JSS Mahavidyapeetha

College of Pharmacy

JSS Academy of Technical Education

C-1/A, Sector-62, Noida-201309

Affiliated to Dr. A.P.J. Abdul Kalam Technical University, Uttar Pradesh, Lucknow

Course Handout

Academic Year: 2022-23

Class: Fourth Year B. Pharm

(Semester VII & VIII)

Name : _____

Roll No. : _____

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VISION

To be a leader in Pharmacy Education, Training, and Research.

MISSION

✓ Providing Knowledge and Skill of Pharmaceutical Sciences to its students

✓ Advancing the Knowledge, Skill, and Attitude of faculty members for transformational research activities in the Pharmaceutical Sciences.

Academic Calendar 2022-23

Fourth Year B. Pharm

1. Commencement of Classes

B. Pharm – VII Semester — **16th August - 2022**

2. Sessional Examination Schedule

I	II	III
3rd Week of September 2022	**3rd Week of October 2022**	**3rd Week of November 2022**

3. Closure of Term: **10th December 2022**

4. End Semester Examination:

Theory Examination — **15th December – 10th January 2023**

Practical Examination — **09th December – 14th December 2023**

5. Commencement of VIII Semester Classes: **21st January 2023**

Program Educational Objectives (PEOs):

PEO 1: To acquire the theoretical knowledge of pharmaceutical sciences

PEO 2: To acquire practical skills in

- Isolation of medicinal compounds from natural sources
- Synthesis and analysis of medicinal compounds
- Screening medicinal compounds for pharmacological activities
- Formulation of pharmaceutical dosage forms and their evaluation

PEO 3: To develop competent Pharmacists with ethical attitudes, research intuition, leadership qualities, to participate in public health programs, and engage in lifelong learning

Program Outcomes (POs):

1. Ability to acquire knowledge of pharmaceutical sciences
2. Ability to design and conduct experiments, to analyze and interpret data
3. Ability to demonstrate effective planning, develop and implement plans within the time frame.
4. Ability to function effectively individually and on teams, including diverse and multidisciplinary, to accomplish a task.
5. Ability to understand and appreciate the role of a pharmacist in healthcare services.
6. Understanding of professional, ethical, legal, security, and social issues and responsibilities.
7. Ability to understand contemporary issues relating to the pharmacy profession and challenges ahead.
8. Awareness of ethical and professional responsibilities.
9. Possess the necessary interpersonal and communication skills to be a productive member of the team in a work environment.
10. Ability to use current techniques, skills, and modern tools.
11. A strong background and motivation to pursue life-long learning

1. Course Details VII Semester

Course Code	Name of the Course	No. of hours	Tutorial	Credit Points
BP701T	Instrumental Methods of Analysis –Theory	3	1	4
BP702T	Industrial Pharmacy II – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System (NDDS) – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School	12	-	2
BP707P	Report on Hospital Training-II	-	-	6
	Total	**28**	**4**	**26**

2. Course Details VIII Semester

Course Code	Name of the Course	No. of hours	Tutorial	Credit Points
BP801T	Biostatistics and ResearchMethodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management*			
BP804ET	Pharmaceutical Regulatory Science*			
BP805ET	Pharmacovigilance*			
BP806ET	Quality Control and Standardization of Herbal*			
BP807ET	Computer Aided Drug Design*			
BP808ET	Cell and Molecular Biology*			
BP809ET	Cosmetic Science*			
BP810ET	Experimental Pharmacology*			
BP811ET	Advanced Instrumentation Techniques*			
BP812ET	Dietary Supplements and Nutraceuticals*			
BP813ET	Pharmaceutical Product Development*			
BP814PW	Project Work (On Elective)			
	Total	**28**	**4**	**26**

*(ET: Elective subject) Every candidate has to opt for two of the elective subjects, and has to carry out project on any one of them.

**The Industrial Tour may be performed at the end of the 7th semester.

3. Attendance and progress

A candidate is required to put at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

2. Evaluation:

a. Sessional examination: Continuous mode

The marks allocated for the Continuous mode of Sessional examination, as per the scheme given below.

