# KADI SARVA VISHWA VIDYALAYA

## K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH

## MASTER OF PHARMACY SYLLABUS

**Effective from Session JUNE 2012**

**SEMESTER-I**

**SCHEME OF TEACHING**

| SUB CODE | NAME OF SUBJECT | CONTACT HOURS PER WEEK | | CREDITS | |
|---|---|---|---|---|---|
| | | T | P | T | P |
| | 111 to 117 are common subjects. | | | | |
| 111 | Advanced Spectroscopic Methods | 3 | - | 3 | |
| 112 | Advanced Spectroscopic Methods Practical | - | 3 | | 3 |
| 113 | Biostatistics And Computer Applications | 2 | - | 2 | |
| 114 | Biostatistics And Computer Applications Practical | - | 3 | - | 3 |
| 115 | Intellectual Property Rights | 2 | - | 2 | - |
| 116 | New Drug Applications | 2 | - | 2 | - |
| 117 | Scientific Communication Skills | 2 | - | 1 | - |
| | Specialization Subjects | | | | |
| 211 | Fundamentals of Pharmaceutics –I Theory | 3 | - | 3 | - |
| 212 | Pharmaceutics and Pharmaceutical Technology Practical-I | - | 9 | - | 5 |
| 311 | Pharmacology I | 3 | - | 3 | - |
| 312 | Pharmacology I Practical | - | 9 | - | 5 |
| 411 | Basic Concepts In Quality Assurance And Separation Science | 3 | - | 3 | - |
| 412 | Basic Concepts In Quality Assurance And Separation Science Practical | - | 9 | - | 5 |
| 511 | Basic Pharmacognosy & Phytochemistry | 3 | - | 3 | - |
| 512 | Basic Pharmacognosy & Phytochemistry Practical | - | 9 | | 5 |
| 611 | Management Concepts-I | 4 | - | 3 | - |
| 612 | Business Communications | 3 | - | 2 | - |
| 613 | Indian Pharmaceutical Regulations And Guidelines | 4 | - | 3 | - |
| 711 | Clinical Pharmacy I | 3 | - | 3 | - |
| 712 | Clinical Pharmacy I Practical | - | 9 | - | 5 |
| | **Total** | | | | |
| 200 | Pharmaceutics | 14 | 15 | 13 | 11 |
| 300 | Pharmacology | 14 | 15 | 13 | 11 |
| 400 | Quality Assurance | 14 | 15 | 13 | 11 |
| 500 | Pharmacognosy | 14 | 15 | 13 | 11 |
| 600 | Pharmaceutical Management And Regulatory Affairs | 22 | 6 | 18 | 06 |
| 700 | Clinical Pharmacy | 14 | 15 | 13 | 11 |

## SCHEME OF EXAMINATION

| SUB CODE | NAME OF SUBJECT | DURATION OF EXAM (Hrs) | MARKS | | | |
|---|---|---|---|---|---|---|
| | | | THEORY | | PRACTICAL | |
| | | | University level evaluation | Institute level evaluation | University level evaluation | Institute level evaluation |
| 111 | Advanced Spectroscopic Methods | 3 | 80 | 20 | -- | -- |
| 112 | Advanced Spectroscopic Methods Practical | 3 | -- | -- | 80 | 20 |
| 113 | Biostatistics and Computer Applications | 3 | 80 | 20 | -- | -- |
| 114 | Biostatistics and Computer Applications Practical | 3 | -- | -- | 80 | 20 |
| 115 | Intellectual Property Rights | 3 | 80 | 20 | -- | -- |
| 116 | New Drug Applications | 3 | 80 | 20 | --- | -- |
| 117 | Scientific Communication Skills | 3 | 80 | 20 | -- | -- |
| 211 | Fundamentals of Pharmaceutics-I Theory | 3 | 80 | 20 | -- | -- |
| 212 | Pharmaceutics and Pharmaceutical Technology Practical - I | 6 | -- | -- | 80 | 20 |
| 311 | Pharmacology - I | 3 | 80 | 20 | -- | -- |
| 312 | Pharmacology - I Practical | 6 | -- | -- | 80 | 20 |
| 411 | Basic Concepts in Quality Assurance and Separation Science | 3 | 80 | 20 | -- | -- |
| 412 | Basic Concepts in Quality Assurance and Separation Science Practical | 6 | -- | -- | 80 | 20 |
| 511 | Basic Pharmacognosy & Phytochemistry | 3 | 80 | 20 | -- | -- |
| 512 | Basic Pharmacognosy & Phytochemistry Practical | 6 | -- | -- | 80 | 20 |
| 611 | Management Concepts - I | 3 | 80 | 20 | -- | -- |
| 612 | Business Communications | 3 | 80 | 20 | -- | -- |
| 613 | Indian Pharmaceutical Regulations and Guidelines | 3 | 80 | 20 | -- | -- |
| 711 | Clinical Pharmacy - I | 3 | 80 | 20 | -- | -- |
| 712 | Clinical Pharmacy - I Practical | 6 | -- | -- | 80 | 20 |
| **Total** | | | **Theory** | | **Practical** | |
| | | | **External** | **Internal** | **External** | **Internal** |
| 200 | Pharmaceutics | 30 | 480 | 120 | 240 | 60 |
| 300 | Pharmacology | 30 | 480 | 120 | 240 | 60 |
| 400 | Pharmaceutical Quality Assurance | 30 | 480 | 120 | 240 | 60 |
| 500 | Pharmacognosy | 30 | 480 | 120 | 240 | 60 |
| 600 | Pharmaceutical Management and Regulatory Affairs | 30 | 640 | 160 | 160 | 40 |
| 700 | Clinical Pharmacy | 30 | 480 | 120 | 240 | 60 |

**SUBJECT** **: Advanced Spectroscopic Methods**
**SUBJECT CODE** **: 111 & 112**
**RATIONALE** : Discussion of all analytical methods with instrumentations to estimate API and impurities in bulk drugs and finished products to maintain quality standards.

**COURSE OBJECTIVES** : By the end of the course the student should be able to:

1. Make proper choice of analytical method for given drug.
2. Demonstrate principles and applications of each analytical techniques.
3. Demonstrate the ability to accurately Interprete the results from instruments
4. Demonstrate to operate all instruments.

**LEARNING OUTCOMES**: At the end of the course students will be able to:

1. Discuss characteristic features of each analytical methods.
2. Discuss applications of all analytical methods in pharmaceuticals.
3. Interprete the spectra obtained.
4. Estimate API purity, Impurity profile of drugs and intermediates.
5. Estimate plasma drug concentrations from in vivo samples.

**PREREQUISITES**: Basic pharmaceutical analysis and related calculations.
**TEACHING & EVALUATION SCHEME**:

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 111 | Advanced Spectroscopic Methods | 3 | - | 3 | 3 | 20 | --- | 80 | --- | 100 |
| 112 | Advanced Spectroscopic Methods Practical | - | 3 | 3 | 3 | --- | 20 | --- | 80 | 100 |

**Course content:**

| | | |
|---|---|---|
| 1 | **Ultraviolet spectroscopy**<br>Energy levels and selection rules, Woodward- fieser rules, Influence of substitution, ring size and strain on spectral characteristics, solvent effect, stereo chemical effect, non-conjugated interaction, spectral correlation with structure. | 20 |
| 2 | **Infrared spectroscopy**<br>Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR | 20 |

| | | |
|---|---|---|
| 3 | **Nuclear Magnetic Resonance spectroscopy**<br>**A**. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, the origin of spin-spin splitting, Pascal triangle, coupling constant, chemical shift reagents, Pharmaceutical applications.<br>**B**. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling. Interpretation of Proton-NMR spectra and 13 C NMR spectra. | 20 |
| 4 | **Mass Spectrometry**<br>Basic principle and theory involved instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, McLafferty rearrangement, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry. | 20 |
| 5 | **Fluorimetry**<br>Emission techniques, Theory and principle, Factors affecting fluorescence, Instrumentation, Applications, enzyme assays and fluorimeters, fluorescence microscopy, flow cytometry. | 20 |

