MODEL CURRICULUM

FOR

POSTGRADUATE PROGRAMME

IN

Masters in (Pharmacy Practice) 2012

ALL INDIA COUNCIL FOR TECHNICAL EDUCATION

7TH FLOOR, CHANDRALOK BUILDING, JANPATH

NEW DELHI – 110 001

FOREWORD

It is with great pleasure and honour that I write a forward for the Model scheme of instruction and syllabi for the Undergraduate and Post Graduate Pharmaceutical Education Program prepared by the All India Board of Pharmaceutical Education with Dr. S.Y. Ghabe as its Chairman and other members. All India Council for Technical Education has the onerous responsibility for uniform development and qualitative growth of the Technical Education system and preparation of syllabi to maintain uniform standards throughout the county. In pursuance to clause 10 (2) of the AICTE Act 1987 AICTE has the objective of bringing about uniformity in the curriculum of Pharmaceutical Education. In that direction, the efforts of the All India Board of Pharmaceutical Education has been quite commendable and praiseworthy. A painstaking effort was made by the Chairman, members of the Board and various working groups composed of experts from leading institutions in framing of the Instruction and Syllabi. The Board was ably assisted by the official of the Academics Bureau in successfully organizing the meetings making available necessary documents and follow up action on the minutes of the meetings.

Chairman

All India Council for Technical Education

SCHEME: PHARMACY PRACTICE

TERMINOLOGY: S- MEANS SEMESTER, MPPP - MEANS MASTER OF PHARMACY PRACTICE, T & TH MEANS THEORY, P & PR MEANS PRACTICAL

CREDIT SYSTEM:- 1 CREDIT = 25 MARKS

Sem	Subject Code	Subject	Hours/ Week		CREDITS		MARKS	
			TH	PR	TH	PR	TH	PR
First	S1-MPP-1	Research & Teaching Methodology	4	00	4	00	100	00
	S1-MPP-2	Hospital and Community Pharmacy	4	8	4	4	100	100
	S1-MPP-3	Computers & Statistics	4	4	4	2	100	50
	S1-MPP-4	Quality use of Medicines - I	4	8	4	4	100	100
		Total:	**16**	**20**	**16**	**10**	**400**	**250**
Second	S2-MPP-1	Research Project	00	8	00	2	00	50
	S2-MPP-2	Quality Use of Medicines- II	4	8	4	4	100	100
	S2-MPP3	Clinical Pharmacy Practice	4	8	4	4	100	100
	S2-MPP-4	Elective – I	4	00	4	00	100	00
		Total:	**12**	**24**	**12**	**10**	**300**	**250**
Third	S3-MPP-1	Drug Regulatory aspects & IPR	4	00	4	00	100	00
	S3-MPP-2	Research work Seminar	00	8	00	4	00	100
	S3-MPP-3	Research Project	00	16	00	6	00	150
	S3-MPP-4	Laboratory Data Analysis & Therapeutic Drug Monitoring	4	00	4	00	100	00
	S3-MPP-5	Elective – II	4	00	4	00	100	00
		Total:	**12**	**24**	**12**	**10**	**300**	**250**
Fourth	S4-MPP-1	Research Project & Colloquium	00	36	00	16	00	400
		Total:	**00**	**36**	**00**	**16**	**00**	**400**
		GRAND TOTAL:	**40**	**104**	**40**	**46**	**1000**	**1150**

Name of the Course :Research and Teaching Methodology	
Course code: S1-MPPP-1[T]	**Semester :** I
Duration : 60 Hrs	**Maximum Marks :** 100
Teaching Scheme	**Examination Scheme**
Theory : 04 Hrs/week	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [If required]	Assignment &Quiz: 10 Marks
Practical : Hrs/week [N A]	End Semester Exam: 70 Marks
Credits : **04**	

Aim :-

Objective :-

S. No	
1	**To familiarize students regarding teaching methodology & research projects.**
2	**To teach students preparation of research projects & different aspects associated with it.**
3	**To acquaint students with experimental data analysis.**
4	**To impress upon students the importance of ethical issues in the profession & plagiarism.**

Pre-Requisite:-

S. No	
1	A B. Pharm. degree from any AICTE approved institution or its equivalent.

	Contents	Hrs
Unit -1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne's condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.	08