Table 1: Scheme for awarding Sessional examination: Continuous mode

THEORY

Criteria	Maximum Marks	
Attendance	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
PRACTICALS		
Attendance	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table 2: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90–94	3	1.5
85–89	2	1
80–84	1	0.5
Less than 80	0	0

b. Sessional Exams

Three Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of the question paper for theory and practical Sessional examinations is given below. The average marks of best two Sessional exams shall be computed for Sessional examination as per the requirements.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly, Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Short notes	=	05 x 2 = 10
II. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
III. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10

Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05

Total	=	40 marks
		----------

3. End semester examinations

The End Semester Examinations for each theory and practical course shall be conducted by the university except for the subjects notified as non-university examinations

Table 3: Scheme for Sessional examinations and university examination - Semester-VII

Course code	Name of the course	Sessional examination				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System (NDDS) – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705P	Instrumental Methods of Analysis – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP706PS	Practice School	50	100	5 Hr	150	--	--	150
BP707P	Report on Hospital Training-II	--	--	--	--	100	--	100

	Total	95	170	13 Hr	265	435	16 Hrs	700

Question paper pattern for end semester theory examinations for 75 marks

For 75 marks paper

I. Short notes	=	10 x 2 = 20
II. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
III. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35
Total	=	75 marks

Question paper pattern for end semester practical examinations for 35 marks

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5
Total	=	35 marks

4. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. programme if he/she secures at least 50% marks in that particular course including Sessional examination. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including Sessional examination and end semester practical examination.

5. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified (in promotion and award of grades), then he/she shall reappear for the university examination of that course. However, his/her marks of the Sessional examination shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

6. Improvement of Sessional examination

A student shall have the opportunity to improve his/her performance only once in the Sessional exam component of the Sessional examination. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

7. Grading of performances

Letter grades and grade points allocations

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.

Table 5: Letter grades and grade points equivalent to percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	A+	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent in any form of evaluation/examination, letter grade allocated to him/her should be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

8. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of. 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

9. Attendance: The marks are allotted based on the attendance percentage (Table 2)

10. Chamber consultation hours: Any time during college hours.

11. Tutorial Class: Objective of the tutorial is to enhance the learning ability and help students in better understanding of the subject. This provides a best opportunity for the students to clarify their subject doubts. This involves discussions, presentations on specified topics, assignments and evaluation.

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

Teacher: **45 Hours (3 Hrs/ week)**

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing..

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

		Hrs
UNIT-I	**UV Visible spectroscopy**: Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. **Applications**- Spectrophotometric titrations, Single component and multi component analysis. **Fluorimetry:** Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications.	**10**

UNIT-II	**IR spectroscopy:** Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations. Instrumentation- Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications. **Flame Photometry-** Principle, interferences, instrumentation and applications. **Atomic absorption spectroscopy**- Principle, interferences, instrumentation and applications. Nepheloturbidometry- Principle, instrumentation and applications	**10**

UNIT- III	**Introduction to chromatography:** **Adsorption and partition column chromatography**- Methodology, advantages, disadvantages and applications. **Thin layer chromatography**- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications. **Paper chromatography**- Introduction, methodology, development techniques, advantages, disadvantages and applications. **Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.	**10**
UNIT- IV	**Gas chromatography** - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications **High performance liquid chromatography (HPLC)-**Introduction, theory, instrumentation, advantages and applications.	**08**
UNIT- V	**Ion exchange chromatography**- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications **Gel chromatography**- Introduction, theory, instrumentation and applications **Affinity chromatography**- Introduction, theory, instrumentation and applications	**07**

Theory Sessional examination syllabus

Sessional No.	**Syllabus**
	Chapters no.
I	1, 2
II	3, 4
III	5

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

Teacher: **4 Hours/week**

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide bycolorimetry.
3. Simultaneous estimation of ibuprofen and Paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate byfluorimetry.
5. Study of quenchingof fluorescence.
6. Determination of sodium by flamephotometry.
7. Determination of potassium by flamephotometry.
8. Determination of chlorides and sulphates bynephelo-turbidimetry.
9. Separation of sugars by thin layerchromatography.
10. Separation of plant pigments bycolumn chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare Paracetamol transdermal patch and evaluate by UV spectroscopy.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP702T. INDUSTRIAL PHARMACYII (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