**SUBJECT : Advanced Spectroscopic Methods Practical**
**SUBJECT CODE : 112**

| |
|---|
| Practical based on instrumental methods of analysis. A sufficient training will be given through exercises given below |
| To perform the assay of cotrimoxazole tablets IP |
| Determination of riboflavin using photo fluorimeter |
| Determination of riboflavin using colorimeter and compare the results obtained by exp no 3 and 4. |
| Estimation of HCl and $CH_3COOH$ in given sample with the help of pH meter. |
| Determination of Dissociation constant of weak acid |
| To find out $\lambda_{max}$ and $A_{1\%, 1\ cm}$ of paracetamol and perform the assay of given sample of Paracetamol tablets as per IP |
| Determination of concentration of glucose and sucrose in given sample by Polarimetry |
| Estimation of sodium and potassium ions in the Oral rehydrating salts (ORS) by flame photometry. |
| To determine %purity of sulpha drugs using B M reagent method. |
| Estimation of caffeine in the given sample by spectrophotometric method |
| Simultaneous estimation of salicylamide and paracetamol without prior separation |
| Determination of concentration of Vanillin in the sample by potentiometry |
| Determination of amoxicillin and cloxacillin by titrimetric method |
| Estimation of Neutralization capacity of Antacid tablets |
| Evaluation of UV spectra of organic compound in different solvents |

**SUBJECT** **: Biostatistics and Computer Applications**
**SUBJECT CODE** **: 113 & 114**
**RATIONALE** : Discussion of application of stastical principles and calculations in pharmacy. The unit builds the concept of experimental design and bio statistical data management in all aspects of pharmaceutical research.

**COURSE OBJECTIVES**: By the end of the course the student should be able to

1. Organize the research data.
2. Present the data in proper manner.
3. Make choice of statistical methods for data analysis.
4. Apply principles of biostatics.

**LEARNING OUTCOMES**: At the end of the unit students will be able to:

1. Collect and organize data in scientific manner.
2. Analyze the data with right statistical method.
3. Apply regression analysis and ANOVA to research data obtained.
4. Calculate parameters like LD50, ED50 etc.
5. Apply design of experiment with set of variables.
6. Interpret the results of data management and derive conclusion.
7. Apply computer software for data management.

**PREREQUISITES:** Basic computer operations and Basic mathematics.

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 113 | Biostatistics and Computer Applications | 2 | - | 2 | 2 | 20 | --- | 80 | --- | 100 |
| 114 | Biostatistics and Computer Applications Practical | - | 3 | 3 | 3 | --- | 20 | --- | 80 | 100 |

## Course content:

| | | |
|---|---|---|
| 1 | An introduction to statistics and biostatistics collection and organization of data: Graphical and pictorial presentation of data, measure of central tendency and dispersion, sampling techniques, sample size, coefficient of variance, mean error, relative error, precision and accuracy. | 15 |
| 2 | Probability: Definition and probability distribution, normal, binomial and polynomial distribution, continuous data distribution, fiducial limit, profit and log analysis. | 10 |
| 3 | Regression: Linear regression and correlation, curvilinear regression, method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression. Parametric test: testing hypothesis, types of error, tests of significance based on normal distribution, test of significance for correlation coefficients | 20<br><br><br>20 |
| 4 | Non- Parametric test: Data characteristics and nonparametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit, Mann-Whitney etc. | 15 |

| | | |
|---|---|---|
| 5 | Experimental design: Randomization completely, randomized and Latin square design, factorial design, cross over and parallel design, bioavailability and bioequivalence | 10 |
| 6 | Techniques: Bioassay, dose effect, relationship, LD50, ED50, probability calculation. Statistical quality control, shew hart control test, statistical procedure in assay development. | 10 |

**SUBJECT : Biostatistics and Computer Applications Practicals**
**SUBJECT CODE : 114**

| | |
|---|---|
| 1. | Computation and application of mean (arithmetic, geometric and harmonic), median and mode. |
| 2. | Use of functions: Standard deviation, variance, standard error of mean |
| 3. | Application of correlation coefficients |
| 4. | Application of Regression Analysis in preparation of calibration curve |
| 5. | Computation and application of mean (arithmetic, geometric and harmonic), median and mode. |
| 6. | Use of Data Analysis (parametric tests) (MS Excel®):<br>t-test, application in comparison of μ and Ẍ, t-test, application in comparison of two methods of analysis (QA) paired t-test, application in comparison of two treatments (Pharmacology) |
| 7. | Use of Data Analysis (parametric tests) (MS Excel®): ANOVA<br>One way ANOVA – application in comparison of more than two treatments<br>Two way ANOVA – Determination of Bioequivalence |
| 8. | Use of Data Analysis (parametric tests) (Prism 5®): ANOVA and post hoc test<br>Tukey test, Dunnet test |
| 9. | Non parametric test (Prism 5®) Chi-square test – Determination of effectiveness of vaccine<br>Wilcoxon-sign rank test, Mann-Whitney U –test |
| 10. | Planning and Design of Experiments<br>• To prove that dissolved oxygen promotes biosynthesis of antibiotics.<br>• To prove that bioassay method of Penicillin is more accurate, precise and reproducible than determination by titration method.<br>• To optimize fermentation conditions for production of Alcohol by yeasts and to evaluate the impact of pH, temperature and humidity on Alcohol yields.<br>• You are given three herbal drug extracts which are reported to possess anti-bacterial activity. Design an experiment to find out the optimum proportion of each of the extracts to be combined to achieve maximum therapeutic efficacy.<br>• To prove that different plant organs show different responses to IBA, GA & and NAA<br>• To prepare and evaluate a tablet dosage form of Paracetamol using three excipients and optimum temperature and humidity condition to achieve the dissolution, disintegration and hardness parameters equivalent to that of a standard market formulation.<br>• To optimize the concentration of excipients (Lactose, Ethyl cellulose and Hydroxy-propyl methyl cellulose) for achieving the desired release profile of 20% in first hour and 90% in tenth hour in development of indomethacin sustained release tablet.<br>• To formulate carbamazepine microspheres with appropriate % drug entrapment efficiency and particle size (micron) by studying the influence of Polymer: Drug ratio, Acetone: Dichloromethane ratio and stirring speed (RPM) at three levels.<br>• For the preparation of mouth dissolving film of salbutamol sulfate, three polymers (Hydroxy propyl methyl cellulose, Poly vinyl alcohol and Poly vinyl pyrrolidone) are to be used where the total amount of three components is restricted to 50 mg. The films are required to be tested for tensile strength, elastic modulus and % strain. Optimize the concentration of each of these polymers through desirability function.<br>• To study the effect of concentration of l-leucine, concentration of PEG 6000 and compression force on residual force, crushing strength and disintegration time and optimize their |

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|---|---|
| | concentration employing an optimizing strategy with more than two levels.<br>The design should describe following:<br>1. Type of design (e.g. Cross-over, 2 x 2 factorial etc.)<br>2. Sample size<br>3. Design table/ Flow chart<br>4. Parameters to be studied<br>5. Sample Selection method<br>6. Statistical Analysis to be involved in the study and the basis |

## Books recommended:

Pharmaceutical Biostatistics. Bolton Sanford, 4th ed, Marcel Dekker Inc.
Pharmaceutical experimental design, S. Gareth et al, Marcel Dekker Inc.

**SUBJECT : Intellectual Property Rights**
**SUBJECT CODE : 115**
**RATIONALE :** Discussion of basic concept behind the intellectual property rights and their rationale. These are different types of IP rights like copyright, trademarks, patents, industrial designs etc. Understanding of this classification and identifying different rights is very important.

**COURSE OBJECTIVES** : After studying this unit, student should be able to:

1. Appreciate the concept of intellectual property (IP) vis-à-vis physical property;
2. Recognize the different kinds of intellectual property;
3. Appreciate the rationale behind IP, and the underlying premises;
4. Know the position of IP under the constitution of India.
5. Understand concept of patentability.

