# List of New Course(s) Introduced

**Department : *Pharmacy***

**Programme Name : *B. Pharm.***

***Academic Year : 2021-22***

## *List of New Course(s) Introduced*

| Sr. No. | Course Code | Name of the Course |
|---|---|---|
| 01. | BP701T | Instrumental Methods of Analysis – Theory |
| 02. | BP702T | Industrial Pharmacy – Theory |
| 03. | BP703T | Pharmacy Practice – Theory |
| 04. | BP704T | Novel Drug Delivery System – Theory |
| 05. | BP705P | Instrumental Methods of Analysis – Practical |
| 06. | BP706PS | Practice School* |
| 07. | BP801T | Biostatistics and Research Methodology – Theory |
| 08. | BP802T | Social and Preventive Pharmacy – Theory |
| 09. | BP803ET | Pharmaceutical Marketing – Theory |
| 10. | BP806ET | Quality Control and Standardization of Herbals – Theory |
| 11. | BP807ET | Computer Aided Drug Design – Theory |
| 12. | BP810ET | Experimental Pharmacology – Theory |
| 13. | BP812PW | Project Work |

**HEAD**
S.L.T. Institute of Pharm. Sciences
Guru Ghasidas Vishwavidyalaya,
Bilaspur (C.G.)

# Minutes of Meetings (MoM) of Board of Studies (BoS)

**Academic Year: 2021-22**

**School : *School of Studies of Natural Resources***

**Department : *Pharmacy***

**Date and Time : *September 07, 2018 – 11:30 AM***

**Venue : *HOD Chamber***

SLT INSTITUTE OF PHARMACEUTICAL SCIENCES
GURU GHASIDAS VISHWAVIDYALAYA. BILASPUR (C.G.)
(A Central University Established by the Central University Act 2009 No 25 of 2009)
Tel.:07752-260027 (O); 98271-50112 (R), fax: 07752-260148

Date: 07.09.2018

## MINITES OF THE MEETING OF BOARD OF STUDIES

The minutes of the Board of Studies in Pharmaceutical Sciences, was scheduled on 07.09.2018 at 11:30AM in Institute of Pharmaceutical Sciences, Guru Ghasidas Vishwavidyalaya, Bilaspur. The following members were present for the meeting.

1. Dr. Vinod D. Rangari - Chairperson
2. Dr. Mukul Tailang - External Member (Received approval by email)
3. Dr. Bharti Ahirwar - Member
4. Dr. Pradeep Samal - Member

Agenda for meeting as follows:

1. Approval of syllabus prepared by Pharmacy Council of India, New Delhi for implementation as such without any changes for B. Pharm. course for the academic year 2018-19 onwards.
2. Approval of the syllabus of subject Research methodology as Section I for Vishwavidyalaya Research Entrance Test (VERT) 2018-19.
3. Approval of the subject specific syllabus: Pharmacy as Section II for Vishwavidyalaya Research Entrance Test (VERT) 2018-19.
4. Approval of the External Examiners for D. Pharm. I and II year, B. Pharm. All semesters and M. Pharm. (All semester of all specializations) for academic year 2018-19.
5. The Committee approved to separate B. Pharm. and D. Pharm. as the separate groups for Merit List in Vishwavidyalaya Entrance Test (VET Exam.) to be conducted by Guru Ghasidas Vishwavidyalaya, in the academic year 2019-20. This has been a necessity as both the courses have different orientations.

