JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION'S

ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY

Approved by: Pharmacy Council of India, New Delhi &

Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.

Accredited by NAAC "A" Grade and ISO Certified

Ethirmedu, B. Komarapalayam - 638183, Namakkal Dist. Tamilnadu, India.

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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

1.3.1 List of courses with topic of gender, human values, environment and sustainability and professional ethics.

SNO	PROGRAME CODE	PROGRAME 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	BP804ET	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
8	26	M.PHARM	MRA 103 T	Clinical research regulations	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 Dont's 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 **10hours**

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 **10hours**

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 **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

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BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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 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 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

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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: **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

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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):

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

Recommended Journals:

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

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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 **10Hours**

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 **10Hours**

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.

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 **10Hours**

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 **08Hours**

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 **07Hours**

Regulatory Concepts

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

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

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CLINICAL RESEARCH REGULATIONS
(MRA 103T)

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

Theory — 60 Hrs

1. Clinical Drug Development Process — 12 Hrs
   - Different types of Clinical Studies
   - Phases of clinical trials, Clinical Trial protocol
   - Phase 0 studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
   - Phase II studies (proof of concept or principle studies to establish efficacy)
   - Phase III studies (Multi ethnicity, global clinical trial, registration studies)
   - Phase IV studies (Post Marketing Studies; PSUR)

   Clinical Investigation and Evaluation of Medical Devices & IVDs

   Different Types of Studies
   Key Concepts of Medical Device Clinical Evaluation
   Key concepts of Clinical Investigation

2 Ethics in Clinical Research: 12 Hrs

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
  - Ethical principles governing informed consent process
  - Patient Information Sheet and Informed Consent Form
  - The informed consent process and documentation

3 Regulations governing Clinical Trials 12 Hrs

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

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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. Text book of Forensic Pharmacy. Calcutta : National : 1988,

Reference books (Theory)

a. Singh, KK, editor. Beitra's the Laws of Drugs, Medicines & cosmetics . Allahabad : Law Book House: 1984
b. Jain, NK. A text book 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

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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
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 & Proprietory 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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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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