



J.K.K.MUNIRAJAH MEDICAL RESEARCH FOUNDATION'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY

Ethirmedu, **B.Komarapalayam** – 638 183, Namakkal Dist. Tamilnadu. India
Approved by : Pharmacy Council of India, New Delhi & The Tamilnadu Dr.M.G.R Medical University, Chennai.
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List of courses with topic of gender, human values, environment and sustainability and professional ethics



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1.3.1 List of courses with topics of Gender, Human Values, Environment and Sustainability and Professional Ethics.

S.NO	Program Code	Program Name	Course Code	Name of The Course	Name of The Subject	Regulation Pharmacy Council of India
1	56	B.PHARM	BP105T	Communication skills	Gender, Human Values	2014
2.	56	B.PHARM	BP206T	Environmental sciences	Environment and Sustainability	2014
3	56	B.PHARM	BP505T	Pharmaceutical Jurisprudence	Professional Ethics	2014
4	56	B.PHARM	BP802T	Social and Preventive Pharmacy	Environment and Sustainability	2014
5	56	B.PHARM	BP804 ET	Pharmaceutical Regulatory Science	Professional Ethics	2014
6.	38	Pharm.D	3816	Pharmaceutical Jurisprudence	Professional Ethics	2014
7	38	Pharm.D	3825	Clinical research	Professional Ethics, Human Values	2014



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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. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

COURSE CONTENT:

UNIT – I

07 Hours

- **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

- **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.




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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

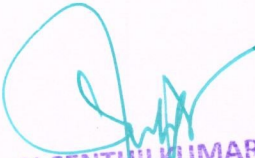
- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

04 Hours

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion




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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.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

COURSE CONTENT:

Unit-I

10 hours

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

10 hours

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

10 hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution




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BP 505 T: PHARMACEUTICAL JURISPRUDENCE (Theory)

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

COURSE CONTENT:

UNIT-I

10 Hours

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 license or permit. Offences and penalties.

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

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 license and repacking license.

UNIT-II

10 Hours

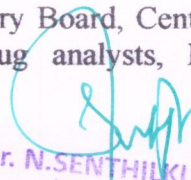
Drugs and Cosmetics Act, 1940 and its rules 1945.

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




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authorities, controlling authorities, Drugs Inspectors.

UNIT-III

10 Hours

- **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 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**

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BP 802T: SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

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 issues related 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 to health 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




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committee, Health survey and development committee, Hathi committee and Mudaliar committee

- **Code of Pharmaceutical ethics** Definition, 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)**




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BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

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

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

COURSE CONTENT:

Unit-I

10 Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit-II

10 Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

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Unit II:

10 Hours

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

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV:

08 Hours

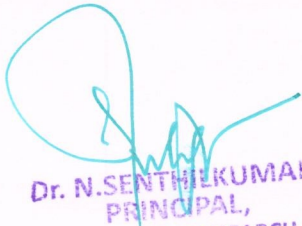
National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V:

07 Hours

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




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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) -

- Practice the Professional ethics:
- Understand the various concepts of the pharmaceutical legislation in India:
- Know the various parameters in the Drug and Cosmetic Act and rules.
- Know the Drug Policy, DPCO, Patent and design act:
- Understand the labeling requirements and packaging guidelines for drugs and cosmetics.
- Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Exciseduties Act: and
- Other laws as prescribed by the Pharmacy Council of India from time to time including international Laws.

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,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. 4.Pharmacy Act – 1948




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Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit-III

10 Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit-IV

08 Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials


Unit-V

07 Hours

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book




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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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Objectives Legal Definition, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

5. Medicinal and Toilet Preparation Act 1955.

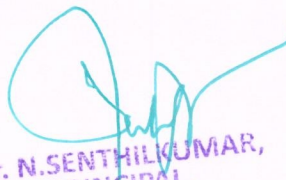
Objectives, Legal Definitions, Licensing, Bonded and Non-Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary preparations.

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 essentials 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.




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