07/09/2018
Dr. Vinod D. Rangari

07/09/2018
Dr. Bharti Ahirwar

7/9/18
Dr. Pradeep Samal

# Scheme and Syllabus

**Course of study for semester VII**

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|---|---|---|---|---|
| BP701T | Instrumental Methods of Analysis – Theory | 3 | 1 | 4 |
| BP702T | Industrial PharmacyII – Theory | 3 | 1 | 4 |
| BP703T | Pharmacy Practice – Theory | 3 | 1 | 4 |
| BP704T | Novel Drug Delivery System – Theory | 3 | 1 | 4 |
| BP705P | Instrumental Methods of Analysis – Practical | 4 | - | 2 |
| BP706PS | Practice School* | 12 | - | 6 |
| | **Total** | **28** | **5** | **24** |

* Non University Examination (NUE)

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# Scheme and Syllabus

## Course of study for semester VIII

| Course code | Name of the course | No. of hours | Tutorial | Credit points |
|---|---|---|---|---|
| BP801T | Biostatistics and Research Methodology | 3 | 1 | 4 |
| BP802T | Social and Preventive Pharmacy | 3 | 1 | 4 |
| BP803ET | Pharma Marketing Management | 3 + 3 = 6 | 1 + 1 = 2 | 4 + 4 = 8 |
| BP804ET | Pharmaceutical Regulatory Science | | | |
| BP805ET | Pharmacovigilance | | | |
| BP806ET | Quality Control and Standardization of Herbals | | | |
| BP807ET | Computer Aided Drug Design | | | |
| BP808ET | Cell and Molecular Biology | | | |
| BP809ET | Cosmetic Science | | | |
| BP810ET | Experimental Pharmacology | | | |
| BP811ET | Advanced Instrumentation Techniques | | | |
| BP812ET | Dietary Supplements and Nutraceuticals | | | |
| BP813PW | Project Work | 12 | - | 6 |
| | **Total** | **24** | **4** | **22** |

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## BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative andquantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Objectives:** Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

### Course Content:

**UNIT –I** **10 Hours**

**UV Visible spectroscopy**

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

**Fluorimetry**

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

**UNIT –II** **10 Hours**

**IR spectroscopy**

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

**Flame Photometry-**Principle, interferences, instrumentation and applications

**Atomic absorption spectroscopy**- Principle, interferences, instrumentation andapplications

**Nepheloturbidometry**- Principle, instrumentation and applications

**UNIT –III** **10 Hours**

**Introduction to chromatography**

**Adsorption and partition column chromatography-**Methodology, advantages,disadvantages and applications.

**Thin layer chromatography-** Introduction, Principle, Methodology, Rf values,advantages, disadvantages and applications.

**Paper chromatography-**Introduction, methodology, development techniques,advantages, disadvantages and applications

**Electrophoresis**–Introduction, factors affecting electrophoretic mobility, Techniquesof paper, gel, capillary electrophoresis, applications

**UNIT –IV** **08 Hours**

**Gas chromatography -** Introduction, theory, instrumentation, derivatization,temperature programming, advantages, disadvantages and applications

**High performance liquid chromatography (HPLC)-**Introduction, theory,instrumentation, advantages and applications.

**UNIT –V** **07 Hours**

**Ion exchange chromatography-** Introduction, classification, ion exchange resins,properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

**Gel chromatography-** Introduction, theory, instrumentation and applications

**Affinity chromatography-** Introduction, theory, instrumentation and applications

## BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

**4 Hours/Week**

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nepheloturbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

## BP 702 T. INDUSTRIAL PHARMACYII (Theory)

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceuticalproduct development and translation from laboratory to market

**Objectives:** Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

**Course Content:**

**UNIT-I** **10 Hours**

**Pilot plant scale up techniques:** General considerations - including significance ofpersonnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

**UNIT-II** **10 Hours**

**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

**UNIT-III** **10 Hours**

**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatoryauthorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

**Regulatory requirements for drug approval:** Drug Development Teams, Non-ClinicalDrug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

**UNIT-IV** **08 Hours**

**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

**UNIT-V** **07 Hours**

**Indian Regulatory Requirements:** Central Drug Standard Control Organization(CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

**Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

## BP 703T. PHARMACY PRACTICE (Theory)

**45 Hours**

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice ofHospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

**Objectives:** Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

**Unit I:** **10 Hours**

**a) Hospital and it's organization**

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

**b) Hospital pharmacy and its organization**

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

**c) Adverse drug reaction**

Classifications- Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

**d) Community Pharmacy**

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

**Unit II:** **10 Hours**

**a) Drug distribution system in a hospital**

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

**b) Hospital formulary**

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

**c) Therapeutic drug monitoring**

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

**d) Medication adherence**

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

**e) Patient medication history interview**

Need for the patient medication history interview, medication interview forms.