	Topic	Hrs
UNIT-I	**Pilot plant scale up techniques:** General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	**10**
UNIT-II	**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE /SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	**10**
UNIT-III	**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.	**10**

UNIT-IV	**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	**08**
UNIT-V	**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	**07**

Theory Sessional examination syllabus

Sessional examination No.	**Syllabus Chapters no.**
I	1, 2
II	3,4
III	5

Recommended Books: (Latest Editions)

- Regulatory Affairs from Wikipedia, the Free Encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory Affairs.
- International Regulatory Affairs Updates, 2005, available at http://www.iraup.com/about.php.
- Textbook of FDA Regulatory Affairs. A Guide for Prescription Drugs, Medical Devices, and Biologics' by Douglas J Pisano and David S. Mantus.
- Regulatory Affairs brought by Learning Plus, Inc., available at http.//www.cgmp.com/ra.htm.
- Intellectual Property Rights in Pharmaceutical Industry Theory and Practice by Bayya Subba Rao and Appaji.
- How to Practice GLP by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- Validation of Active Pharmaceuticals Ingredients by Ira R. Bony & Daniel Harpaz., CRC Press.
- Drugs and Pharmaceutical Sciences by Richard A. Guarina, 4th edition, Vol 139.

BP703T. PHARMACY PRACTICE (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of this course student shell able to:

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Course Content:

Topics		Hrs
UNIT-I	**Hospital and it's organization**: Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. **Hospital pharmacy and its organization:** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **Adverse drug reaction:** Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. **Community Pharmacy:** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.	**10**

UNIT-II	**Drug distribution system in a hospital**: Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling. Dispensing of drugs to ambulatory patients and dispensing of controlled drugs. **Hospital formulary:** Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary. **Therapeutic drug monitoring:** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.	**10**

	Medication adherence: Causes of medication non-adherence, pharmacist role in the medication adherence and monitoring of patient medication adherence. **Patient medication history interview**: Need for the patient medication history interview, medication interview forms. **Community pharmacy management:** Financial, materials, staff, and infrastructure requirements.	
UNIT-III	**Pharmacy and therapeutic committee**: Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. **Drug information services:** Drug and Poison information center, Sources of drug information, Computerized services, and storage and retrieval of information. **Patient counselling**: Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist **Education and training program in the hospital:** Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. **Prescribed medication order and communication skills:** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescriber and patients.	**10**
UNIT-IV	**Budget preparation and implementation:** Budget preparation and implementation. **Clinical Pharmacy:** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring- medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. **Over the counter (OTC) sales:** Introduction and sale of over the counter and rational use of common over the counter medications.	**08**
UNIT-V	**Drug store management and inventory control:** Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure. **Over the counter (OTC) sales:** Introduction and sale of over the counter and rational use of common over the counter medications. **Investigational use of drugs**: Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee. **Interpretation of Clinical Laboratory Tests:** Blood chemistry, haematology and urine analysis	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Unit
I	1, 2
II	3,4
III	5

Recommended Books (Latest Edition):

- A Textbook of Hospital Pharmacy by Merchant S.H. and Dr. J.S. Quadry, 4th ed. Ahmadabad: B.S. Shah Prakashan.
- A Textbook of Clinical Pharmacy Practice- Essential Concepts and Skills by Parthasarathi G., Karin Nyfort-Hansen, Milap C. Nahata, 1st ed. Chennai: Orient Longman Private Limited.
- Hospital Pharmacy by William E. Hassan, 5th ed. Philadelphia: Lea & Febiger; 1986.
- Hospital Pharmacy by Tipnis Bajaj, 1st ed. Maharashtra: Career Publications.
- Basic Skills in Interpreting Laboratory Data by Scott L.T., 4thed. American Society of Health System Pharmacists Inc.
- Health Education and Community Pharmacy by Parmar N.S. 18th ed. India: CBS Publishers & Distributers.

