S.N.D.T. WOMEN'S UNIVERSITY

MUMBAI

M. PHARM. SYLLABUS

SPECIALIZATION: HERBAL DRUG TECHNOLOGY

FOUR SEMESTER PROGRAMME

Effective from Academic Year 2013-14

The M. Pharm. (Herbal Drug Technology) course, a very unique one has been proposed to introduce in Maharashtra for the FIRST TIME at C.U. Shah College of Pharmacy, by SNDT Women's University after due sanction from the DTE, Govt. of Maharashtra and AICTE. The course is devised with a focus on the aptitude, talents and job potential for women in herbal drug industry and research and development institutes.

This four semester programme has the following specific features.

1) Emphasis on modern analytical techniques like UV, spectroflurometry, infrared spectrophotometry, NMR, Spectrometry HPLC, X-ray diffraction analysis and spectral analysis.

2) Thrust on good manufacturing practices, quality audits, documentation and validation with a view to create total quality consciousness in herbal drug industry

3) Herbal product development and Packaging courses designed to teach current trends in formulation of herbal pharmaceuticals and newer herbal drug delivery systems.

4) Understanding of Regulatory affairs, New Drug Application and Patenting procedures for herbal products.

5) Students work on a research project for two semesters and submit a dissertation at the end of fourth semester for which they are evaluated by subject experts.

6) One month in plant training in industry to correlate theory with professional practice.

7) Guest lectures and seminars are routinely arranged where visiting faculty impart insights in state-of-art technology and current advances in herbal drug development.

ADMISSION CRITERIA:

Only Female candidates shall be admitted as per rules of Directorate of Technical Education, Maharashtra: (a) Non Sponsored Seats (b) Sponsored Seats (c) Seats for reserved Category candidates. Admission will be given on purely merit basis to candidates with valid GPAT/CET score. Any additional rules prescribed by the AICTE or SNDT Women's University will be applicable.

SCHEME: M.Pharm (Herbal Drug Technology)

Sem	Subject Code	Subject	Hours/ Week TH	Hours/ Week PR	Credits TH	Credits PR	Marks TH	Marks PR
First	S1-HDT-1	Modern Analytical Techniques I	4	8	4	4	100	100
	S1- HDT -2	Advanced Pharmacognosy and Phytochemistry I	4	-	4	-	100	100
	S1- HDT -3	TQM,Patent Regualtion & Validation	4	8	4	4	100	-
	S1- HDT -4	Herbal Product Development I	4	-	4	-	100	-
		Total	**16**	**16**	**16**	**8**	**400**	**200**
Second	S2- HDT -1	Modern Analytical Techniques II	4	8	4	4	100	100
	S2- HDT -2	Advanced Pharmacognosy and Phytochemistry-II	4	-	4	-	100	100
	S2- HDT -3	Herbal Product Development II	4	-	4	-	100	-
	S2- HDT -4	Ayurveda & Allied Plant based therapies	4	8	4	4	100	-
		Total	**16**	**16**	**16**	**8**	**400**	**200**
Third	S3 – HDT -1	Industrial Training	**One Month**		**2**		**50**	
	S3- HDT -2	Biological Evaluation	4	4	4	-	100	-
	S3- HDT -3	Computing & Statistics	4	4	4	-	100	-
	S3- HDT -4	Research Methodology	4	-	4	-	100	-

	S3- HDT -5	Research Seminar	2	-	**2**	**-**	**50**	-
	S3- HDT -6	Research Project	-	8	8	-	200	-
		Total	**14**	**16**	**24**	**-**	**600**	-
Four th	S4 - HDT -1	Research Project	**32**	**-**	12	**-**	300	-
		Research Colloquiam	-	-	4	-	100	-
		& Viva	-	-	8	-	200	-
		Total		**-**	**24**	**-**	**600**	**-**
		Grand Total	78	48	**80**	**16**	**2000**	**400**

Examination Pattern for M. Pharm. in Herbal Drug Technology

Semester I

SR. NO	**SUBJECT**	**Exam Dur.**	**Theory**				**Exam Dur.**	**Practicals**			
			Int.	**Ext.**	**Total**	**Credits**		**Int**	**Ext.**	**Total**	**Credits**
1	Modern Analytical Techniques I	2	50	50	100	4	6	50	50	100	4
2	Advanced Pharmacognosy and Phytochemistry I	2	50	50	100	4	6	50	50	100	4
3	TQM,Patent Regualtion & Validation	2	50	50	100	4	-	-	-	-	-
4	Herbal Product Development I	2	50	50	100	4	-	-	-	-	-