**f) Community pharmacy management**

Financial, materials, staff, and infrastructure requirements.

**Unit III:** **10 Hours**

**a) Pharmacy and therapeutic committee**

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

**b) Drug information services**

Drug and Poison information centre, Sourcesof drug information, Computerised services, and storage and retrieval of information.

**c) Patient counseling**

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

**d) Education and training program in the hospital**

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

**e) Prescribed medication order and communication skills**

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

**Unit IV 8 Hours**

**a)Budgetpreparation and implementation**

Budget preparation and implementation

**b) Clinical Pharmacy**

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

**c) Over the counter (OTC) sales**

Introduction and sale of over the counter, and Rational use of common over the counter medications.

**Unit V 7 Hours**

**a) Drug store management and inventory control**

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

**b) Investigational use of drugs**

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

**c) Interpretation of Clinical Laboratory Tests**

Blood chemistry, hematology, and urinalysis

**Recommended Books (Latest Edition):**

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of ClinicalPharmacy Practice- essential concepts and skills,* 1st ed. Chennai: OrientLongman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea &Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

**Journals:**

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

## BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

**45 Hours**

**Scope:** This subject is designed to impart basic knowledge on the area of novel drugdelivery systems.

**Objectives:** Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

### Course content:

**Unit-I** **10 Hours**

**Controlled drug delivery systems**: Introduction, terminology/definitions and rationale,advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

**Polymers:** Introduction, classification, properties, advantages and application ofpolymers in formulation of controlled release drug delivery systems.

**Unit-II** **10 Hours**

**Microencapsulation:** Definition, advantages and disadvantages, microspheres/microcapsules, microparticles, methods of microencapsulation, applications

**Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

**Implantable Drug Delivery Systems:**Introduction, advantages and disadvantages,concept of implantsand osmotic pump

**Unit-III** **10 Hours**

**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factorsaffecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

**Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages,approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

**Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes ofdrug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

**Unit-IV** **08 Hours**

**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages,introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

**Unit-V** **07 Hours**

**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods toovercome –Preliminary study, ocular formulations and ocuserts

**Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages,development of intra uterine devices (IUDs) and applications

**Recommended Books: (Latest Editions)**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

**Journals**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

## BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

**45 Hours**

**Scope:** To understand the applications of Biostatics in Pharmacy. This subject deals withdescriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

**Objectives:** Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB® , DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems**.**

### Course content:

**Unit-I** **10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution

**Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples

**Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceuticalproblems

**Correlation**: Definition, Karl Pearson'scoefficient of correlation, Multiple correlation - Pharmaceuticals examples

**Unit-II** **10 Hours**

**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x= a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

**Probability:**Definition of probability, Binomial distribution, Normal distribution,Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

**Parametric test**: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One wayand Two way), Least Significance difference

**Unit-III** **10 Hours**

**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest, Friedman Test

**Introduction to Research:** Need for research, Need for design of Experiments,Experiential Design Technique, plagiarism
**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph
**Designing the methodology:** Sample size determination and Power of a study, Reportwriting and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

**Unit-IV** **8 Hours**

Blocking and confounding system for Two-level factorials
**Regression modeling:** Hypothesis testing in Simple and Multiple regressionmodels
**Introduction to Practical components of Industrial and Clinical Trials**
**Problems**:Statistical Analysis Using Excel, SPSS, MINITAB® , DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

**Unit-V** **7Hours**

**Design and Analysis of experiments:**
**Factorial Design:** Definition, $2^2$, $2^3$design. Advantage of factorial design
**Response Surface methodology**: Central composite design, Historical design,Optimization Techniques

