



Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences

Siddhartha Nagar, Vijayawada - 520010, AP, INDIA

(Sponsors : Siddhartha Academy of General & Technical Education)

ISO 9001:2015, ISO 14001:2015 & ISO 50001:2011 CERTIFIED INSTITUTION

Affiliated to Krishna University, Machilipatnam

Approved by AICTE, PCI, New Delhi and Govt. of Andhra Pradesh

E-mail : kvsrsiddharthapharma@gmail.com

Web: www.kvsrsiddharthapharma.edu.in

1.3.1 Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum

Response:

The institution makes a consistent effort towards enriching the curriculum by integrating various cross-cutting issues such as Professional Ethics, Gender issues, Human Values, Environment and Sustainability

Professional Ethics

The curriculum incorporates the subjects like pharmaceutical jurisprudence, pharmaceutical administration, social and preventive pharmacy to bring awareness in professional, moral and social commitments. These courses impart basic knowledge on important legislations related to pharmacy profession in India. It also instructs to implement code of ethics of Pharmacist in relation to his job, trade and profession. It furnishes particulars regarding the prevention of cruelty towards animals by following CCSEA guidelines while carrying out animal experiments, breeding and stocking of animals.



Moreover, the institute has been conducting events like the World Pharmacist Day, pharmacy week celebrations in order to nurture the students and staff to make good judgements and take quick



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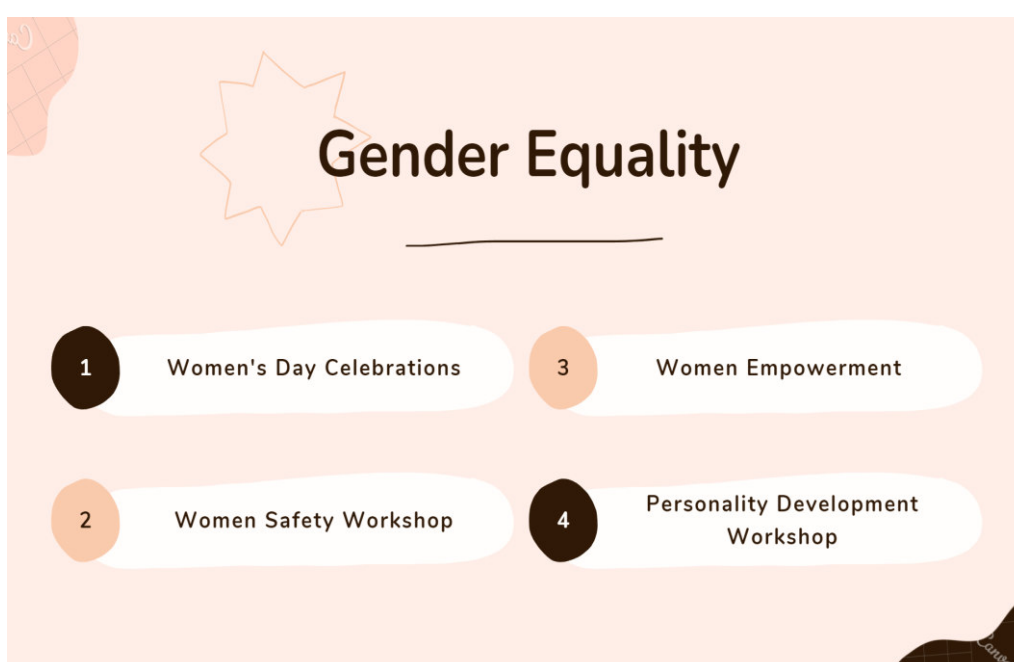
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decisions. Moreover, as a part of community service, college organizes blood donation camps to motivate students and employs to donate blood. The College organizes special lectures in the institution to inculcate professional ethics in their day-to- day life.