**LEARNING OUTCOMES**: At the end of this unit the student will be able to:

1. Understand the terms Patent act, Trademark, WTO and its importance.
2. Apply concept of patentability to relevant field.
3. Provide technical details to convert into legal form for paten.
4. Demonstrate patent infringement and its applications.
5. Use patent search engine efficiently.

**PREREQUISITES:** Basics of Drug Laws.
**TEACHING AND EVALUATION SCHEME**:

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 115 | Intellectual Property Rights | 2 | --- | 2 | 2 | 20 | ---- | 80 | ---- | 100 |

**Course content:**

| | |
|---|---|
| 1 Intellectual Property, Importance and Types of Intellectual Property | 10 |
| 2 Paris Convention, World Trade Organization and GATT | 05 |
| 3 The Indian Patent Act, 1970 and the Indian Patent(Amendments) Act, 2005 | 10 |
| 4 The US Patent and Trade Organization, European Patent Office | 05 |
| 5 Patent, Importance and parts of a Patent, Types of Patent in the United States, Europe and India, Provisional Application | 10 |
| 6 PCT route to filing of a Patent | 10 |
| 7 Concepts of Patentability – Issues of Novelty, Inventive Step and Industrial Application with special reference of differences in India, US and European Patents | 10<br>05 |
| 8 Priority Dates, Filing Dates, Unity of Invention and Importance | 05 |
| 9 Examination of the Patent Application, differences in Indian, US and European Patents, Office actions | 05 |
| 10 Continuation, Continuation in Part and Divisional Applications, Interference proceedings, Oppositions | 05 |
| 13 Allowance and Issue of Patents, Patent Terms and Extensions and Renewal Fee requirements in the US, Europe and India | 05<br>05 |
| 14 Patent Infringement – literal Infringement and Doctrine of Equivalence | 05 |
| 15 Patent Search Engines, Key Words and Databases | 05 |

**SUBJECT : New Drug Applications**
**SUBJECT CODE : 116**

**RATIONALE** : Discussion of stages of product development in context with drug approval process. The unit involves the discussion about approval authorities, documents and data required for approval process, Preclinical and clinical studies, NDA contents and guidelines for NDA and ANDA.

**COURSE OBJECTIVES** : At the end of the course the student should be able to:

1. Understand NDA, ANDA,
2. Understand importance of development stages, Preclinical and clinical phases of drug product.
3. Use toxicity data and Pharmacokinetic data for approval process.
4. Derive all necessary data for new drug application.

**LEARNING OUTCOMES**: At the end of the unit student will be able to:

1. Describe current requirements for NDA and ANDA for different approving authorities.
2. Demonstrate use of Stability data, Toxicity data and pharmacokinetic data in drug approval process.
3. Define Bio-waiver requirements in ANDA, Para I, II and III and IV approvals
4. Explain contents of NDA and ANDA in accordance with current guidelines.

**PREREQUISITES**: NA.

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 116 | New Drug Applications | 2 | - | 2 | 2 | 20 | ---- | 80 | ---- | 100 |

## Course content:

| | | |
|---|---|---|
| 1 | US-FDA, Food and Drug Administration Act, History, Hatch-Waxman Amendment | 5 |
| 2 | New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) | 5 |
| 3 | Chemistry, Pharmacy, Manufacturing. Pharmaceutical Developments, Packing Material, Active Ingredients, Excipients, Control Tests on Finished Products, Stability Data, Analytical Method Validation Bio Pharmaceutics | 20 |
| 4 | Preclinical Pharmacology and Toxicology. single dose, repeat dose, reproductive toxicities, mutagenicity, oncogenicity / carcinogenicity, animal pharmacokinetics and toxicokinetics | 10 |
| 5 | CLINICAL: Clinical Pharmacology and Pharmacodynamics, Pharmacokinetics in man, ethnic genetic and environmental factors, Good Clinical Practice, Clinical Trials – general aspects of design and interpretation, Statistical analysis of clinical data | 20 |
| 6 | Biological Products and Biotechnology: Clinical aspects of recombinant DNA products, Preclinical Pharmacological and Toxicological Requirements for biological and biotechnological products | 10 |
| 7 | Preclinical studies: Clinical Trials, Phases and Interpretation | 5 |
| 8 | NDA, contents and formats, guidelines for filing NDA | 5 |
| 9 | New Drug Approval, Executivities, Orange Book | 5 |
| 10 | ANDA, contents and formats, guidelines for filing ANDA | 5 |
| 11 | Bio-waiver requirements in ANDA, Para I, II and III and IV approvals<br>505(b)2 application | 5 |
| 12 | DMFs and their Importance | 5 |

**SUBJECT : Scientific Communication Skills**
**SUBJECT CODE : 117**
**RATIONALE** : This course provides students with instruction on the development of effective scientific communication skills. The skills learned in this course will be of value in independent learning projects, written assignments and class presentations, as methods of assessment. It will also help students in preparing for their post-graduate careers.

**COURSE OBJECTIVES** : The general aims of this course are:

1. To assist students in developing clear, concise and logical approaches to scientific communications.
2. To enhance students' writing abilities, both in the translation of complex scientific language to lay terms that can be understood by the general public and in discussing research results in a clear and concise fashion.
3. To develop students' ability to collect scientific information and synthesize it into coherent short oral presentations

**LEARNING OUTCOMES:**

- Identify interesting communication research questions, perform research, and produce academic writing of a standard suitable for target academic journals
- Effectively engage in the practical application of communication skills and knowledge
- Demonstrate the ability to communicate effectively both orally and in writing on a variety of topics related to scientific writing.

**PREREQUISITES**: English
**TEACHING AND EVALUATION SCHEME**:

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 117 | Scientific Communication Skills | 2 | --- | 2 | 1 | 20 | --- | 80 | --- | 100 |

**Course content:**

**117 Scientific Communication Skills**

1 Introduction, information retrieved systems.
2 Writing term papers and reports.
3 Organization of scientific material, dissertation and reports.
4 Reading research papers.
5 Skill on oral presentation.
6 Each student has to present a seminar

**SUBJECT : Fundamentals of Pharmaceutics – I**
**SUBJECT CODE : 211**

**RATIONALE** : This unit discusses importance of preformulation studies of API, which leads to design suitable dosage forms using various additives. Discussion of different adjuvant, their functional classification and factors affecting their choice is the basis of selecting formulations for given API. Knowledge of Biopharmaceutical factors and pharmacokinetic calculations leads to judge the fate of Dosage form after administration.

**COURSE OBJECTIVES** : At the end of the course the student should be able to:

1. Discuss key preformulation tests for developing dosage forms.
2. Refer important drug information from literature necessary to develop stable formulation.
3. Compare and contrast various formulation additives.
4. Profiling drug and excipients for correct combination.
5. Discuss co relation between physicochemical properties of drug and physiological factors affecting fate of drug.

**LEARNING OUTCOMES**: At the end of the unit student will be able to:

1. Conclude best possible stable formulations for given API, along with route of administration.
2. Choose correct formulation adjuvants from similar functional classes.
3. Derive basic general formulation for any dosage form.
4. Predict rate and extent of absorption of drug from given formulations.