Semester I : Total credits = 24

Semester- II

SR. NO	SUBJECT	Exam. Dur.	Theory				Exam. Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
1	Modern Analytical Techniques-II	2	50	50	100	4	6	50	50	100	4
2	Advanced Pharmacognosy and Phytochemistry-II	2	50	50	100	4	6	50	50	100	4
3	Herbal Product Development II	2	50	50	100	4	-	-	-	-	-
4	Ayurveda & Allied Plant based therapies	2	50	50	100	4	-	-	-	-	-

Semester II : Total credits = 24

Semester III

SR. NO	SUBJECT	Exam Dur.	Theory				Exam Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int	Ext.	Total	Credits
1	Biological Evaluation	2	50	50	100	4					
2	Computing & Statistics	2	50	50	100	4					
3	Research Methodology	2	50	50	100	4	6	-	-	-	-
4	Research Seminar	1	25	25	50	2	1	-	-	-	-
5	Research Project	-	-	-	-	-	-	-	-	200	8
6	Industrial Training				50	2					

Semester III: Total credits = 24

Semester IV

SR. NO	SUBJECT	Exam Dur.	Theory				Exam Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int	Ext.	Total	Credits
1	Research Project (Thesis)		200	200	400	12	-	-	-	-	-
2	Colloquia		100		100	4		-	-	-	-
3	Viva	-		100	100	8		-	-	-	-
	Total		300	300	600	24					

Semester IV: Total credits = 24

Semester I+ II + III + IV = 96 Credits Course

Internal Assessment

Internal Assessment will be carried out in two Steps:

(a) Formative Assessment that envisages deployment of variety of tools and technique for diagnostic and remedial assessment of students

- **Pen-paper Assessment** in the form of question bank for class tests, home assignments, oral tests, quizzes, and MCQs
- **Practical Assessmen**t with viva questions based on various skills involved in doing Experiments
- **Individual/Group Assessment** in the form of activities with questioning tool kit, role plays, seminars, symposium, presentations, group discussions, projects, surveys, interviews, campaigns, site visits, data handling and data interpretation

(b) Summative Assessment that provides a large number of question types such as,

- VAS (very short answer)
- SA(short answer)
- LA (long answers)
- MCQs(multiple choice questions)
- HOTS(higher order thinking skill) questions

SR. NO.	HEAD	MARKS
1	Assignments	15
2	Presentation	10
3	Unit Test	25
	TOTAL	50

SEMESTER III & IV

Project and Thesis work

Every student for the degree of Master of Pharmacy shall be required to undertake a project involving methodical research under the supervision of an approved guide and submit three copies of the thesis, duly certified by the supervisor to the Head of the Department/Principal.

SEMESTER III

Research Project and Industrial training

The student should complete industrial training for one month during the course work.

The research project will be evaluated as follows:

Research Project	**Marks**
Reference work	100
Experimental work	100
Total marks	**200**

Research seminar	**Marks**
Total marks	50

Industrial Training	**Marks**
Total marks	50

SEMESTER IV

Research Project and Thesis work

The research project will be evaluated as follows:

Internal Assessment

Head	**Marks**
Experimental work	**75**
Presentation/ communication	**50**
Result/ conclusion	**75**
Research Colloquium	**100**
Total marks	**300**

External Assessment

Head	**Marks**
Viva voce and external assessment	**300**

Semester I

M. Pharm (Herbal Drug Technology)

SEMESTER I

1. **Analytical Techniques-I (Theory & Practical)**
2. **Advanced Pharmacognosy and Phytochemistry-I – (Theory & Practical)**
3. **TQM and Patent Regulation and Validation Theory**
4. **Herbal Product Development-I Theory**

SEMESTER II

1. **Analytical Techniques-II (Theory & Practical)**
2. **Advanced Pharmacognosy and Phytochemistry-II (Theory & Practical)**
3. **Herbal Product Development-II Theory**
4. **Ayurveda and Applied plant based therapies**

SEMESTER III

1. **Biological Evaluation (Theory & Practical)**
2. **Computing & Statistics**
3. **Research Methodology**

SEMESTER I

M.Pharm. S1-HDT-1: Analytical Techniques I (Theory)