**Recommended Books (Latest edition):**

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,

4.Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

## BP 802T SOCIAL AND PREVENTIVE PHARMACY

**Hours: 45**

**Scope:**
The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

**Objectives:**
After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues

**Course content:**

**Unit I: 10 Hours**

**Concept of health and disease:** Definition, concepts and evaluation of public health.Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

**Social and health education:** Food in relation to nutrition and health, Balanced diet,Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

**Sociology and health:** Socio cultural factors related to health and disease, Impact ofurbanization on health and disease, Poverty and health

**Hygiene and health:** personal hygiene and health care; avoidable habits

**Unit II: 10 Hours**

**Preventive medicine:** General principles of prevention and control of diseases such ascholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

**Unit III: 10 Hours National health programs, its objectives, functioning and outcome of the following:**
HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

**Unit IV:** **08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

**Unit V:** **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

**Recommended Books (Latest edition)*:***

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy RabindraNath, SahaIndranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, HiremathLalita D, HiremathDhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

## BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

**45 Hours**

**Scope:**

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

**Course Objective:** The course aims to provide an understanding of marketing conceptsand techniques and their applications in the pharmaceutical industry.

**Unit I 10 Hours Marketing:**

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

**Pharmaceutical market:**

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation&targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

**Unit II 10 Hours Product decision:**

Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

**Unit III** **10 Hours**

**Promotion:**

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

**Unit IV 10 Hours Pharmaceutical marketing channels:**

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

**Professional sales representative (PSR):**
Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

**Unit V 10 Hours Pricing:**

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

**Emerging concepts in marketing:**
Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

**Recommended Books: (Latest Editions)**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. DhruvGrewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. RajanSaxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S &Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. SubbaRaoChanganti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

**BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)**

**Scope:** In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

**Objectives:** Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

**Unit I** **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

**Unit II** **10 hours**

**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP intraditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

**Unit III** **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

**Unit IV** **08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

**Unit V** **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

**Recommended Books: (Latest Editions**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

## BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

**45 Hours**

**Scope:** This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

**Objectives:** Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

**Course Content:**

**UNIT-I** **10 Hours**

**Introduction to Drug Discovery and Development**

Stages of drug discovery and development

**Lead discovery and Analog Based Drug Design**

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

**Analog Based Drug Design:**Bioisosterism, Classification, Bioisostericreplacement. Any three case studies

**UNIT-II** **10 Hours**

**Quantitative Structure Activity Relationship (QSAR)**

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

**UNIT-III** **10 Hours**

**Molecular Modeling and virtual screening techniques**

**Virtual Screening techniques:** Drug likeness screening, Concept ofpharmacophore mapping and pharmacophore based Screening,

**Molecular docking**: Rigid docking, flexible docking, manual docking,Docking based screening. *De novo* drug design.

**UNIT-IV** **08 Hours**

**Informatics & Methods in drug design**

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

**UNIT-V** **07 Hours**

**Molecular Modeling:** Introduction to molecular mechanics and quantummechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

**Recommended Books (Latest Editions)**

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Korolkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

## BP810 ET. PHARMACOLOGICAL SCREENING METHODS

**45 Hours**

**Scope:**This subject is designed to impart the basic knowledge of preclinical studies inexperimental animals including design, conduct and interpretations of results.

**Objectives**

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinicalresearch
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

| **Unit –I** | **08 Hours** |
|---|---|
| **Laboratory Animals:**<br>Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.<br>Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia. | |
| **Unit –II** | **10 Hours** |
| **Preclinical screening models**<br>a. Introduction:Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.<br>b. **Study of screening animal models for**<br>Diuretics, nootropics, anti-Parkinson's,antiasthmatics,<br>**Preclinical screening models:** for CNS activity-<br>analgesic,antipyretic,anti-inflammatory, general anaesthetics,<br>sedative and hypnotics, antipsychotic, antidepressant,<br>antiepileptic, antiparkinsonism, alzheimer's disease | |

| | |
|---|---|
| **Unit –III**<br><br>**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics | |
| **Unit –IV**<br><br>**Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants<br>Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics. | |
| **Research methodology and Bio-statistics**<br>Selection of research topic, review of literature, research hypothesis and study design<br>Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data | **05 Hours** |