Gender Issues:

The Management brings special emphasis in promoting value among the students to eliminate gender bias in the campus through co-education system. Courses in UG and PG programmes like Human Anatomy & Physiology, Pathophysiology, Community Pharmacy, Pharmacotherapeutics-I, II and III Clinical Pharmacy, Hospital Pharmacy address various gender issues. Male and Female Reproductive Systems, Oral Contraceptive Methods for men and women, Prescribing Guidelines for pregnant and lactating women, Menstrual Hygiene, Breast Cancer, Endocrine Disorders, Sexual Disorders and Sports Physiology are some of the Units in the curriculum which provide a comprehensive understanding of the gender related health issues.

Women Empowerment cell was constituted as per rules with the aim of encouraging women in various activities. Women's Day Celebrations, Menstrual Health & Hygiene Management and other programmes aim at transforming their personalities.





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Human Values:

The curriculum incorporates Universal Human values and ethics for the development of a holistic perspective based on self-exploration about themselves (human beings), family, society and nature/existence, strengthening of self-reflection and development of commitment and courage to act. It also includes courses like Dispensing Pharmacy & Ethics, Pharmaceutical Jurisprudence, Medicinal Biochemistry, Community Pharmacy, Pathophysiology, Pharmacotherapeutics, I, II and III, Hospital Pharmacy, Clinical Pharmacy, Clinical Research, Pharmacoepidemiology and Pharmacoeconomics.



Therapeutic Drug Monitoring explains the legislations and working procedures related to human health. Community service activities are organized by the institution where students are made participatory in health camps to create health awareness among the rural men and women.



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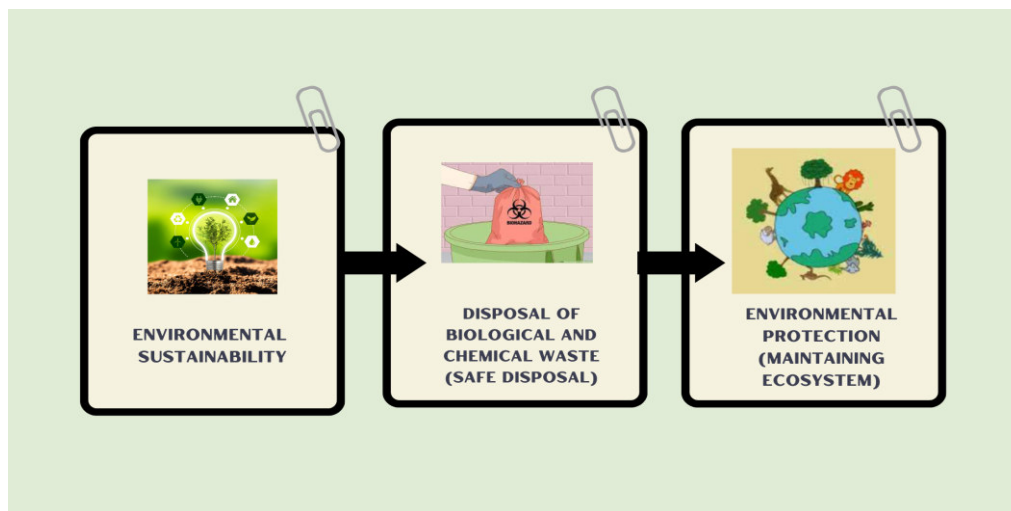
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Environmental and Sustainability:

Environmental Sciences address the importance of environment and sustainability and makes every student responsible and accountable for the resources. The greenery on the campus speaks of a balanced eco-system. In order to educate and sensitize the students about environment and sustainability issues, college organizes Seminars, Guest lectures, Workshops and various activities in the name of World Water Day, Plantation Programme, Swachh-Bharath programme, NSS special camp etc.

APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. **Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and their imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. **Course materials:**

Text books

 - a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology
Publisher Harpercollins college New York.
 - b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.
Publisher: Churchill Livingstone, Edinburg.

Reference books

 - a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
 - b. Chatterjee, C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
 - c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
 - d. *Gray's anatomy*. Publisher: Churchill Livingstone, London.