Unit -2	**Curriculum development** A six step approach- Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	06
Unit -3	**Funding & Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship, types of scholarships in education.	03
Unit -4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	03
Unit -5	**Basics of Research** Definition, objectives, motivation, types of research and approaches: descriptive research, conceptual, theoretical, applied and experimental.	03
Unit -6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literature review: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints, steps, problems in scheduling, limitations.	04
Unit -7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	05
Unit -8	**Experimental Modeling** a) Definition of experimental design, examples, single factor experiments blocking and Nuisance factors, guidelines for designing experiments. b) General model of process: Input factors/ variables, Output parameters / variables controllable / uncontrollable variables, dependent / independent variables, experimental validity. c) Introduction to Risk assessment, reliability, sustainability, and uncertainty.	04

Unit -9	**Analysis of data** a) Types of data: parametric and nonparametric, descriptive and inferential data, b) Collection of data: normal distribution, calculation of co-relation coefficient c) Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity/nonlinearity of model, testing adequacy of model. d) Test to be used in data exploration and their choice e) Introduction of software used in data analysis.	08
Unit-10	**Research Deliverables** a) Various Forms of Publication: Thesis, paper, research proposal. b) Thesis Writing: Introduction, literature review or state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. c) Presentation: Poster, thesis, proposal, and paper.	04
Uni-11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
Unit-12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.	02
	Total	**60**

Text Books:

Reference books :

- B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press.
- J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education*", 7th Ed.* Boston: McGraw-Hill.
- K.E. David, 2009. Curriculum Development for Medical Education: *A Six-Step Approach,* 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.
- N. Peter, 2009. "Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. *Medical Education, 37*(4): 376-385.
- B.J. Avolio, F.O. Walumbwa, T.J. Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*: 421-449.
- C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
- D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.

- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill.
- D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons.
- Cochran & Cocks, 1957. 2nd Ed. "Experimental Design" New York, John Willy & sons.
- J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.
- S.S. Rao, 1983. "Optimization Theory & Applications". 2nd Ed. Wiley Eastern Ltd. ND.
- P.D. Kulkarni, 1986. "Independent Study Techniques", TTTI Chandigarh.

Suggested List of Laboratory Experiments : [N A]

Suggested List of Assignments/Tutorial : [N A]

Name of the Course : Hospital and Community Pharmacy		
Course code: S1-MPP-2 [T& P]	**Semester :**I	
Duration : 60 Hrs [T], 120 Hrs [P]	**Maximum Marks : 100**	
Teaching Scheme	**Examination Scheme**	
Theory : 04 Hrs/week	Mid Semester Exam: 20 Marks	
Tutorial: Hrs/week [If required]	Assignment & Quiz: 10 Marks	
Practical :08 Hrs/week	End Semester Exam: 70 Marks	
Credits : **04 Each [T & P]**		
Aim :-		
Objective :-		
S. No.		
1	Know the professional practice management skills in hospital pharmacies.	
2	Know various drug distribution methods.	
3	Know pharmaceutical care services.	
4	Do patient counseling & provide health screening services to public in community pharmacy.	
Pre-Requisite:-		
S. No.		
1	**Basic knowledge in Pharmaceutics.**	
2	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**	
Contents		Hrs
A	**. COMMUNITY PHARMACY** 1. Introduction to the concept of community pharmacy - its activities and professional responsibilities. 2. The role of the community pharmacy and its relationship to other local health care	**2** **2**

	providers. 3. Prescribed medication order - interpretation and legal requirements. 4. Patient counseling in community pharmacy. 5. Over the counter (OTC) sales. 6. Health education and community pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs. 7. Services to Nursing homes/clinics. 8. Community Pharmacy management : Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy. 9. Code of ethics for community pharmacists. 10. Polypharmacy and its implications	 **4** **4** **2** **2** **2** **1** **1**
	COMMUNICATION SKILLS	
B	Principal and elements of communication skills, non verbal communication in pharmacy, barriers in communication, listening skills, questioning skills, explaining skills and ethics in communication	**03**
	HOSPITAL PHARMACY 1. The role of hospital pharmacy department and its relationship to other hospital departments and staff. 2. Pharmacy and Therapeutics Committee: Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines. Other hospital committees such as infection control committee and research & ethics committee.	 **2** **2**