**Recommended Books (latest edition):**

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS SundarRao and J Richard

# List of New Course(s) Introduced

**Department : *Pharmacy***

**Programme Name : *M. Pharm. (All Specializations)***

***Academic Year : 2021-22***

## *List of New Course(s) Introduced*

| Sr. No. | Course Code | Name of the Course |
|---|---|---|
| 01. | MRM301T | Research Methodology and Biostatistics* |
| 02. | MRM302P | Journal club |
| 03. | MRM303P | Discussion / Presentation (Proposal Presentation) |
| 04. | MRM304P | Research work* |
| 05. | MRM401P | Journal club |
| 06. | MRM402P | Research work* |
| 07. | MRM403P | Discussion / Presentation (Final Presentation) |

**HEAD**
S.L.T. Institute of Pharm. Sciences
Guru Ghasidas Vishwavidyalaya,
Bilaspur (C.G.)

# Minutes of Meetings (MoM) of Board of Studies (BoS)

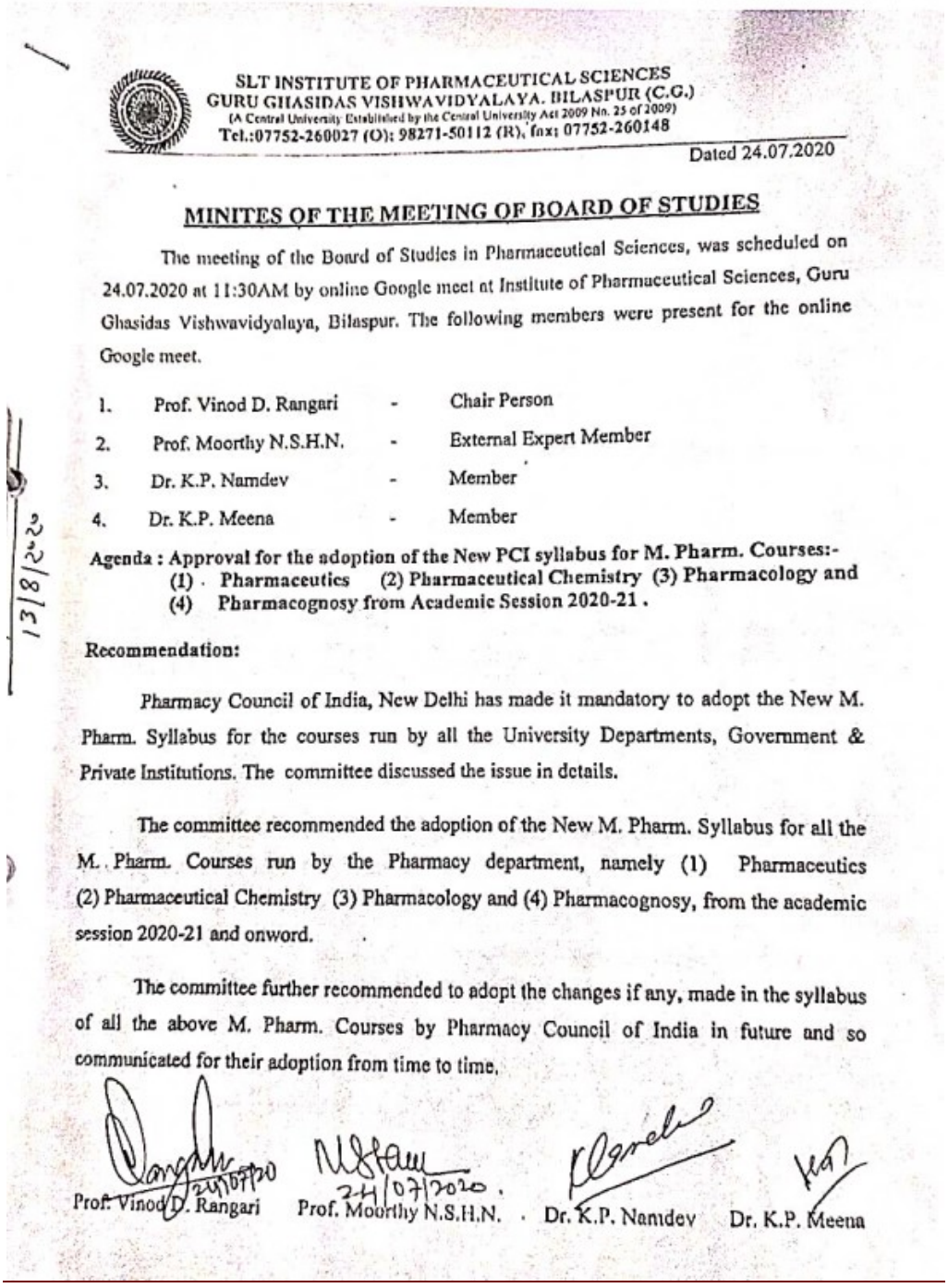
**Academic Year: 2021-22**

**School : *School of Studies of Natural Resources***

**Department : *Pharmacy***

**Date and Time : *July 24, 2020 – 11:30 AM***

**Venue : *HOD Chamber***



SLT INSTITUTE OF PHARMACEUTICAL SCIENCES
GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.)
(A Central University Established by the Central University Act 2009 No. 25 of 2009)
Tel.:07752-260027 (O); 98271-50112 (R), fax: 07752-260148

Dated 24.07.2020

## MINITES OF THE MEETING OF BOARD OF STUDIES

The meeting of the Board of Studies in Pharmaceutical Sciences, was scheduled on 24.07.2020 at 11:30AM by online Google meet at Institute of Pharmaceutical Sciences, Guru Ghasidas Vishwavidyalaya, Bilaspur. The following members were present for the online Google meet.

| | | | |
|---|---|---|---|
| 1. | Prof. Vinod D. Rangari | - | Chair Person |
| 2. | Prof. Moorthy N.S.H.N. | - | External Expert Member |
| 3. | Dr. K.P. Namdev | - | Member |