Journals:

- Therapeutic Drug Monitoring. ISSN: 0163-4356
- Journal of Pharmacy Practice. ISSN: 0974-8326
- American Journal of Health System Pharmacy. ISSN: 1535-2900 (Online)
- Pharmacy Times (Monthly Magazine)

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

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

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course Content:

Topics		Hrs
UNIT-I	**Controlled drug delivery systems:** Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations. **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.	**10**
UNIT-II	**Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications. **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion/ mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems. **Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump.	**10**
UNIT-III	**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches. **Gastro-retentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications. **Naso-pulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.	**10**

UNIT-IV	**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.	**08**
UNIT V	**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome– Preliminary study, ocular formulations and ocuserts. **Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications.	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Chapters no.
I	1, 2
II	3 ,4
III	5

Recommended Books (Latest Editions)

- Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker, Inc., New York, 1992.
- Encyclopaedia of Controlled Drug Delivery by Edith Mathiowitz, Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.
- Controlled and Novel Drug Delivery by N.K. Jain, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Controlled Drug Delivery-Concepts and Advances by S.P. Vyas and R.K. Khar, Vallabh Prakashan, New Delhi, First edition 2002.
- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (vol-121), Marcel Dekker, Inc., NY.
- Handbook of Pharmaceutical Controlled Release Technology by Donald L. Wise**,** Marcel & Dekker Inc., NY.
- Dermatological and Transdermal Formulations by Kenneth A. Walters**,** Mercell & Dekker Inc., NY.
- Drug Delivery System by Vasant V. Ranaday, Manffred A. Hollinger**,** CRC Press, NY.
- Design of Controlled Release Drug Delivery System by Xialing Li, Bhaskara R. Jasti**,** Mc-Graw Hill.

Journals

- Indian Journal of Pharmaceutical Sciences (IPA)
- Indian Drugs (IDMA)
- Journal of Controlled Release (Elsevier Sciences)
- Drug Development and Industrial Pharmacy (Marcel & Decker)
- International Journal of Pharmaceutics (Elsevier Sciences)

BP706PS. PRACTICE SCHOOL

150 Hours

Course content:

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. Every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages).

Domains (anyone to be opted):

- Phytomedicine
- Formulation development
- Quality control and quality assurance
- Drug design and process chemistry
- Pharmaceutical software
- Artificial intelligence
- 3D printing
- Nutraceuticals
- Cosmeceuticals
- Alternative medicine

Recommended Books (Latest Editions)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Sounders & Co., London.
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P. W., Business Horizons Publishers, New Delhi, India, 2002.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar, BSP Books.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- Introduction to the Principles of Drug Design by Smith H.J., Williams H, Wright Boston.
- Industrial Microbiology by Prescott and Dunn, 4th edition, CBS Publishers & Distributors, Delhi.
- Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak: ASM Press Washington, D.C.
- Harry's Cosmetology by Wilkinson, Moore, Seventh Edition.
- Poucher's Perfumes, Cosmetic and Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.

BP707P. HOSPITAL TRAINING-II

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports etc.

May be performed at the end of the 6th semester.

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment).
- Know the various statistical techniques to solve statistical problems.
- Appreciate statistical techniques in solving the problems**.**

Course content:

Topics		Hrs
UNIT-I	**Introduction:** Statistics, Biostatistics, Frequency distribution. **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems. **Correlation**: Definition, Karl Pearson's coefficient of correlation, multiple correlation- Pharmaceuticals examples.	**10**
UNIT-II	**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical examples. **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties– problems. Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples. **Parametric test**: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.	**10**

UNIT-III	**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal- Wallis test, Friedman Test. **Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, Plagiarism. **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	**10**
UNIT-IV	Blocking and confounding system for Two-level factorials. **Regression modeling:** Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, Design of experiment, R- Online Statistical Software's to Industrial and Clinical trial approach.	**8**
UNIT-IV	**Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3design. Advantages of factorial design. **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques.	**7**

Recommended Books (Latest edition):

- Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisherMarcel Dekker Inc. New York.
- Fundamental of Statistics – Himalaya Publishing House- S.C. Guptha.
- Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam.
- Design and Analysis of Experiments– Wiley Students Edition, Douglas and C.Montgomery.

BP802T. SOCIAL AND PREVENTIVE PHARMACY (Theory)

45 Hours

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 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:

Topics		Hrs
UNIT-I	**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.	**10**

UNIT-II	**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.	**10**
UNIT-III	**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.	**10**
UNIT-IV	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.	**8**
UNIT-IV	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.	**7**