	Hospital pharmacy management Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and Planning, Infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs), Workload statistics. 4. Hospital Pharmacy Services Purchasing, storage, stability and safety of drugs, drug distribution, Radiopharmaceuticals, IV additive services and total parenteral nutrition.	**2** **2** **3**
C	**PHARMACOEPIDEMIOLOGY** Definitions and scope. Methods [qualitative, quantitative and Meta-analysis models]. System for monitoring drug effects. Advantages and disadvantages of pharmacoepidemiology	**5**
	PHARMACOECONOMICS Definitions and scope, types of economic evaluation, cost models and cost effectiveness analysis.	**4**
D	**PUBLIC HEALTH POLICY AND HEALTH CARE SYSTEM**	**2**
	CONCEPT OF RATIONAL USE OF DRUGS Importance of rational drug use. Pharmacists role. Drug use indicators. Guidelines for rational prescribing.	**5**

E	**EVIDENCE BASED MEDICINE** Formulating clinical questions. Searching for the best evidence. Critical appraisal of the evidence. Applying evidence to patients. Evaluation.	**5**
	MEDICATION ERROR AND MEDICATION ADHERENCE Categories and causes of medication error, tools to measure the performance of the medication use process, categories of medication non-adherence, role of pharmacist in medication error and medication adherence.	**5**
	Total	**60**

Text Books: N A

Reference books :

1. Hospital Pharmacy - Hassan W E. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood M C and Blackwell.
3. Avery's Drug Treatment, 4th Ed, 1997, Adis international limited.
4. Evidence based medicine: How to practice and teach EBM. Sharon E Straus III, Edition Churchill Livingston.

Suggested List of Laboratory Experiments :

1. The student is expected to perform ABC and VED analysis on the given data on drugs used in the hospital, participate in activity session involving issues regarding pharmacy and therapeutic committee, prepare a model monograph for a drug formulary, critically analyse the given data on hospital pharmacy budget, work flow patterns etc., perform patient medication interview and counselling and present drug profiles one new drugs.

Suggested List of Assignments/Tutorial :

The student is expected to perform the following and report.

1. Comparison of prescription handling in two community pharmacies.
2. Audit of OTC sales over a 24 hour period in a local community pharmacy.

3. Role of community pharmacists in health education, family planning, first aid, smoking cessation screening programmes, immunisation, etc.
4. Code of ethics for community pharmacies.
5. Summary of the advice and recommendations which should be provided to the customers at a community pharmacy.
6. Select a new drug, which has recently been marketed in India for the first time.
7. Prepare a report for a hospital's Drug and Therapeutic Committee, and make a case either for or against the addition of this new drug on to the hospital's formulary. Issues, which you may need to cover, include the drug's pharmacology, its clinical use, the opinions | of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.
8. Examine and report on the drug distribution methods used in a local hospital.
9. Examine and report on the purchase and inventory of drugs in a local hospital.

Name of the Course :Computer and Statistics	
Course code: S1-MPP-3 [T]	**Semester :** I
Duration : 60 Hrs[T], 60 Hrs [P]	**Maximum Marks :** 100 [T] 50 [P]
Teaching Scheme	**Examination Scheme**
Theory : 04 Hrs/week	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [If required]	Assignment &Quiz: 10 Marks
Practical : 04 Hrs/week	End Semester Exam: 70 Marks
Credits **: 04 [T] & 02 [P]**	

Aim :-

Objective :-

S. No	
1	**To train students in basics of computer hardware.**
2	**To train them on hands on experience in use of different software.**
3	**To teach them applications of computers in different areas of Pharmacy.**
4	**To train the students for applications of various statistical methods available for analysis of data.**

Pre-Requisite:-

S. No	
1	**A 10 + 2 level mathematics & rudimentary knowledge of computers.**
2	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**

	Contents	Hrs
Computers		
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03

Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	06
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	04
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	06
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	04
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	03
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	02
Statistics		
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	03
Unit -4	Hypothesis testing.	04
Unit -5	Optimization.	04
Unit -6	Designing experiment.	04

Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	02
	Total	**60**

Text Books:

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Suggested List of Laboratory Experiments :

S. No	
1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).

2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.
Suggested List of Assignments/Tutorial : N A	

Name of the Course : Quality Use of Medicines – I	
Course code: S1-MPP-4 [T & P]	**Semester :** I
Duration : 60 Hrs	**Maximum Marks :** 100
Teaching Scheme	**Examination Scheme**
Theory : 04Hrs/week	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [If required]	Assignment &Quiz: 10 Marks
Practical : 08 Hrs/week	End Semester Exam: 70 Marks
Credits : **04 Each [T& P]**	

Aim :-

Objective :-

S. No	
1	The therapeutic approach to management of these diseases.
2	The controversies in drug therapy.
3	Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence.
4	The importance of preparation of individualized therapeutic plans based on diagnosis.