**PREREQUISITES**: Principles of Physical pharmaceutics.

**TEACHING & EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 211 | Fundamentals of Pharmaceutics – I | 3 | - | 3 | 3 | 20 | --- | 80 | --- | 100 |
| 212 | Pharmaceutics and Pharmaceutical Technology Practical - I | - | 9 | 9 | 5 | --- | 20 | --- | 80 | 100 |

**Course content:**

| | | |
|---|---|---|
| 1 | Preformulation studies<br>Brief overview of physicochemical aspects of drug substances and its correlation with formulation development: Solubility, Dissolution rate, pKa, Partition coefficient, Micromeritical properties, Wettability, Hygroscopicity, Polymorphism and crystal habit, Drug excipient compatibility study | 25 |
| 2 | Formulation additives<br>Importance, Ideal requirements, Functional classification systems , factors affecting choice of excipients, and Efficiency Evaluation of various additives: Preservatives, Antioxidants, Suspending agents, Emulsifying agents, Colours, Flavors, Solvents, Semisolid bases (for topical and suppository), Diluents, Binders, Disintegrants, Anti frictional agents.. | 25 |
| 3 | Biopharmaceutics:<br>a. Effect of physicochemical and physiological and formulation parameters on drug absorption.<br>b. Mechanisms of drug absorption: Passive diffusion, Active transport and pH partition theory. | 25 |

| | | |
|---|---|---|
| 4 | Pharmacokinetics:<br>a. Introduction and terminologies<br>b. Concept of compartmental modeling- Brief discussion of One and two compartment models<br>c. Concentration time pro-file, plotting the data, different fluid compartments and blood flow rates to various compartments.<br>d. Pharmacokinetic characterization of drugs: Absorption rate constants (Wagner Nelson, Loo Reigelman methods), limitations, lag-time, pharmacokinetics in presence of lag-time; Flip-flop model.<br>e. Introduction & Significance of ADME concepts.<br>f. Pharmacokinetic characterization of drug (linear and nonlinear pharmacokinetics) (Mathematical representation)<br>g. Bioavailability-Bioequivalence, methods to determine bioavailability of drugs. Methods to enhance bioavailability of drugs. | 25 |

**SUBJECT : Pharmaceutics and Pharmaceutical Technology Practical - I**
**SUBJECT CODE : 212**

- Particulate characterization of various API.
- Rheological measurements of polymer gels and market products like liquid orals, topical products.
- Preformulation studies of various APIs and Excipients. Parameters: solubility, derived properties, drug-excipient interactions, solid and aqueous state stability studies.
- Evaluation of Excipients:
- Comparative evaluation
- Optimization of concentration
- Evaluation of efficiency.
- Preservative challenge test, Microbial limit test, Identification of contamination

**Books Recommended**


1. Lieberman and Lechman; Pharmaceutical Dosage Forms: Tablets Vol:1-3
2. Lieberman and Lechman; Pharmaceutical Dosage Forms: Parenteral Vol:1-3
3. Lieberman and Rieger; Pharmaceutical Dosage Forms: Disperse Systems Vol:1-3
4. Swarbric and Boylan; Encyclopedia of Pharmaceutical Technology,Vol1-22
5. Jens Thur Cartensen; Pharmaceutical Preformulation, Informa Healthcare
6. Sarfaraz K. Niazi; Handbook of Pharmaceutical Manufacturing Formulations: VOL:1-6, CRC PrI Llc
7. Howard C. Ansel, Shelly J. Prince; Pharmaceutical Calculations: The Pharmacist's Handbook, Lippincott Williams & Wilkins
8. N. K. Jain; Pharmaceutical Product Development CBS publishers
9. Stanford Bolton; Pharmaceutical Statistics, 4th edition, Marcel Dekker Inc., NY.
10. Handbook of Pharmaceutical Excipients 4th Edition, Pharmaceutical Press
11. Stephan Curry & Robin Whelpton; Manual of Laboratory Pharmacokinetics
12. Nina Washington; Physiological Pharmaceutics, Tylor & Francis, New York.
13. Dressman & Kramar; Pharmaceutical Dissolution Testing, Tylor & Francis, NY.
14. Umesh Banakar; Pharmaceutical Dissolution Testing, Marcel Dekker Inc., NY.
15. R.E.Notari; Biopharmaceutics and Clinical Pharmacokinetics, 4TH Ed. Marcel Dekker Inc., NY.
16. Gibaldi & Perrier; Pharmacokinetics, Marcel Dekker Inc., New York.

**SUBJECT : Pharmacology -I**
**SUBJECT CODE : 311 & 312**

**RATIONALE** : This unit discusses the basic principles of general pharmacology with Emphasis on drug receptor theory and mechanisms of drug actions. This is supported by pharmacokinetic calculations to quantify the effective dose. Systemic pharmacology involves CNS and ANS drugs, their mechanism of action and other pharmacological aspects.

**COURSE OBJECTIVES**: At the end of the course the student should be able to:

1. Understand roll of receptors, receptor targets and functions.
2. Discuss drug receptor interaction theory.
3. Describe pharmacological classification of ANS and CNS drugs,

**LEARNING OUTCOMES**: At the end of the course the student will be able to:

1. Establish drug receptor combinations.
2. Locate correct targets for drug action.
3. Establish dose response relationship.
4. Predict extent of protein binding and amount of free drug.
5. Calculate rate and extent of drug absorption.
6. Handle animal experiments based on dose response relationship, Bioassays.

**PREREQUISITES**: Basic knowledge of APHE.

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 311 | Pharmacology - I | 3 | - | 3 | 3 | 20 | -- | 80 | -- | 100 |
| 312 | Pharmacology - I Practical | - | 9 | 9 | 5 | -- | 20 | -- | 80 | 100 |

## Course content:

| | | |
|---|---|---|
| 1 | Drug Receptor Interaction Theories, Occupation Theory, Rate Theory etc. | 20 |
| 2 | Receptor occupation and Response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and post synaptic receptors | |
| 3 | Receptor down regulation and up regulation. | |
| 4 | Dose response relationship and different types of antagonisms, Inverse agonism. | 10 |
| 5 | Mechanisms involved in Receptor Desensitization and Tachyphylaxis | |
| 6 | Protein and Tissue binding, Factors affecting binding, kinetics of protein binding. | 20 |
| 7 | Determination of various rate constants (Drug absorption, Elimination, etc.). | |
| 8 | Volume of Distribution | |
| 9 | Mechanisms of clearance. Factors affecting clearance rate, Integration kinetics | |
| | Systemic Pharmacology (10 to 13) | |
| 10 | Autonomic Pharmacology: Chemical transmission of the ANS, Pharmacodynamics, pharmacokinetic and toxicological facets of agents acting on adrenergic and cholinergic receptors, neuromuscular junction blockers, Ganglion stimulants and blockers, MAO and COMT inhibitors, Adrenergic neuron blockers. | 10 |
| 11 | Antiulcer, antacids, antidiarrheal, purgative, emetics and antiemetic, cholagogues, antiflatulence | 10 |

| | | |
|---|---|---|
| | drugs. | |
| 12 | Central Nervous system (Neurotransmitters, Functions, Types, Distribution)<br>Chemical neurotransmitters in CNS, Drugs used in Schizophrenia, Depression, Anxiety, Alzheimer's disease, Parkinson's Disease, Epilepsy, Pain management, Local anesthetics, Analeptics, Anti migraine drugs | 20 |
| 13 | Animal Handling and Various guidelines of OECD, ICH, Sch. Y. | 10 |

**SUBJECT : Pharmacology - I Practical**
**SUBJECT CODE : 312**

| | | |
|---|---|---|
| 1-3) | Introduction to pharmacology lab. and animals, handling of animals, Methods for euthanasia and anesthesia, blood sampling, animal breeding, ethical practices in pharmacological experimentation, CPCSEA and OECD Guidelines, IAEC-CPCSEA Form B, Procedure & maintenance of records keeping Practicing IAEC –KBIPER guidelines as per CPCSEA Guidelines. | |
| 4-5) | Study of Animal Behavior | 6 Rats, 6 Mice |
| 6) | Dosing and Blood collection by various methods (retro-orbital Plexus, sublingual, cardiac puncture, i.v.). | 3 Rats, |
| 7) | Normal physiology and biochemical parameters of laboratory animals and maintaining Records of animals food & water intake. | 6 Rats |
| 11) | Bioassays of Graphical, Matching and 3 Point, 4 point methods of various agonists by using isolated tissue using Physiographs. | 6 Rats, 6 G pigs |
| 12 -13) | Bioassays of Antagonists of agonist on various isolated tissue. | 4 Rats, 4 G pigs |
| 14-15) | Computer aided and simulation experiments. | |
| 16-17) | Statistics for animal experiments. | |
| 18) | Normal physiological and biochemical parameters of each lab | 2 Rats, 2 Mice 2 Rabbits animal. |
| Drug Administration by various routes. (i.v., oral, i.p., s.c., i.c.v., i.m.) | | |
| Total 18 Experiments | | Total 27 Rats, 8 Mice, 10 G Pigs 2 Rabbits |

**SUBJECT : Basic Concepts in Quality Assurance and Separation Science**
**SUBJECT CODE : 411 & 412**

**RATIONALE** : This unit discusses the procedures involved in quality control and quality assurance of drug substance and dosage forms. The procedures like maintenance of records and archives, check in and rechecking procedures at each manufacturing stage, and requirements of approving drug authorities are also discussed. The detailed discussion of chromatogrphical analysis of products is also discussed.