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4. Lecture wise program :

Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)
- 5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoiesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation
- 6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 Respiratory system
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
- 9 Digestive system
a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)


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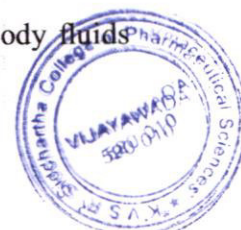


- 10 Nervous system
- Definition and classification of nervous system
 - Anatomy, physiology and functional areas of cerebrum
 - Anatomy and physiology of cerebellum
 - Anatomy and physiology of mid brain
 - Thalamus, hypothalamus and Basal Ganglia
 - Spinal cord: Structure & reflexes – mono-poly-planter
 - Cranial nerves – names and functions
 - ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system
- Anatomy and physiology of urinary system
 - Formation of urine
 - Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
 - Clearance tests and micturition
- 12 Endocrine system
- Pituitary gland
 - Adrenal gland
 - Thyroid and Parathyroid glands
 - Pancreas and gonads
- 13 Reproductive system
- Male and female reproductive system
 - Their hormones – Physiology of menstruation
 - Spermatogenesis & Oogenesis
 - Sex determination (genetic basis)
 - Pregnancy and maintenance and parturition
 - Contraceptive devices
- 14 Sense organs
- Eye
 - Ear
 - Skin
 - Tongue & Nose
- 15 Skeletal muscles
- Histology
 - Physiology of Muscle contraction
 - Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
- Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - Drugs and athletics



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1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

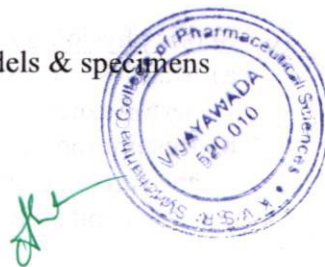
Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.



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1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- know the metabolic process of biomolecules in health and illness (metabolic disorders);
- understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- Harpers review of biochemistry - Martin
- Text book of biochemistry – D.Satyanarayana
- Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

- Principles of biochemistry -- Lehninger
- Text book of biochemistry -- Ramarao
- Practical Biochemistry-David T.Plummer.
- Practical Biochemistry-Pattabhiraman.

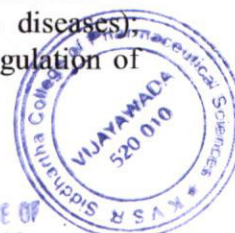
3. Lecture wise programme:

Topics

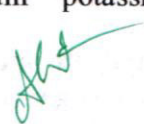
- Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases). Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

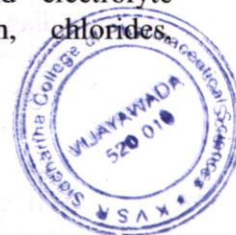
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- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.


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Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** 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 of its application in other subject of pharmacy.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

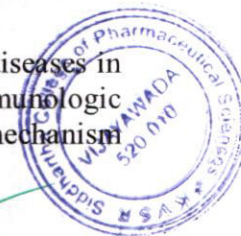
Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1 **Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 **Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 **Diseases of Immunity**
 - a) Introduction to Tand B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)



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- Amyloidosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

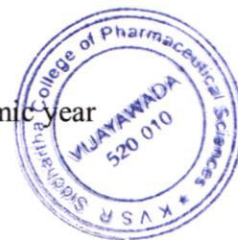
- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

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2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

- | | |
|---|----|
| 1. Synopsis | 10 |
| 2. Major Experiment
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion) | 30 |
| 3. Minor Experiment (Ability to measure B.P/ CBG / Lung function) | 15 |
| 4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) | 15 |
| 5. Viva – Voce | 10 |

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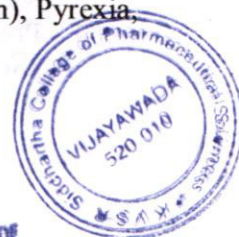


4. Lecture wise programme :

Topics

- 1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist
- 2 **Community Pharmacy Management**
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- 5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.
- 6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels
- 7 **Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function and Cholesterol testing
- 9 **OTC Medication- Definition, OTC medication list & Counselling**
- 10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhoea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist
- 11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- 12 **Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist
- 13 **Code of ethics for community pharmacists**

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2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week


1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.