Pre-Requisite:-

S. No	
1	A B. Pharm. degree from any AICTE approved institution or its equivalent.

	Contents	Hrs
Unit -1	**Cardiovascular system** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidemias, Electrophysiology of heart and Arrhythmias.	10
Unit -2	**Respiratory system** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways	8

	disease, Drug induced pulmonary diseases.	
Unit -3	**General prescribing guidelines for** 1.1 Pediatric patients 1.2 Geriatric patients 2.3 Pregnancy and breast feeding	5
Unit -4	**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.	8
Unit -5	**Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.	08
Unit -6	Pain management including Pain pathways, neuralgias, headaches.	05
Unit -7	**Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infections- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphillis	8
Unit -8	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	08
	Total	**60**

Text Books:

Reference books :

1. Applied therapeutics: Mary Anne Koda-Kimble, Lloyd Yee Young et al, 8th Edn. Lippincott Williams and Wilkins publications 2005.
2. Pharmacotherapy, A Pathophysiologic Approach: Joseph T Dipiro. 5th Edn. McGraw-Hill Medical publishing division 2002.
3. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwards. 3rd Edn. Churchill Livingstone, Edinburgh, 2003.
4. Textbook of therapeutics, Drug and disease management: Eric T Herfindal. 7th Edn. Williams & Wilkins Publications 2003.
5. Avery's Drug Treatment: Trevor M Speight, Nicholas HG et al, 4th Edn. Adis International Ltd. 1997.

6. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
7. Principles of Internal Medicine: Harrisons: Braunwald et al, 16th Edn. Mc Graw Hill Publications, 2005
8. Pathological Basis of Disease: Robins SL, 7th Edn. WB Saunders Publications, 2004
9. Current Medical Diagnosis Treatment: Tierney et al, 44th Edn. Lange Medical Publications, 2005.
10. .Basic and Clinical Pharmacology: Bertram G Katzung, 9th Edn. Lange Medical Publications, 2004.

Suggested List of Laboratory Experiments :

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the above clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

Suggested List of Assignments/Tutorial : [N A]

Name of the Course : Research Project	
Course code: S2-MPP-1 [P]	**Semester :** II
Duration : 120 Hrs	**Maximum Marks : 50**
Teaching Scheme	**Examination Scheme**
Theory : Hrs/week [N A]	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week] N A]	Assignment & Quiz: Marks [NA]
Practical : 08 Hrs/week	End Semester Exam: 30 Marks
Credits : **02**	

Aim :-

Objective :-

S. No	
1	**To give exposure on how to do literature survey for the project work.**
2	**To develop technical writing skills in the form of a research report.**
3	**To develop report presentation ability, orally.**
4	**To develop question answer capability confidently.**

Pre-Requisite:-

S. No	
1	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**

	Contents	Hrs
S. NO	Nil	

Text Books: N A

Reference books: Choice of books & other literature shall depend on the topic of research & the choice is left with the individual faculty.

Suggested List of Laboratory Experiments : N A
Suggested List of Assignments/Tutorial : N A

Name of the Course : Quality Use of Medicines – I I	
Course code: S2-MPP-2[T]	**Semester :** II
Duration : 60 Hrs	**Maximum Marks :** 100
Teaching Scheme	**Examination Scheme**
Theory : 04Hrs/week	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [If required]	Assignment &Quiz: 10 Marks
Practical : Hrs/week [N A]	End Semester Exam: 70 Marks
Credits : **04**	

Aim :-

Objective :-

S. No	
1	The therapeutic approach to management of these diseases
2	The controversies in drug therapy
3	Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence
4	The importance of preparation of individualized therapeutic plans based on diagnosis

Pre-Requisite:-

S.No	
1	A B. Pharm. degree from any AICTE approved institution or its equivalent.