**COURSE OBJECTIVES** : At the end of the course the student should be able to:

1. Understand clearly all documents required for records.
2. Derive that which documents and data are required for drug authorities.
3. Know the procedures involved in QA and QC of drug products.
4. Understand principles of GLP.
5. Learn principles of chromatographic analysis of drug products.

**LEARNING OUTCOMES**: At the end of the course the student will be able to:

1. Work as per GLP procedures.
2. Prepare SOPs for manufacturing process and equipments.
3. Perform qualification of process and equipments.
4. Prepare documents for drug approving authorities.
5. Define QC and IPQC parameters for each dosage forms and interpret the results.
6. Handle HPLC and HPTLC instruments.

**PREREQUISITES**: Basic pharmaceutical analysis.

**TEACHING AND EVALUATION SCHEME**:

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 411 | Basic concepts in Quality Assurance and Separation Science | 3 | - | 3 | 3 | 20 | --- | 80 | --- | 100 |
| 412 | Basic concepts in Quality Assurance and Separation Science Practical-I | - | 9 | 9 | 5 | --- | 20 | --- | 80 | 100 |

**Course content:**

| | | |
|---|---|---|
| 1 | Concepts of quality management, GLP | 10 |
| 2 | C-GMP-Schedule M and T | 20 |
| 3 | Introduction to US-FDA, TGA, ICH,WHO guidelines | 10 |
| 4 | Manufacture and control of dosage form, Manufacturing documents, master formula, Batch formula records, SOPs. | 10 |
| 5 | In process quality controls on various dosage forms sterile and non-sterile standard operating procedure for various operations like cleaning, filling, drying, compression, coating, disinfection, fumigation, sterilization, membrane filtration etc. | 30 |
| 6 | Chromatography: General principles, theory, classification of chromatographic techniques, normal and reversed phase, bonded phase, separation mechanisms. | 20 |

**SUBJECT : Basic Concepts in Quality Assurance and Separation Science Practical**
**SUBJECT CODE : 412**

Practicals based on syllabus to give practical trainings to the students.

1. To find out %purity of NaH2PO4 and Na2HPO4 by potentiometry.
2. Estimation of paracetamol from the tablet by colorimetry.
3. Determination of isosbestic point and perform assay of methyl orange.
4. Determination of isosbestic point of bromocresol green.
5. To perform in process quality control test in formulation and prepare its documentation.
6. Estimation of norfloxacin from its dosage form by extractive UV-Vis spectroscopy.
7. Spectrophotometric determination of promethazine derivative by acid dye method.
8. Estimation of perindopril erbumine by potentiometry.
9. To find out λmax and A1%, 1cm of paracetamol and perform the assay of given sample of paracetamol tablets as per IP.
10. To study the metal ligand binding ratio of salicylic acid (drug) and ferric ammonium sulphate.
11. Estimation of aspirin by colorimetry.
12. Estimation of vanillin by conductometry.
13. Recovery study of diclofenac sodium by UV-Vis spectroscopy.
14. Estimation of Nimesulide by UV-Vis spectroscopy.
15. Estimation of paracetamol by RP-HPLC methods

**BOOK RECOMMENDED:**


1. R.M.Silverstein, F.X.Webster, Spectrometric Identification of Organic Compounds, John Wiley & Sons, New-York, 6th Ed, 1998.
2. H. H. Willard, L. L. Merritt, J. A. Dean, Instrumental Methods Of Analysis, CBS Publishers 7th Ed., 1986
3. Skoog, Holler-Nieme, Principle Of Instrumental Analysis, Harcourt Asia Pvt. Ltd. 5th Ed.,2001
4. W. Kemp, Organic Spectroscopy, ELBS-Macmillan publishers, 3rd Ed.,1991
5. P. Jurg, Good Laboratory Practice, Springer,Berlin,1st Ed., 2001
6. S. Willig, J. R. Stoker, Good Manufacturing Practices For Pharmaceuticals, Marcel Dekker Inc. NY, Vol-78 ,4th Ed. 97
7. M. Parkany, Quality Assurance & Total Quality Management for Analytical Lab., Royal Soc. of Chem, 1st Ed., 1995
8. J. Kennedy, Analytical Chemistry, Sounders College, New York, 2nd Ed.,1990
9. R. G. Alfonso, Remington: The Science & Practice of Pharmacy, Lippincott Williams & Wilkins pub., Vol-I &II, 20th Ed., 2001
10. D. Harvey, Modern Analytical Chemistry, MC Graw-Hill International publication, Latest edition
11. D.E. Robert, Principles Of Quantitative Chemical Analysis, Mc Graw Hill, New Delhi, 1st Ed.,1997
12. J. R. Dyer, Application Of Absorption Spectroscopy Of Organic Compounds, Prentice Hall, New Delhi,10th Ed.,1997
13. M. Valcarcel, Principles Of Analytical Chemistry, Springer,Berlin,1stEd.,2000
14. D.H.Shah, SOP :Guidelines, ,Business Horizons, New Delhi,1stEd.,1997
15. D.H.Shah., QA :Manual, , Business Horizons, New Delhi, 1st Ed.,2000
16. V. N. Alexeyev, Quantitative Analysis, ,CBS Publishers, New Delhi, 1st Ed., 1994
17. L. Ohannesian, Anthony J. Streeter, Handbook Of Pharmaceutical Analysis, Marcel Dekker Inc. NY, 1st Ed., 2002
18. J. Bank, Essence of Total Quality Management, Prentice Hall Of India, 1st Ed., 2004
19. F. A. Settle, Handbook of Instrumental Techniques for Analytical Chemistry, Pearson Edu. Asia, Delhi, 1st Ed., 2004
20. Mca ,Rules And Guidance For Pharmaceutical Manufacturers And Distributors, London, 6th Ed., 2002
21. G. Currell, Analytical Instru. Performance Characteristics And Quality, John Willey & Sons, Chichester, 3rd Ed., 2000
22. G. D. Christian, Analytical Chemistry, John Willey & Sons Inc., 6th Ed,2003
23. S. Weinber, Good Laboratory Practice Regulations, Informa Healthcare, 4th Ed., 2007.

**SUBJECT : Basic Pharmacognosy & Phytochemistry**
**SUBJECT CODE : 511 & 512**

**RATIONALE**: This unit builds basis of Pharmacognosy by discussing pharmacognostic properties of various parts of medicinal plants and its importance in future identification techniques. It also discusses authantification techniques for qualitative and quantitative analysis of drugs. The unit also gives knowledge about alternative herbal medicines like nutraceuticals, herbal cosmetics, edible dyes and sweeteners derived from plant.

**COURSE OBJECTIVES** : At the end of the course the student should be able to:

1. Discuss characteristic features of various parts of the medicinal Plants.
2. Learn importance of identification parameters.
3. Understand taxonomy and microtomy.
4. Know about nutraceuticals and herbal cosmetic ingredients.

**LEARNING OUTCOMES**: At the end of the course the student will be able to:

1. To identify given part, microscopically and morphologically.
2. Authenticate pharmacognostical characters.
3. Quantify the phytoconstituents.
4. Use literature resources of herbal medicines.
5. Identify the plants having pharmaceutical adjuvants like sweeteners, irritants, edible colours etc.