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3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

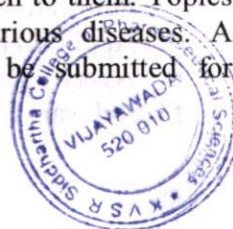
Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

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3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

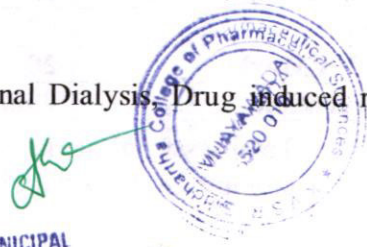
- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
2. **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders



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- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

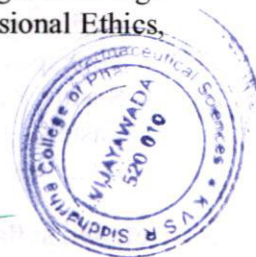
4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.



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3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

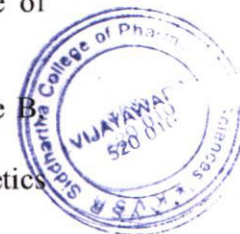
Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics
Provisions Relating to Indigenous Systems.
Constitution and Functions of DTAB, DCC, CDL.
Qualification and duties –Govt. analyst and Drugs Inspector.



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Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

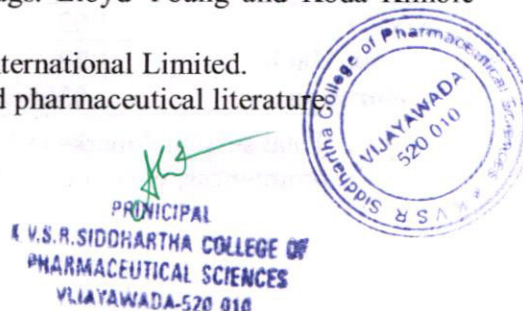
1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature



4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **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 dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication - Newsletter



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5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

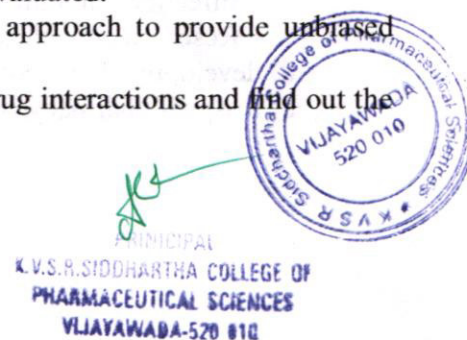
Education and training

8 Radio Pharmaceuticals – Handling and packaging**9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)****Practical : 3 Hrs./Week**

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.




Special requirements:

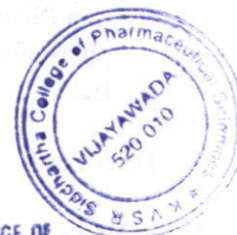
1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).


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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data, - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

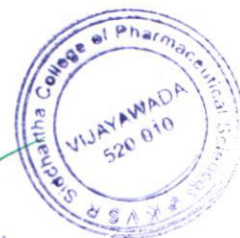
References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services



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Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.



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3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

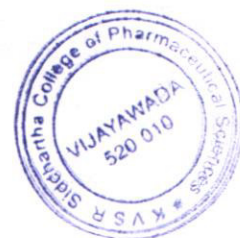
4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

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5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
3. **Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
4. **Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
5. **Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
6. **Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
7. **Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations



5.2 PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology :

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation


Outcome assessment and types of evaluation

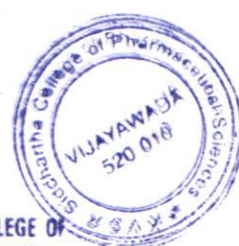
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies


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 VIJAYAWADA-520 016



Fifth year**5.1 CLINICAL RESEARCH (THEORY)****Theory : 3 Hrs. /Week****1. Drug development process:**

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.



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K.V.S.R.SIDDHARTHA COLLEGE OF
PHARMACEUTICAL SCIENCES
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4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad