CHALAPATHIINSTITUTEOFPHARMACEUTICALSCIENCES, GUNTUR
(AUTONOMOUS)

IV/IV B.PHARMACY 7TH SEMESTER (150 HOURS)

GUIDELINES FOR PRACTICE SCHOOL MODULE

Objective

The objectives of practice school are to:

Enable students to acquire learning by applying the knowledge and skills they possess, in unfamiliar, open-ended real life situations and also the practice school will provide excellent in skill to put in the students main core.

Why

The program would be a simulation of real work environment and requires students to undergo the rigor of professional setting, both in form and in substance. In the process, it provides an opportunity for students to satiate their inquisitiveness about the corporate world, exposure to practicing professional skills and also helps them acquire social skills by being in constant interaction with the professionals of an organization. This program benefits students to understand what he/she has studied in the classroom and what is being practiced in the industry.

Practice School involves task orientation, teamwork, goal orientation and managing the interpersonal relationships. Therefore, it helps students to develop the qualities required by a graduate. A good Practice School program undertaken with all the seriousness provides an excellent learning opportunity to the student and also paves the way for successful career path.

- Enables students to have a smoother transition from academics to professional world.
- Enhances interpersonal skills, communication skills, leadership qualities etc.
- Provides an opportunity to students to apply some of the ideas/skill sets in their careers,which also enhances their confidence levels.
- Enables students to be aware of their personal strengths and limitations as professionals.
- Increases marketability of students after graduation.
- Provides link with potential future employers.

Concept of Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester.

The student shall opt any one of the domains for practice school declared by the academic (program) committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student.

The knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

Practice school in our curriculum

1. Basic Introduction
2. Scientific method
3. Application
4. Training
5. Research
6. Documentation

PRACTICE SCHOOL ON INDUSTRIAL PHARMACY
(150 HOURS)

COURSE MODULES	TOPICS	DURATION(HRS)
Module-1	1) Pharma Industry and Pharmaceutics. 2) Preformulation 3) General aspects of formulation selection • Physical and chemicals considerations. • Buffer capacity. • Partition coefficient. • Solubility and PH. • The phase rule. • Melting point depression. • Age and sex of patient. 4) Steps in Pharmaceutical Research • Discovery. • Product Characterization. • Formulation, Delivery, Packaging Development. • Pharmacokinetics and Drug Disposition. • Preclinical Toxicology Testing and INDA. • Bioanalytical Testing. • Clinical Trials.	**25 hrs**
Module–2	**Instrument handling:** • SOP Handling • Tablet compression • Dissolution Apparatus • Friability Tester • Tapped density apparatus • Monsanto Hardness testing • Fluidized bed processor • Spray dryer • Freeze dryer • Aerosol filling machine • High speed homogenizer (Ika ultra turrex T25)	**50 hrs**

Module–3	**Formulation (Conventional)** **Tableting in Industrial Aspect** • Literature Search • Requirement Short listing • Vendor selection • Providing Control number and documentation. • Preformulation • Trail batch and optimization • Lab Validation. • Scale up validation • Tech Transfer • Regulatory clearance in detail	**25 hrs**
Module–4	**Novel Drug Delivery** • Development and evaluation of bovine serum albumin microspheres loaded withdiclofenac sodium • Formulation and evaluation of diclofenac gel • Formulation and comparative evaluation of sustained release diclofenac sodium matrixtablets • Formulation and evaluation of niosomes by thin film hydration technique • Formulation and evaluation of gelatin microspheres of diclofenac sodium • Formulation and evaluation of liquid crystalline nanoparticle by using High speedhomogenizer (Ika ultra turrex T25)	**25hrs**
Module–5	**Quality control, Regulatory Affairs, Industry needs** • Dissolution • Basic consideration • Basic of Pharmaceutical regularity affairs • Role of regularity profession in industry	**25hrs**

PRACTICE SCHOOL ON PRECLINICAL PHARMACOLOGY AND TOXICOLOGY (150 HOURS)