	Contents	Hrs
Unit -1	**Endocrine system** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	5
Unit -2	**General prescribing guidelines for** 1.3 Pediatric patients	2

	1.4 Geriatric patients 2.3 Pregnancy and breast feeding	
Unit -3	**Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial	4
Unit -4	**Introduction to rational drug use** Definition, Role of pharmacist Essential drug concept Rational drug formulations	6
Unit -5	**Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,	04
Unit -6	**Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	05
Unit -7	Evidence Based Medicine	05
Unit -8	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	05
Unit -9	**Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	10
Unit-10	**Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	04
Uni-11	**Dermatology:** Psoriasis, Scabies, Eczema, Impetigo	10
	Total	**60**

Text Books:

Reference books :

11. Applied therapeutics: Mary Anne Koda-Kimble, Lloyd Yee Young et al, 8th Edn. Lippincott Williams and Wilkins publications 2005.
12. Pharmacotherapy, A Pathophysiologic Approach: Joseph T Dipiro. 5th Edn. McGraw-Hill Medical publishing division 2002.

13. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwards. 3rd Edn. Churchill Livingstone, Edinburgh, 2003.
14. Textbook of therapeutics, Drug and disease management: Eric T Herfindal. 7th Edn. Williams & Wilkins Publications 2003.
15. Avery's Drug Treatment: Trevor M Speight, Nicholas HG et al, 4th Edn. Adis International Ltd. 1997.
16. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
17. Principles of Internal Medicine: Harrisons: Braunwald et al, 16th Edn. Mc Graw Hill Publications, 2005
18. Pathological Basis of Disease: Robins SL, 7th Edn. WB Saunders Publications, 2004
19. Current Medical Diagnosis Treatment: Tierney et al, 44th Edn. Lange Medical Publications, 2005.
20. .Basic and Clinical Pharmacology: Bertram G Katzung, 9th Edn. Lange Medical Publications, 2004.

Suggested List of Laboratory Experiments :

The students are required to be posted to various clinical wards for their exposure with therapeutic anagement and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

Suggested List of Assignments/Tutorial : [N A]

Name of the Course :Clinical Pharmacy Practice		
Course code: S2-MPP-3[T]		**Semester :**II
Duration :60 Hrs		**Maximum Marks :**100
Teaching Scheme		**Examination Scheme**
Theory : 04Hrs/week		Mid Semester Exam: 20Marks
Tutorial: Hrs/week [If required]		Assignment &Quiz: 10Marks
Practical :Hrs/week [N A]		End Semester Exam: 70 Marks
Credits :**04**		
Aim :-		
Objective :-		
S.No		
1	Understand the elements of pharmaceutical care and provide comprehensive patient care services	
2	Interpret the laboratory results to aid the clinical diagnosis of various disorders	
3	Provide integrated, critically analyzed drug and poison information to enable healthcare professionals in the efficient patient management	
4	Understand the concept and practice of the quality use of medicines	
Pre-Requisite:-		
S.No		
1	**A B. Pharm. degree from any AICTE approved institution or its equivalent.**	
Contents		Hrs
Unit -1	**. Introduction to Clinical Pharmacy Practice** • Definition, evolution and scope of clinical pharmacy • International and national scenario of clinical pharmacy practice	04

	• Pharmaceutical care	
Unit - 2	**Clinical Pharmacy Services** • Ward round participation • Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) • Patient medication history interview • Basic concept of medicine and poison information services • Patient medication counselling • Drug utilisation evaluation • Quality assurance of clinical pharmacy services	2 4 2 2 2 2 1
Unit -3	**Patient Data Analysis** ***Patient Data & Practice Skills*** • Patient's case history - its structure and significances in drug therapy management • Common medical abbreviations and terminologies used in clinical practice Communication skills: Verbal and non-verbal communications, its applications in patient care services.	**10**
Unit -4	**. Medicine & Poison Information Services** ***Medicine Information Service*** • Definition, need for and medicine information resources • Systematic approach in answering medicine information queries • Preparation of verbal and written response • Establishing a drug information centre ***Poison Information Service*** Definition, need, organization and functions of poison information centre	5
Unit -5	**Quality Use of Medicines** ***Evidence Based Medicine*** • Definition, concept of evidence based medicine • Approach and practice of evidence based medicine in clinical settings ***Essential Drug*** • Definition, need, concept of essential drug • National essential drug policy and list	5 4

