गुरू घासीदास विश्वविद्यालय (केंद्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

List of Courses which focuses on Professional Ethics, Gender, Human Values, Environment & Sustainability and other value framework

### Department

: Pharmacy

: B. Pharm.

### Programme Name

### Academic Year : 2021-22

Courses which focuses on Professional Ethics, Gender, Human Values, Environment & Sustainability and other value framework:

Sr. No.	Course Code	Name of the Course
01.	BP105T	Communication skills – Theory *
02.	BP204T	Pathophysiology – Theory
03.	BP205T	Computer Applications in Pharmacy – Theory *
04.	BP206T	Environmental sciences – Theory *
05.	BP505T	Pharmaceutical Jurisprudence – Theory
06.	BP606T	Quality Assurance – Theory
07.	BP703T	Pharmacy Practice – Theory
08.	BP802T	Social and Preventive Pharmacy

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

### Scheme and Syllabus

### Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I-Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
<b>BP105T</b>	Communication skills – Theory *	2	-	2
BP106RB T BP106RM T	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RB P	Remedial Biology – Practical*	2	-	1
	Total	32/34 <sup>\$</sup> /36 <sup>#</sup>	4	27/29\$/30#

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course.

sApplicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

\* Non University Examination (NUE)

The

गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिनेयम 2009 इ. 25 के अंतर्गत स्वापित केन्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

### **Scheme and Syllabus**

Course code	Name of the course	No. of hours	Tutorial	Credit points
	Human Anotomy and Dhysiology II Theory	3	1	· .
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
<b>BP204T</b>	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	_	3
<b>BP206T</b>	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II – Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	_	1
	Total	32	4	29

### Course of study for Semester II

\*Non University Examination (NUE)

The

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### Scheme and Syllabus

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
<b>BP505T</b>	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	27	5	26

### Course of study for Semester V

The

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### Scheme and Syllabus

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance – Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	30	6	30

### Course of study for Semester VI

The

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## **Scheme and Syllabus**

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
<b>BP703T</b>	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

### Course of study for Semester VII

\*Non University Examination (NUE)

The

गुरू घासीदास विश्वविद्यालय (केटीय विश्वविद्यालय अधिन्यम 2009 इ. 25 के अंतर्गत रचापित केट्रीय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



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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
BP802ET	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management			4+4 =8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance	3+3= 6	1+1 = 2	
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design	3+3=0		
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

The

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

Courses Focus on Employability/Entrepreneurship/Skill Development

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

### **BP105T. COMMUNICATION SKILLS (Theory)**

### **30 Hours**

**Scope:** This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

### **Objectives:**

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation

2. Communicate effectively (Verbal and Non Verbal)

3. Effectivelymanage the team as a team player

4. Develop interview skills

5. Develop Leadership qualities and essentials

**Course content:** 

### UNIT – I

# • **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

• **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

• Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment UNIT – II 07 Hours

### 07 Hours

07 Hours

• Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

• **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

### UNIT – III

### **07 Hours**

• **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

• Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

• Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

### UNIT – IV

### 05 Hours

• Interview Skills: Purpose of an interview, Do's and Dont's of an interview

• Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

### 04 Hours

• Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

#### BP 204T.PATHOPHYSIOLOGY (THEORY)

#### 45Hours

**Scope:** Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

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

- 1. Describe the etiology and pathogenesis of the selected disease states;
- 2. Name the signs and symptoms of the diseases; and
- 3. Mention the complications of the diseases.

#### Course content:

#### Unit I

#### 10Hours

- Basic principles of Cell injury and Adaptation: Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury,Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis,Electrolyte imbalance
- Basic mechanism involved in the process of inflammation and repair: Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

### Unit II

#### 10Hours

- Cardiovascular System: Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- Respiratory system: Asthma, Chronic obstructive airways diseases.
- Renal system: Acute and chronic renal failure



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### Unit II

### 10Hours

- Haematological Diseases: Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones
- Nervous system: Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- Gastrointestinal system: Peptic Ulcer

### Unit IV

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- · Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout
- · Principles of cancer: classification, etiology and pathogenesis of cancer
- Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout
- · Principles of Cancer: Classification, etiology and pathogenesis of Cancer

#### Unit V

• Infectious diseases:Meningitis, Typhoid, Leprosy, Tuberculosis

#### Urinary tract infections

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

#### Recommended Books (Latest Editions)

- Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
- 2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
- Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
- Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
- 5. William and Wilkins, Baltimore; 1991 [1990 printing].
- Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
- Guyton A, John .E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
- Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
- V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
- Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

#### 8 Hours

7 Hours

Courses Focus on Employability/Entrepreneurship/Skill Development

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Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

#### BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

#### 30 Hrs (2 Hrs/Week)

06 hours

06 hours

06 hours

06 hours

06 hours

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

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

- 1. know the various types of application of computers in pharmacy
- 2. know the various types of databases
- 3. know the various applications of databases in pharmacy

#### Course content:

#### UNIT – I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

**Concept of Information** Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

#### UNIT -II

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

#### UNIT – III

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

#### $\mathbf{UNIT} - \mathbf{IV}$

UNIT-V

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS) गुरू घासीदास विश्वविद्यालय (केन्रीय विश्वविद्यालय अधिनम्म 2009 इ. 25 के अंतर्गत स्वारित केन्न्रेय विश्वविद्यालय) कोनी, बिलासपुर - 495009 (छ.ग.)