COURSE MODULES	TOPICS	DURATION (HRS)
Module-1	**Phases of Drug Development:** Drug Discovery, Characterization of investigational drug, Formulation of investigational drug, Pharmacokinetics aspect and Drug Disposition, Preclinical Toxicity studies and Investigational New Drug (IND) Application, Bioanalytical Testing and Clinical Trials.	**20 Hrs**
Module–2	**Historical Approaches in Drug Discovery** Indian system of Traditional medicines like Ayurveda, Siddha and Unani, traditional Chinesemedicine, and European Galenic medicine.	**10 Hrs**
Module–3	**New Approaches in Drug Discovery** Combinatorial Chemistry, High-Throughput Screening, Ultra-High-Throughput Screening and High-Content Screening.	**10 Hrs**
Module–4	**The Committee for the Purpose of Control and Supervision of Experiments onAnimals (CPCSEA) Guidelines for the Care and Use of Laboratory Animals:** Goal, Veterinary Care, Quarantine, Stabilization and Separation, Surveillance, Diagnosis, Treatment and Control of Disease, Animal Experimentation Involving Hazardous Agents, Durations of Experiments, Physical Restraint of Animals for Examination, Functional Areas of Animal House, Physical Facilities of Animal House, Environment (A) Temperature and Humidity Control (B) Ventilation (C) Power and Lighting (D) Noise Control, Animal Husbandry (A) Caging or Housing System (B) Social Environment, Animal Food and Water, Bedding, Sanitation and Cleanliness, Waste Disposal, Record Keeping in the Animal House, Animal Facility Staff and Their Training, Anesthesia and Euthanasia Methods used in Experimental Animals.	**10 Hrs**

Module–5	**Preclinical Study:** Types of Preclinical Testing, Important Consideration of Conducting Preclinical Studies, Steps Involved in Preclinical Trials, Safety Pharmacology, Toxicity Studies such as Acute, Subacute, Chronic, Inhalational, Dermal, Reproductive and Carcinogenic Toxicity Studies.	**20 Hrs**
Module–6	**Animal Models in Preclinical Research:** The Animal Models used to screen Analgesic, Anti-Inflammatory, Antipyretic, Local Anesthetic, Antiulcer, Antiemetic, Antidiarrheal, Antiasthmatic, Antiallergic, Antifertility, Aphrodisiacs, Muscle Relaxant, Anticonvulsant, Antipsychotic, Antidepressant, Antianxiety, Antiparkinsonian, Nootropic, Antihypertensive, Antiarrhythmic, Antihyperlipedimic, Antihyperglycemic, Hepatoprotective, Diuretic, and Anticancer activities.	**60 Hrs**
Module-7	**Biostatistics in Preclinical Studies:** Introduction to Biostatistics in Preclinical studies, Types of data, Summarizing the data, Describing data & Normality Selection, Statistical tests (Parametric and Nonparametric), Hypothesis testing & Significance level (p-value) and Data presentation.	**20 Hrs**

PRACTICE SCHOOL ON PHARMACEUTICAL REGULATORY AFFAIRS (150 HOURS)

COURSE MODULES	TOPICS	DURATION (HRS)
Module-1	**Introduction to Regulatory Affairs** General terminology, Roles and Responsibilities of RA in Pharmaceutical Industry, Regulatory guidance documents, Rules and Regulations, New amendments in pharmaceutical regulations.	**10 hrs**
Module–2	**Introduction to Regulatory Authorities** Over view of Regulatory authorities and their role and responsibilities including its organization chart: India,USA, EU, Canada, Japan, Australia.	**25 hrs**
Module–3	**Introduction to ICH** Over view of ICH Guidelines: QSEM (Quality, Safety, Efficacy and Multi disciplinary. Introduction to CTD (Common Technical Documentation) and eCTD (Electronic Common Technical Documentation)	**25 hrs**
Module–4	**Introduction to Regulatory Approval Process** Approval Process and timelines involved in IND (Investigation of New Drug), NDA (New Drug Application), ANDA (Abbreviated New Drug Application) and BLA (Biological License Application).	**50 hrs**
Module–5	**Introduction to Clinical Trails** Over view of Non – clinical and Clinical trials, Clinical trial protocol development, Institutional Review Board, Role and Responsibilities of Sponsor and Investigators and Safety monitoring in clinical trials.	**20 hrs**
Module–6	**Introduction to General Regulatory Concepts** Orange Book, Purple Book, Federal Register and Codeof Federal Register. DMF (Drug master Files), AnnualReports, Changes to an Approved NDA/ANDA.	**20 hrs**