**PREREQUISITES: none**
**TEACHING AND EVALUATION SCHEME**:

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 511 | Basic Pharmacognosy & Phytochemistry | 3 | - | 3 | 3 | 20 | --- | 80 | --- | 100 |
| 512 | Basic Pharmacognosy & Phytochemistry Practical- I | - | 9 | 9 | 5 | --- | 20 | --- | 80 | 100 |

## Course content:

| | | |
|---|---|---|
| 1. | Morphology, microscopy and various modifications of leaf. | 05 |
| 2. | Morphology, microscopy and various modifications of Root. | 05 |
| 3. | Morphology, microscopy and various modifications of stem. | 05 |
| 4. | Morphology and inflorescence of flower. | 05 |
| 5. | Morphology, microscopy and various types of barks. | 05 |
| 6. | Morphology and microscopy various fruits. | 05 |
| 7. | Morphology and microscopy various seeds. | 05 |
| 8. | Morphology and microscopy of wood. | 05 |
| 9. | Introduction to taxonomy & its terminology | 05 |
| 10. | Authentication: Preparation of herbarium specifications, use of flora and keys of Plant identification. Microtomy and advanced histological techniques as applied to pharmacognostical specimen, pharmacognostical drawings and macro and microphotography. Quantitative and qualitative microscopic evaluation of drug. | 15 |

| | | |
|---|---|---|
| 11. | Concepts of Complementary medicine, Nutraceuticals | 10 |
| 12. | Phytoconstituents, primary and secondary plant metabolites. | 10 |
| 13. | Herbal medicine information sources: Books, Journals, On-line databases, various institutions and funding agencies for herbal research | 05 |
| 14. | Skin irritants and sensitizing agents from plant | 05 |
| 15. | Plant sweeteners and edible dyes | 05 |
| 16. | Study of some cosmetic herbs and formulations | 05 |

**SUBJECT : Basic Pharmacognosy & Phytochemistry Practical - I**
**SUBJECT CODE : 512**

1. Morphology and Microscopic examination of monocot and dicot root
2. Morphology and Microscopic examination of monocot and dicot stem
3. Morphology and Microscopic examination of monocot and dicot leaf
4. Morphology of Flower
5. Morphology of inflorescence
6. Morphology and Microscopic examination of Fruit.
7. Morphology and Microscopic examination of Seed
8. Morphology and Microscopic examination of Bark
9. Morphology and Microscopic examination of Wood
10. Introduction to family:
11. Microscopical examination of non-living cell contents: starch grains, calcium oxalate & carbonate crystals
12. Determination of stomatal number and stomatal index of given leaf
13. Determination of vein islet and vein termination number of given leaf.
14. Determination of starch grain number and palisade cell ratio of given drugs.
15. Determination of length and breadth of phloem fiber and xylem vessel.
16. Chemical tests of various phyto-constituents.
17. Preparation of herbarium sheets

**BOOKS RECOMMENDED:**


1. Pulok Mukherjee, Quality Control Of Herbal Drugs : An Approach To Evaluation Of Botanicals
2. Atal C.K. And Kapur B.M., Cultivation and Utilization Of Medicinal Plants, RRL Jammu.
3. Rangari & Rangari, Text Book Of Pharmacognosy
4. Datta A.C., A Class Book Of Botany, Oxford Uni.
5. Bendre A. M, Ashokkumar. A Textbook Of Practical Botany Ii Rastogi Publications, Meerut, India.
6. Quadry J S, Shah And Qadry Pharmacognosy, B.S.Shah Publication.
7. Wallis T.E., Text Book Of Pharmacognosy, 5th Edition, Cbs Publishers And Distributors
8. Kalia, Industrial Pharmacognosy
9. Kokate C.K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
10. Kokate C.K, Purohit A.P. And Gokhale S.B. Pharmacognosy (Degree) Nirali Prakashan, Pune.
11. Khandelwal K R, Practical Pharmacognosy, Nirali Prakashan
12. Trease E and Evans W.C., Pharmacognosy, Balliere Tindall. Eastbourne, U.K.
13. Tyler V.C., Brady L.R. And Robers W.E. , Pharmacognosy, Lea And Febiger,
14. Iyengar, Text Book Of Pharmacognosy, Manipal Power Press.
15. Experimental Pharmacognosy, by Tyler and Schwarting
16. Practical evaluation of Phytopharmaceuticals by Brain and Turner
17. MG Chauhan, Microscopy Of Leaf Drug, Jamnagar Ayurved University
18. MG Chauhan, Microscopy Of Bark Drug, Jamnagar Ayurved University
19. Jackson Betty P., Atlas Of Microscopy Of Medicinal Plants, Culinary Herbs And Spices,
20. Fahn A., Plant Anatomy, Aditya Books Publication
21. Swain T. (1963) Chemical Plant Taxonomy, by Swain T. Academic Press London.
22. WHO Monographs On Selected Medicinal Plants Vol-1-2
23. Ansari, Pharmacognosy Textbook of Natural Products, Latest Edition.
24. Edwin And Edwin, Textbook Of Pharmacognosy And Phytochemistry, CBS Publication

**SUBJECT : Management Concepts - I**
**SUBJECT CODE : 611**

**RATIONALE:**
As the course essentially needs Management concepts and the Department of Regulatory Affairs is rich with official communication, the students need to be trained with management concepts and Communication skills. As Regulatory affairs is a part of pharmaceutical business organization and highly connected with all other departments of an organization, the students should learn all management skills to excel.

**COURSE OBJECTIVES:**
1. To provide conceptual knowledge about the functions of Management.
2. To assist students in analyzing factors affecting business environment.
3. To provide a view on personnel policies of companies.
4. To give an overview of financial aspects of business.
5. To give an idea on legal issues of Business world
6. To provide the basic knowledge about the importance of project management in completing tasks

**LEARNING OUTCOMES:**
1. Shall involve in effective planning and organizing any event
2. Shall develop an effective personnel policy for an organization.
3. Shall plan a project or a plan for any business.
4. Shall deal with legal issues in starting a business.
5. Shall evaluate the HR policies of any company and to suggest remedies.

**PREREQUISITES:** Any graduate degree.

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT [Theory] | TOTAL HRS/ Week | CREDITS | EVALUATION SCHEME | | TOTAL MARKS |
|---|---|---|---|---|---|---|
| | | | | INTERNAL | EXTERNAL | |
| 611 | Management Concepts - I | 4 | 3 | 20 | 80 | 100 |

**CONTENT:**

| | | |
|---|---|---|
| 1 | **Fundamentals of Management:** Management – Introduction, principles. Planning-types of plans and principles of planning, Organizing – types of organizational structures, hierarchy in regulatory affairs department, Decision making and delegation, coordinating and controlling | 15 |
| 2 | **Human Resource Management-:**<br>Planning and Procurement, Training and Development, Performance appraisal, Job analysis. | 15 |
| 3 | **Organizational Behaviour:**<br>Role of managers, Attitude and its components, Types of Personality and leadership, Techniques for employee motivation, types of teams and team building. | 15 |

| | | |
|---|---|---|
| 4 | **Pharma Business environment:**<br>Political environment –Preamble, fundamental rights, Growth and control of Pharmaceutical corporate sector in India, Exim policies, Special economic zones, Trade barriers, Policy for research and development, Problems in technology transfer. | 15 |
| 5 | **Financing decisions**<br>Types of securities, Asset based financing, Determination of dividend policies, Types of cost, Types of budgets, Introduction to accounting terminologies | 10 |
| 6 | **Project management:** Projects – Meaning, types and Project life cycle, Project organization structure-project performance measurement and control-project evaluation and termination – multiple project handling – project risk management-, | 15 |
| 7 | **Business Law:** Law of contract – Definition, Types of contracts, Indian Contract Act 1872 – Free consent, Discharge of contract, Breech of contract, Companies Act- 1956 – Company, Types of Companies, Steps in formation of a company, Memorandum, Articles of Association, Consumer Protection Act 1986, Environmental Protection Act 1986. RTI act. | 15 |

**Reference Books:**


1. Mercantile law by ND Kapoor – sultan Chand
2. Financial Management by I M Pandey – Vikas Publications
3. Production and Operations management by Ashwathappa – Himalaya Publications
4. Quantitative techniques in management by ND Vohra – Tata McGraw Hill
5. Business Environment by Ashwathappa – Himalaya Publication
6. Business Environment by Francis cherunilam - Himalaya Publication
7. Organizational Behaviour by Stephen Robbins - Pearson Publications
8. Human resource Management – Gary Dessler – Pearson Publication
9. Management by James Stoner – Pearson Publication
10. Principles of Management by Tripathi – Sultan Chand

**SUBJECT : Business Communication**
**SUBJECT CODE : 612**

**RATIONALE:**

As globalization is a part of every business, communicating across borders have become an inevitable part for any professional. As the communication differs from region to region, learning a proper etiquette is essential to climb the ladder of success. This course will give an insight into various business communication skills that would assist the students to communicate in an efficient way.