	Rational Drug Use • Definition, concept and need for rational drug use • Rational drug prescribing • Role of pharmacist in rational drug use	2
	Pharmacovigilance • Definition, aims and need for pharmacovigilance • Types, predisposing factors and mechanism of adverse drug reactions (ADRs) • Detection, reporting and monitoring of ADRs • Causality assessment of ADRs • Management of ADRs • Role of pharmacists in pharmacovigilance	4 8
	Medication errors • Definition, categorization and causes of medication errors • Detection and prevention of medication errors • Role of pharmacist in monitoring and management of medication errors	3
	Total	**60**

Text Books:

Reference books :

1. PracticeStandardsandDefinitions -TheSocietyofHospitalPharmacistsofAustralia (latest edition)
2. BasicskillsininterpretinglaboratorydataScottLT,AmericanSocietyofHealthSystem PharmacistsInc(latest edition)
3. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G Karin Nyfort-Hansen and MilapNahata (latest edition)
4. Relevantreviewarticlesfrom recentmedicalandpharmaceuticalliterature.

Journals:

- PharmaceuticalJournal. RoyalPharmaceuticalSociety,London
- Journal ofPharmacyPracticeandResearch,SocietyofHospitalPharmacists ofAustralia
- International JournalofPharmacyPractice,UnitedKingdom
- HospitalPharmacist,UK
- IndianJournalofHospitalPharmacy

•

Suggested List of Laboratory Experiments :

Patient medication history interview, answering drug information questions, patient medicationcounseling, participation in ward rounds. Case studies related to laboratory investigationscovering the topics dealt in theory class.

1.Answering drug information questions (Any four)(Queries related to Dosage, administration, Contraindications, Adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)

2. Patient medication counseling (Any three) Common diseases like Diabetes, Asthma, Hypertension, TB, and COPD

3. Case studies related to laboratory investigations (Any four) LFT, Hematology, Thyroid, Renal, Cardiac enzymes

4. Detection and assessment of adverse drug reactions and their documentation (Any two)

5. Identification and assessment of medication errors (Any two)

Suggested List of Assignments/Tutorial : N A

Name of the Course :Elective – 1		
Course code: S2-MPP-4 [T]		**Semester :** II
Duration : 60 Hrs		**Maximum Marks :** 100
Teaching Scheme		**Examination Scheme**
Theory : 04 Hrs/week		Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [N A]		Assignment & Quiz: 10 Marks
Practical : Hrs/week [N A]		End Semester Exam: 70 Marks
Credits: **04**		
Aim :-		
Objective:-		
S. No.		
1	**To give aditional knowledge to the students of their choice.**	
Pre-Requisite:-		
S. No.		
1		
2	**A B. Pharm. degree from any institution approved by AICTE or its equivalent.**	
Contents		Hrs
1	Pharmacoepidemiology	
2	Clinical Pharmacology	
3	Clinical Research	
4	Biotechnology	
5	Chromatographic methods of qualitative and quantitative analysis	
6	Mass spectrometry and drug metabolism	

	Total	**60**
Text Books:N A		
Reference books : N A		
Suggested List of Laboratory Experiments : N A		
Suggested List of Assignments/Tutorial : N A		

Name of the Course :Drug Regulatory Aspects and IPR		
Course code: S3-MPP-1 [T]	**Semester :** III	
Duration : 60 Hrs	**Maximum Marks :** 100	
Teaching Scheme	**Examination Scheme**	
Theory : 04 Hrs/week	Mid Semester Exam: 20 Marks	
Tutorial:Hrs/week [If required]	Assignment & Quiz: 10 Marks	
Practical : Hrs/week [N A]	End Semester Exam: 70 Marks	
Credits **: 04**		
Aim :-		
Objective :-		
S. No.		
1	**To impart information on various drug regulatory aspects involved in the profession.**	
2	**To teach the import / export related regulations with respect to some countries.**	
3	**To make the students understand the importance & implications of IPR & related matters.**	
4	**To train the students in GMP & the latest developments there.**	
Pre-Requisite:-		
S. No.		
1	**A course at UG level regarding regulatory aspects, laws governing Pharmacy profession.**	
2	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**	
	Contents	Hrs
Unit -1	**DRUG REGULATORY ASPESTS**	**40**
(a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA). 2. Drugs and Cosmetics Act and Rules with latest Amendments (selective). 3. Special emphasis – Schedule M and Y.	10

