectroscopy, 3rd Edition, Palgrave, New York.
10. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.

11. Pavia D.L.,Lampman G.M., and Kriz G.S., Introduction to spectroscopy, 3rd Edition, Harcourt College Publishers, Philadelphia.
12. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier.
13. WHO-Quality Assurance of Pharmaceuticals, Vol. I & II, AITBS Publisher & Distributors, Delhi.
14. Berry I.R. and Harpaz, D., Validation of API, 2nd Edition, CRC Press.

RPH-738P

HOSPITAL TRAINIGNG-II

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports etc.

May be performed at the end of the 6th semester.