**COURSE OBJECTIVES:**

1. To teach students about the different types and ways to write business letters in different situations.
2. To provide a platform to improve learner's professional etiquette.
3. To plan a public speech or an article for publication.
4. To make learners ready to communicate effectively with confidence.
5. To teach the dos and don'ts of communication.

**LEARNING OUTCOMES:**

1. Learners shall become good in social skills and interpersonal skills.
2. Learners convincing and leadership skills will be reflected in their mode of communication.
3. Shall improve their non-controversial communication skills.
4. Shall understand the verbal and non-verbal language of others in a better way.

**PREREQUISITES:** Any graduate degree.

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT [Theory] | TOTAL HRS/ Week | CREDITS | EVALUATION SCHEME | | TOTAL MARKS |
|---|---|---|---|---|---|---|
| | | | | INTERNAL | EXTERNAL | |
| 612 | Business Communication | 3 | 2 | 20 | 80 | 100 |

**CONTENT:**

| Chapter Number | Chapters | Weightage |
|---|---|---|
| 1 | **Module I: Business Communication:** Meaning, Importance, Process, Types, Principles of Communication, Barriers of effective communication, | 15 |
| 2 | **Module II : Nonverbal Communication:** Body language, Gesturers, Manners and etiquettes, Cross cultural Dimensions, Listening skills and observation. | 20 |
| 3 | **Module III: Oral Communication :** Principles of effective speech in different occasions, Different interview techniques, Group discussions, Video conferencing, Telephone etiquette, Mobile communication, Negotiation skills, Creativity in Oral communication | 20 |
| 4 | **Module IV: Written Communication:** Letters- Types and formats, Memos, Circulars, Minutes writing during meetings, Report writing – Types and format, SMS, E-mails, Case study analysis, Writing CVs, Power point presentations. | 30 |
| 5 | **Module V:Media Communication:** Planning Press conference, Press reports, Articles for publication, Media interviews, and | 15 |

| | | |
|---|---|---|
| | Importance of Public relations. | |

**Reference Books:**


1. Lesikar, R.V. & Flatley, M.E. (2005). Basic Business Communication Skills for Empowering the Internet Generation. Tata McGraw Hill Publishing Company Ltd. New Delhi.
2. Ludlow, R. & Panton, F. (1998). The Essence of Effective Communications. Prentice Hall of India Pvt. Ltd.
3. Nageshwar Rao and Rajendra Das, Business Skills, HPH
4. Mary ellen Guffy, Business Communication, Thomson
5. Effective Technical Communication By M Ashraf Rizvi .- TMH,2005
6. Busines Communication – Rai and Rai
7. Handouts and website sources.

**SUBJECT** : **Indian Pharmaceutical Regulation and Guidelines**
**SUBJECT CODE : 613**
**RATIONALE :** It is essential for students to know about various drugs guidelines & Drugs related laws in India & Drug's National & International authorities & its functions so as to make application for drug approval process to different authorities in appropriate way.

**COURSE OBJECTIVES :**

1. To Study the drug regulatory authority as per the Indian legislation.
2. To study the guidelines and provisions of different laws of drugs enforced in India.
3. To know the various international drug authorities and its functions.

**LEARNING OUTCOMES:**

1. Students will be aware of the drug related guidelines in India.
2. Students will be able to understand the pharmaceutical legislations in India.
3. Students will be able to understand the Working of international drug authorities and its functions.
4. Student will understand the proper procedure for getting product /license approval from proper authority.

**PREREQUISITES: B.Pharm Graduate**

**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 613 | Indian Pharmaceutical Regulation and Guidelines | 4 | -- | 4 | 3 | 20 | -- | 80 | -- | 100 |

**Contents:**

| | |
|---|---|
| 1 | Drugs and Cosmetic Act 1940 and Rules 1945, Present policies for import and export of drugs and pharmaceuticals. |
| 2 | DCGI guidelines for manufacturing and registration of pharmaceuticals. |
| 3 | State FDA guidelines for manufacturing and registration of pharmaceuticals. |
| 4 | Narcotic Drugs and Psychotropic substances Act 1985 and Rules |
| 5 | Drugs( Price Control) Order 2013 |
| 6 | Drugs and Magic remedies (Objectionable Advertisements) Act 1954 |
| 7 | Prevention of cruelty to animals Act 1960 with special reference to IAEC. |
| 8 | Introduction and applications of: ISO standards, ORANGE BOOK, Six sigma and White papers in pharmaceutical practices. |
| 9 | Introduction to all International pharmaceutical regulatory authorities like: IIG, IPEC, CTFA and COLIPA. WHO, USFDA, MHRA, EMEA, TGA, ANVISA, OECD, ICH etc. |

**Books Recommended:**


1. The Drugs And Cosmetics Act, 1940 and rules 1945", Law Publication
2. Drugs And Cosmetics Act, 1940 and rules 1945", Malik Vijay, Eastern Book Company
3. The Drugs (Price Control) Order, 2013: Along with New Drugs Policy, 2012
4. A Text Book of Forensic Pharmacy, By- Jain N.K., Vallabh Prakashan
5. The Prevention Of Illicit Traffic In Narcotic Drugs And Psychotropic Substances Act, 1988, Law Publication
6. Guide lines of IIG, IPEC, CTFA and COLIPA. WHO, USFDA, MHRA, EMEA, TGA, ANVISA, OECD, ICH, ISO etc.
7. Drugs and Magic remedies (Objectionable Advertisements) Act 1954- Law Publication
8. 8. Prevention of cruelty to animals Act 1960 with special reference to IAEC- Law Publication

**SUBJECT : Clinical Pharmacy - I**
**SUBJECT CODE : 711 & 712**
**RATIONALE** : To train and teach students on clinical service
To train and teach students on pharmaceutical care and provide comprehensive patient care and information.
To train students on interpret the laboratory results to aids the clinical diagnosis and effect of medicine

**COURSE OBJECTIVES** :
Upon completion of this semester course it is expected that student should be able to:

- Understand the elements of clinical and pharmaceutical care and provide comprehensive care
- Interpret the laboratory results to aid the clinical diagnosis and management
- Provide integrated, critically analyzed drug and poison information to enable health care professionals and information seekers in the efficient use of medicine;

**LEARNING OUTCOMES**: At the end of the course the student will be able to:

1. Understand roll of clinical pharmacist.
2. Perform in hospital in clinical department.
3. Understand common medical terminology and diseases.
4. Collect and manage patient data.