	4. New Drugs – Importation, Registration, development, clinical trials, BE NOC & B.E. studies. 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	
(b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification. 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10). 3. Export permissions and manufacturing for semi-regulated countries. 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, water systems, stores management, effluent etc.). 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
(c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations). 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, vanilla ANDA's, exhibit/pivotal batches, validation batches, various guidance issued by CDER, OGD, Orange Book (and patents), RLD (reference listed drug) for BE studies and the norms for US submission, bioequivalence and dissolution recommendations, packaging, stability studies and the product information leaflet, US FDA inspection (audits), pre-approval inspections and approvals. 3. European Union Requirements – 4. All the aspects for European registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1). 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of quality assurance, product approvals and supplies.	18
Unit -2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
(a)	**Introduction to IPR & Patents –** Development of IP law in India, IPR regime, introduction to IP laws in India, role of IP in pharma industry growth.	
(b)	**Patenting in India –** Introduction, patent legislation, Indian Patents Act 1970 and amendments, procedure for patent application, grant and opposition proceedings, patent licensing, patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP case laws.	
(c)	**American & European patent system –** Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe.	
(d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay	

	TRIPS, WIPO.	
(e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003.**	
(f)	**Introduction to** geographical indication / trademark/ copyright: filing procedures.	
(g)	**Patent search, patent analysis & patent drafting**.	
(h)	**Allied Patents Related Issues**: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.	
	Total	**60**

Text Books:

It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. Kanfer& L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
12. USPTO and WIPO Guidelines, Indian Patents Act

Suggested List of Laboratory Experiments : N A

Suggested List of Assignments/Tutorial : N A

Name of the Course : Research Work Seminar	
Course code: S3-MPP-2 [P]	**Semester :** III
Duration : 120 Hrs	**Maximum Marks :** 100
Teaching Scheme	**Examination Scheme**
Theory : Hrs/week [N A]	Mid Semester Exam:20 Marks
Tutorial:Hrs/week [N A]	Assignment & Quiz: 10 Marks
Practical : 08 Hrs/week	End Semester Exam: 70 Marks
Credits **: 04**	

Aim :-

Objective :-

S. No.	
1	**To effectively present the research work carried out by the student.**

Pre-Requisite:-

S. No.	
1	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**

	Contents	Hrs
S.No	**Nil**	

Text Books: N A

Reference books : N A

Suggested List of Laboratory Experiments : N A

Suggested List of Assignments/Tutorial : N A

Name of the Course :Research Project	
Course code: S3-MPP-3 [P]	**Semester :** III
Duration : 240 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : Hrs/week [N A]	Mid Semester Exam: Marks [N A]
Tutorial: Hrs/week [N A]	Assignment & Quiz: Marks[N A]
Practical : 16 Hrs/week	End Semester Exam:150 Marks
Credits **: 06**	

Aim :-

Objective :-

S. No.	
1	**To manage the research work in time bound manner.**

Pre-Requisite:-

S. No.	
1	**To manage the research work in time bound manner.**

Contents		Hrs
S. No	**Nil**	

Text Books: N A

Reference books : Choice is discretionary depending on the topic selected.

Suggested List of Laboratory Experiments : N A

Suggested List of Assignments/Tutorial : N A

Name of the Course : Laboratory Data Analysis And Therapeutic Drug Monitoring	
Course code: S3-MPP-4[T]	**Semester :**III
Duration :60 Hrs [T]	**Maximum Marks :**100
Teaching Scheme	**Examination Scheme**
Theory : 04 Hrs/week	Mid Semester Exam: 20 Marks
Tutorial: Hrs/week [If required]	Assignment & Quiz: 10 Marks
Practical : Hrs/week [NA]	End Semester Exam: 70 Marks
Credits :**04 [T]**	

Aim :-

Objective :-

S.No	
1	**To Train the students on Lab data interpretation**
2	**To understand the TDM**
3	
4	

Pre-Requisite:-

S.No	
1	**A B. Pharm. Degree from any institution approved by AICTE or its equivalent.**

	Contents	Hrs
Unit -1	***Lab Data Interpretation*** • Haematological tests • Renal function tests • Liver function tests • Tests associated with cardiac disorders • Pulmonary function tests • Thyroid function tests • Fluid and electrolyte balance	10