Guru Ghasidas Vishwavidyalaya (A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Koni, Bilaspur – 495009 (C.G.)

#### BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope:Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

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

- 1. Create the awareness about environmental problems among learners.
- 2. Impart basic knowledge about the environment and its allied problems.
- 3. Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- 6. Strive to attain harmony with Nature.

#### Course content:

#### Unit-I

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

#### Unit-II

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

#### Unit- III

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

- Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
- 2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
- 3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad 380 013, India,
- 4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
- 5. Clark R.S., Marine Pollution, Clanderson Press Oxford
- Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
- 7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
- 8. Down of Earth, Centre for Science and Environment

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.3.1)

10hours

10hours

10hours

UNIT-II

UNIT-I

authorities, controlling authorities, Drugs Inspectors

### UNIT-III

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs - Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules - Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing

Pharmacy Act -1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

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

Scope: This course is designed to impart basic knowledge on important

- 1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- 2. Various Indian pharmaceutical Acts and Laws

legislations related to the profession of pharmacy in India.

- 3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- 4. The code of ethics during the pharmaceutical practice

Course Content:

#### Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs - Classes of drugs and cosmetics prohibited from import, Import under

Manufacture of drugs - Prohibition of manufacture and sale of certain drugs,

license and repacking license.

license or permit. Offences and penalties.

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria – I (1.3.1)

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#### BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

#### 45 Hours

### 10 Hours

#### 10 Hours

10 Hours

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#### Penalties

- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

#### UNIT-IV

#### 08 Hours

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

#### UNIT-V

#### 07 Hours

- Pharmaceutical Legislations A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

#### Recommended books: (Latest Edition)

- 1. Forensic Pharmacy by B. Suresh
- 2. Text book of Forensic Pharmacy by B.M. Mithal
- 3. Hand book of drug law-by M.L. Mehra
- 4. A text book of Forensic Pharmacy by N.K. Jain
- 5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
- 6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
- 7. Narcotic drugs and psychotropic substances act by Govt. of India publications
- 8. Drugs and Magic Remedies act by Govt. of India publication
- 9.Bare Acts of the said laws published by Government. Reference books (Theory)

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#### BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

#### 45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

- understand the cGMP aspects in a pharmaceutical industry
- · appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

#### Course content:

#### UNIT – I

#### 10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedures

#### UNIT - II

#### 10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

#### UNIT – III

#### 10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing

#### materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

#### UNIT – IV

#### 08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

**Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

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### UNIT – V

#### 07 Hours

**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

#### Recommended Books: (Latest Edition)

- 1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
- 2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
- 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
- 4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
- 5. How to Practice GMP's P P Sharma.
- 6. ISO 9000 and Total Quality Management Sadhank G Ghosh
- The International Pharmacopoeia Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
- 8. Good laboratory Practices Marcel Deckker Series
- 9. ICH guidelines, ISO 9000 and 14000 guidelines

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#### BP 703T. PHARMACY PRACTICE (Theory)

#### 45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital 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
- 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
- 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:

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

#### 10 Hours

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

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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:

#### 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)

information services

# Drug

10 Hours

Courses Focus on Employability/Entrepreneurship/Skill Development

Criteria - I (1.3.1)

# 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.

Definition of patient counseling; steps involved in patient counseling, and Special

### 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

cases that require the pharmacist

a)

preparation 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

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

#### c) counseling

### Criteria – I (1.3.1)

#### Budget

Patient

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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):

- Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
- Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1<sup>st</sup> ed. Chennai: Orient Longman Private Limited; 2004.
- William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
- 4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
- Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
- 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)

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#### 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 of urbanization on health and disease, Poverty and health

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

#### Unit II:

**Preventive medicine:** General principles of prevention and control of diseases such as cholera, 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

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 गुरू घासीदास विश्वविद्यालय (केन्रीय विस्तविद्यात्य अधिनेयम 2009 ज्ञ. 25 के अंतर्गत रचावित केन्न्रीय विश्ववेद्यात्य) कोनी, बिलासपुर - 495009 (छ.ग.)



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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):

- Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2<sup>nd</sup> Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4<sup>th</sup> Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
- Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6<sup>th</sup> Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
- Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2<sup>nd</sup> Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
- Park Textbook of Preventive and Social Medicine, K Park, 21<sup>st</sup> 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