PRACTICE SCHOOL ON HOSPITAL PHARMACY

(150 HOURS)

COURSE MODULE	TOPICS	DURATION (HRS)
Module–1	**Introduction** 1. Pharmacy practice and pharmaceutical care 2. Rational use of drugs 3. Hospital pharmacy and role of hospital pharmacist 4. Clinical pharmacy and evidenced based medicines 5. Pharmacovigilance 6. Public health and. pharmacoepidemiology 7. Introduction to clinical research and basic clinical trials	**25hrs**
Module–2	**Community Pharmacy** 1. Requirements and licensing procedure to establish community pharmacy 2. Treating of minor ailments 3. Health screening techniques 4. Arrangement of drugs in community pharmacy 5. Indent keeping 6. Dispensing of medicines 7. Inventory control at Janaushadi Kendra 8. OTC medications	**25hrs**
Module–3	**Clinical and hospital pharmacy** 1. Inventory control 2. Processing drug information queries. 3. Assessment of drug related problems 4. Patient counseling and preparation of leaflets 5. Interpretation of laboratory data 6. PMH interviews 7. Patient medication adherence 8. Preparation of essential drug list for a hospital	**25hrs**

Module–4	**Clinical research and Pharmacovigilance** 1. Clinical trial rule 2019. 2. Good clinical Practice ICH, GCP, CDSCO guidelines 3. Designing of clinical study documents 4. Safety monitoring in clinical trials. 5. Ethics in clinical trials 6. Declaration of Helsinki and Belmont report 5. Practical aspects of ADR identification, monitoring, reporting and management 6. Pharmacovigilance	**50hrs**
Module–5	**Public health and basics research methodology** 1. Vaccination schedule 2. Calculating the Determinants of health 3. Sustainable developmental goals 4. National and international health organizations 5. Communicable diseases and Role of pharmacist in preventing communicable diseases. 6. Community awareness on national health programmes. 7. Balanced diet and nutritional deficiency disorders 8. Types of data 9. Usage of graphpad instat and SPSS Softwares.	**25 hrs**

PRACTICE SCHOOL ON PHARMACEUTICAL ANALYSIS

(150 HOURS)

COURSE MODULES	TOPICS	DURATION (HRS)
Module-1	**Introduction to Pharmaceutical Analysis** General introduction of analysis in Pharmacy. Types of analysis in pharmacy. Different techniques of analysis. Importance of analysis in pharma industry.Importance of Pharmacopeia in analysis **Introduction to Standard operating procedures in analysis** 1.Study of SOP 2.Preparation of SOP 3.Importance of SOP **Preparation of Reagents and Standard solutions** Importance of reagents and standard solutions in analysis.	**20hrs**
Module–2	**Theory, Principle, Instrumentation, Application of following Analytical Instruments** 1.Analyticla balance 2.pH meter 3.UV Visible spectroscopy 4. IR spectroscopy 5.Fluorimetry 6.High performance liquid chromatography 7.HPTLC 8.DSC 9.Dissolution 10.Particle size analyzer 11.NMR 12.Mass spectroscopy 12. Analytical method validation.	**25hrs**

Module–3	**Operation and Handling of Analytical Instruments** 1. Analytical balance 2. pH meter 3. UV Visible spectroscopy 4. IR spectroscopy 5. Fluorimetry 6. High performance liquid chromatography 7.HPTLC 8.DSC 9.Dissolution 10.Particle size analyzer	**45hrs**
Module–4	**Preparation of Analytical Methods For Various Drugs** 1. Selection of drugs 2**.** Collection of Monographs 3. Literature Search 4. Selection of equipment 5. Method Development 6. Method Validation 7. Quantification of Drugs.	**25hrs**
Module–5	**Calibration of Analytical Instruments** 1. Definition and importance of calibration in pharmacy. 2. Calibration of Glassware 3. Calibration of following instruments: 1. Analytical balance 2. pH meter 3. UV Visible spectroscopy 4. IR spectroscopy 5. Fluorimetry 6. High performance liquid chromatography 7. HPTLC 8. DSC	**25hrs**
Module-6	**Good Documentation Practice** 1. Writing of Laboratory Note Book 2. Preparation of Protocols 3. Preparation of Validation Reports	**10hrs**