	• Microbiological culture sensitivity tests	
Unit -2	**Therapeutic Drug Monitoring:** Introduction, Necessity of TDM, Criteria for valid TDM, Essentials for effective TDM, Organization of a TDM service, Effectiveness of TDM.	5
Unit -3	Analytical aspects of TDM, Uses of HPLC and Immunoassays in TDM for measurement of serum drug concentrations.	3
Unit -4	Dosage regimen design, Dosing of drug in special population – Pregnancy & lactation, Paediatrics & Geriatrics, Dosage adjustment in renal and hepatic impairment, Patient compliance.	6
Unit -5	TDM. of selected individual drugs-Aminoglycosides, Carbamazepine, Cyclosporine, Digoxin and Methotrexate.	6
	Introduction to Pharmacokinetics, Types of pharmacokinetic models, Their advantages and limitations. Model-Independent calculations (from equations as well as graphs) for pharmacokinetic parameters – Area under the curve, k_a, k_e, Biological half-life, Apparent volume of distribution and Clearance.	2 10
	Compartment models: a) One compartment open model – monoexponential decline – IV bolus (blood & urine analysis), IV infusion and oral (Blood analysis). b) Two compartment model – biexponential disposition – IV bolus. c) Three compartment model – triexponential disposition – The concept. d) Multiple dosing – consequences, equations to calculate C_{min}, C_{max} and C_{ss}, accumulation index, concept of loading dose and maintenance dose.	6 2 1 3
	Drug distribution: a) Factors affecting (perfusion & permeability) b) Protein binding – Kinetics of protein binding & Clinical significance.	6

	Total	**60**

Text Books:

Reference books :

1. Robert E. Notari, Biopharmaceutics and Pharmacokinetics.
2. Leon Shargel, Pharmacy Review.
3. James Swarbrick, Current Concepts in Pharmaceutical Sciences.
4. Leon Shargel and Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 1985.
5. Alfonso. R. Gennaro, Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 2001.
6. Abdou, Dissolution, Bio-availability and Bio-equivalence, Mack Publishing Company, 1989.
7. Shobha Rani. R. Hiremath, Textbook of Biopharmaceutics and Pharmacokinetics, Prism, 2000.
8. Mike Hallworth and Nigel Caps, Therapeutic Drug Monitoring and Clinical Biochemistry.
   Milo Gibaldi & Donald Perrier, Pharmacokinetics

Suggested List of Laboratory Experiments : N/A

-

Suggested List of Assignments/Tutorial : N A

Name of the Course :Elective – 2	
Course code: S3-MPP-5 [T]	**Semester :** III
Duration : 60 Hrs	**Maximum Marks :** 100
Teaching Scheme	**Examination Scheme**
Theory : 04 Hrs/week	Mid Semester Exam:20 Marks
Tutorial:Hrs/week [N A]	Assignment & Quiz:10 Marks
Practical : Hrs/week [N A]	End Semester Exam: 70 Marks
Credits **: 04**	

Aim :-

Objective :-

S.No	To give additional knowledge/ information to the students of their choice
1.	
2.	
3	

Pre-Requisite:-

S. No.	
1	**A B. Pharm degree from any AICTE approved institution or its equivalant**
2	

	Contents	Hrs
1	Pharmacgenomics	
2	Clinical Pharmacokinetics	
3	Proteomics	
4	Nanotechnology and TDM	
	Total	**60**

Text Books: N A
Reference books :
Suggested List of Laboratory Experiments : N A
Suggested List of Assignments/Tutorial : N A

Name of the Course :Research Project and Colloquium	
Course code: S4-MPP-1 [P]	**Semester :** IV
Duration : 540 Hrs	**Maximum Marks :** 400
Teaching Scheme	**Examination Scheme**
Theory : Hrs/week [N A]	Mid Semester Exam: Marks [N A]
Tutorial:Hrs/week [N A]	Assignment & Quiz: -- Marks [N A]
Practical : 36 Hrs/week	End Semester Exam: 400Marks
Credits : **16**	

Aim :-

Objective :-

S. No.	
1	**To complete the given research project.**
2	**To effectively defend the work before a group of qualified evaluators.**

Pre-Requisite:-

S. No.	
1	**A B. Pharm. degree from any institution approved by AICTE or its equivalent.**

Contents		Hrs
S.No	Nil	

Text Books: N A

Reference books : N A

Suggested List of Laboratory Experiments : N A

Suggested List of Assignments/Tutorial : N A