| 4. | Dr. K.P. Meena | - | Member |

13/8/2020

**Agenda : Approval for the adoption of the New PCI syllabus for M. Pharm. Courses:- (1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and (4) Pharmacognosy from Academic Session 2020-21 .**

**Recommendation:**

Pharmacy Council of India, New Delhi has made it mandatory to adopt the New M. Pharm. Syllabus for the courses run by all the University Departments, Government & Private Institutions. The committee discussed the issue in details.

The committee recommended the adoption of the New M. Pharm. Syllabus for all the M. Pharm. Courses run by the Pharmacy department, namely (1) Pharmaceutics (2) Pharmaceutical Chemistry (3) Pharmacology and (4) Pharmacognosy, from the academic session 2020-21 and onword.

The committee further recommended to adopt the changes if any, made in the syllabus of all the above M. Pharm. Courses by Pharmacy Council of India in future and so communicated for their adoption from time to time.

24/07/2020

Prof. Vinod D. Rangari | Prof. Moorthy N.S.H.N. | Dr. K.P. Namdev | Dr. K.P. Meena

# Scheme

Course of study for M. Pharm. III Semester
(Common for All Specializations)

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| MRM 301T | Research Methodology and Biostatistics* | 4 | 4 |
| - | Journal club | 1 | 1 |
| - | Discussion / Presentation (Proposal Presentation) | 2 | 2 |
| - | Research Work | 28 | 14 |
| Total | | 35 | 21 |

* Non University Exam

Course of study for M. Pharm. IV Semester
(Common for All Specializations)

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal Club | 1 | 1 |
| - | Research Work | 31 | 16 |
| - | Discussion/Final Presentation | 3 | 3 |
| Total | | 35 | 20 |

HEAD
S.L.T. Institute of Pharm. Sciences
Guru Ghasidas Vishwavidyalaya,
Bilaspur (C.G.)

## Semester III

## MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.