**PREREQUISITES: NONE**
**TEACHING AND EVALUATION SCHEME:**

| SUB CODE | TITLE OF SUBJECT | TEACHING SCHEME | | | CREDITS | EVALUATION SCHEME | | | | TOTAL MARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | INTERNAL | | EXTERNAL | | |
| | | T | P | TOTAL HRS | | Theory | Practical | Theory | Practical | |
| 711 | Clinical Pharmacy - I | 3 | - | 3 | 3 | 20 | --- | 80 | ---- | 100 |
| 712 | Clinical Pharmacy - I Practical | - | 9 | 9 | 5 | --- | 20 | ---- | 80 | 100 |

## Course content:

| | |
|---|---|
| **1. Introduction to clinical pharmacy**<br>1. Definition, evolution and scope of clinical pharmacy<br>2. Role and responsibility<br>3. International and national scenario of clinical pharmacy practice<br>4. Pharmaceutical care | 20 |
| **2. Concept of Pharmaceutical Care and Clinical Services.**<br>a. Ward Round Participation.<br>b. Medication /drug utilization Evaluation/Review.<br>c. Drug Therapy Monitoring ( Medication chart review, Clinical Review, Concept of TDM and intervention<br>d. Patient counseling - ( Concept & Introduction)<br>e. ADR Management and role of pharmacist<br>f. Medication History<br>g. Quality Assurance of Clinical Pharmacy Services | 30 |

| | |
|---|---|
| h. Medication adherence | |
| 3. **Patient Data Analysis 15 Hours:**<br>Patient Data & Practice Skills<br>a) The Patient Case History, its Structure and Evaluation of Drug therapy.<br>b) Understanding Common medical abbreviation and terminology used in clinical practice.<br>c) Communication skill including medication history interview.<br>Concept and understanding on clinical laboratory tests used in evaluation of disease states and it's normal value theory, significance and role of pharmacist 3<br>a. Hematological tests 2<br>b. Liver function tests 1<br>c. Renal function 1<br>d. Thyroid function test. 1<br>e. Test associated with cardiac 2<br>f. Fluid & electrolyte tests. 1<br>g. Pulmonary function test 1<br>h. Microbial culture sensitivity tests. 1<br>i. Basic of ECG 2<br>j. routine urine analysis 4 | 25 |
| 4. **Drug/medicine & Poison Information:**<br>Drug/medicine Information<br>a) Introduction, need to drug information and its resources. 1<br>b) Systematic approach to answering DI queries. 1<br>c) Critical evaluation of drug information and literature. 2<br>d) Preparation verbal & written reports its filing & compilation. 1<br>e) Establishment of drug information Centre 2<br>Poison information. Definition, need, organization and functions of poison information Centre. | 25 |

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| 1. Relevant articles from recent medical/cp/ prepare pharmaceutical literature. |
| 2. Journals :<br>a. Pharmaceutical Journal<br>b. International journal of pharmacy Practice<br>c. Hospital Pharmacist.<br>d. International journal of Hospital Pharmacy<br>e. Pharmacy Practice<br>f. Journal of pharmacy Practice of Australia. |
| 3. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone Edinburg/London. |
| 4. Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/Glasgow/Madras. |
| 5. Text Book of Therapeutics: Drug and Disease Management. 7th Edition, Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins, 2000. |
| 6. Davidson's Principles and Practice of Medicine, Eds. Christopher R. W. Edwards and Lan A. D. Bouchier ELBS with Churchill Livingstone, Edinburgh, Latest Edition. |
| 7. Applied Therapeutics: The Clinical Use or Drugs Eds. Brain S. Katcher, Lioyd Yee Young. Marry Anne Koda-kimble, Applied Therapeutics Inc. Spokane. Latest Edition. |
| 8. Melmon and Morrelli's Clinical Pharmacology, 4th Edition, Author : S. George Carrathers, Brian B. Hoftman, Kenneth L. Melmon and David W. Nierenberg, McGrow Hill, 2000. |
| 9. Pathology & Therapeutics for Pharmacists, Greene, R. J.& Harris, N. D. (1993). The Pharmaceutical Press. |

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| 10. De Gruchi's Clinical Hematology in Medical Practice. Frank Firkin, Bryan Rush, David Penington, Colin Chesterman, Blactwell Scientific, Publication. 5th edition. |
| 11. Robbins Pathologic Basis of Disease, Cartan, Kumar, Collins, W. B. Godkar, Saunders. 6th edition. |
| 12. Text book of Medical laboratory Technology. Praful B. Godkar, Bhalani Publication House, Mumbai, 2nd edition. |
| 13. Manual of basis techniques for a health laboratory, 2nd edition, World Health Organization, Geneva. |

## 712. Clinical Pharmacy – I Practical

Practical based on theory viz:

1) Patient medication history interview and preparation of CRF.
2) Answering drug information question
3) Patient Counseling especially medication counseling.
4) Participation in ward Round.
5) Case Studies related to laboratory investigation covering the topics covered classes.
6) Demonstration on blood withdrawal techniques, separation and storage.
7) Finding normal values of hematological & Urine analysis.
8) Critical approval/evaluation of publish article in journal that dealt with Clinical pharmacy.
9) Evaluation of primary source of information
10) Biochemical estimation of important parameters

NOTE: Answering drug information questions. (Any four)

1) Related to Dosage Administrations, ADR, Drug used in women, pediatric, geriatric, safety and rational uses.
2) Patient medication Counseling on any three /Four on common difference in Diabetes mellitus, Asthma, H.T.,T.B, COPD.
3) Case Studies Related to Laboratory investigation any four LFT, RFT, Hematological, thyroid, Cardiac Markers.
4) Patient Medication therapy interviews – Any two.
5) Medication /Order Review – Any Five.
6) Detection and assessment of ADR & their Documentation. – Any One.

Assignments and Seminars – Based on theory & Practical Drug information, Patient medication history (Interview), Patient Medication Counseling, Literature Evaluation Books

1. Practice Standards and Definitions ;
2. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc. (latest edition)
3. Basic skills in interpreting laboratory data MARY lee
4. Basic skills in interpreting laboratory data walliss
5. Interpretation of ECG – PM Mehta
6. Communication skill by William Tindall
7. Pharmacist talk/consult with patient
8. Pharmacists Talking With Patients: A Guide to Patient Counseling Melanie J. Rantucci
9. Communication Skills in Pharmacy Practice: A Practical Guide for Students by Robert S. Beardsley,
10. Oxford Handbook of Clinical Pharmacy By Philip Wiffen
11. Pharmaceutical Care By Calvin H. Knowlton
12. Interpersonal Communication in Pharmaceutical Care By Helen Meldrum
13. Social and Behavioral Aspects of Pharmaceutical Care By Nathaniel M. Rickles
14. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarthi G Karin Nyfort-Hansen and Milap Nahata (latest edition) Relevant review articles from recent medical and pharmaceutical literature. Journals

- Pharmaceutical Journal. Royal Pharmaceutical Society, London
- Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia
- International Journal of Pharmacy Practice, United Kingdom
- Hospital Pharmacist, UK
- Indian Journal of Hospital Pharmacy
- Indian Journal of Pharmaceutical Education and Research - IJPER
- Indian Journal of Pharmacy Practice - IJPP
- Clinical Pharmacotherapeutics

**BOOKS RECOMMENDED:**

Relevant articles from recent medical/cp/ pharmaceutical literature.

1. Journals :
   a. Pharmaceutical Journal
   b. International Journal Of Pharmacy Practice
   c. Hospital Pharmacist.
   d. International journal of Hospital Pharmacy
   e. Pharmacy Practice
   f. Journal of pharmacy Practice of Australia.
   g. clinical chemistry
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Interpretation of ECG – PM Mehta
4. Communication skill by William Tindall
5. Pharmaceutical Care By Calvin H. Knowlton
6. Interpersonal Communication in Pharmaceutical Care By Helen Meldrum
7. Social and Behavioral Aspects of Pharmaceutical Care By Nathaniel M. Rickles
8. Pharmacists Talking With Patients: A Guide to Patient Counseling Melanie J. Rantucci
9. Communication Skills in Pharmacy Practice: A Practical Guide for Students By Robert S. Beardsley,
10. Oxford Handbook of Clinical Pharmacy By Philip Wiffen
11. Concept of pharmaceutical care
12. Text book of Drug Information for Pharmacist
13. Comprehensive pharmacy review - Leon Shargel
14. Encyclopedia of clinical pharmacy – J. T. Dipiro
15. Practice Standards and Definitions – AmSHPH
16. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarthi G, Karin Nyfort-Hansen and Milap Nahata
17. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
18. Basic skills in interpreting laboratory data – Mary Lee
19. Basic in interpretation of laboratory data/result – Wallis
20. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone Edinburg/London.
21. Pathology & Therapeutics for Pharmacists. Russell. J. Greene and Normal F. Harris. Chapman & Hall, London/Glasgow/Madras.
22. Text Book of Therapeutics: Drug and Disease Management. 7th Edition, Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins, 2000.
23. Davidson's Principles and Practice of Medicine, Eds. Christopher R. W. Edwards and Lan A. D. Bouchier ELBS with Churchill Livingstone, Edinburgh, Latest Edition.
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