Module 1	UV & IR Spectrometry & Spectrofluorimetry	1 credit
Objectives	• To make students familiar with the principles of quantitative estimation using UV-visible spectrometry • To enable students to use spectrometers with proper understanding • To make students competent for the basic quality control requirements or needs of industries • To make students familiar with the principles of selective quantitative estimation using instrumental methods • To enable students to use spectrofluorometer with proper understanding • To make students familiar with the principles of absorption and emission spectrometry • To enable students to use atomic absorption spectrometer with proper understanding and make them competent for quality control activities of industry • To enable students to use IR spectrometers with proper understanding	
Contents	**Topics covered**	hrs
	• **Ultraviolet-Visible Spectrometry** General Principles of Spectrometry: Instrumentation, single and double beam UV spectrometers, Applications of UV spectroscopy, Fisher Woodward rules for calculation of λmax values. Introduction to Optical rotatory Dispersion and Circular Dichroism. Principle and applications of Derivative UV Spectroscopy • **Spectrofluorimetry** Principle, definition and types of luminescence, Resonance fluorescence and	(5)

	Mechanism of fluorescence and phosphorescence, singlet and triplet states, fluorescence, factors affecting fluorescence, intrinsic structure of a molecule and fluorescence, instrumentation and applications. • **IR Spectrometry** Principle, types of vibrations, Instrumentation Michelson interferometer applications, various regions in IR spectrum and their use for characterization of functional groups. Interpretation of IR spectrum	(3) (5)

Module 2	**Atomic Absorption And Emission Spectrometry, X-Ray Diffraction Thermal Methods of Analysis & Electrophoresis**	**1 credit**
Contents	**Topics covered**	Hrs
	• **Atomic Absorption And Emission Spectrometry** Principle, Sample atomization techniques & Applications • **X-Ray Diffraction Analysis** Principle, Bragg's Law, instrumentation, sources of X-rays, Applications • **Thermal Methods of Analysis** Thermogravimetry (TG), Differential thermal Analysis (DTA),Differential Scanning Calorimeter (DSC) - Principles, technique, instrumentation and applications including interpretation of data • **Electrophoresis** Theory and principles, Zeta potential, classification, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF), Immuno-electrophoresis and applications of electrophoresis	(3) (3) (5) (3)

Module 3		**1 credit**
Contents	**Topics covered**	Hrs
	• Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc • Microscopy: SEM, TEM, cryomicroscopy, AFM, confocal microscopy	(6) (5)

	• **Determination of Water** Importance of determination of water or moisture content. Various methods used for determination of water and moisture content	(2)

Module 4	**Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**

Assigned Reading/ References	1. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical chemistry, Part 1 & 2, Athlone Press, London. 2. Pharmacopoeia of India,6th Edition, Govt. of India, Ministry of Health & welfare, 2010. 3. British Pharmacopoeia, General Medicine Commision, UK., 2011. 4. United State Pharmacopeia, 34th Edition, Convention, Inc., Rockville, MD 20852, 2011. 5. Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, Prentice Hall, 2000 6. Robert M. Silverstein, Francis X. Webster, David J. Kiemle, 2009. "Spectrometric identification of organic compounds". 7th Ed. John Wiley & Sons 7. Pavia D. L., 2009. "Introduction to spectroscopy". 4th, Belmont CA 8. Munson & Munson, "Pharmaceutical analysis: modern methods". edited by James W. Munson, New York : M. Dekker 9. Kenneth A. Connors, 2007. "A Textbook Of Pharmaceutical Analysis" 3rd Ed. Wiley India-wse 10. Jens Thuro Carstensen, 2001. "Advanced pharmaceutical solids" Marcel Dekker, New York 11. Joseph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham Cooks, 2010. 12. "Organic structural spectroscopy", 2nd Ed. Pearson Education, Limited.	

	13. Principles of Instrumental Analysis: Douglas A. Skoog (Author), F. James Holler, Stanley R. Crouch, 6th edition, Publisher: Brooks Cole. 2006. 14. Instrumental Methods of Analysis: S. S. Mahajan, , Popular Prakashan Pvt. Ltd., Mumbai, 2010. 15. Quantitative Analysis of Drugs in Pharmaceutical Formulations: P.D. Sethi, 3rd edition, CBS Delhi. 2008. 16. Published articles pertaining to the learnt techniques in reputed journals like Analytical Chemistry, Analytical Communications, The Analyst, Indian Drugs, etc.	

Analytical Techniques I –Practical

Module 1	**UV –Visible spectrometry**	**1 credit**
Contents	**Experiments**	(30)
	1 Calibration of UV –Visible spectrophotometer for absorption and wavelength	(4)
	2 Determination of λmax of a compound by Fisher Woodward Rule	(4)
	3 Determination of molecular absorptivity or $E_{1cm}^{1\%}$ of a substance	(4)
	4 Determination of range of linearity in accordance with Beer- Lambert Law	(6)
	5 Analysis of a single component system from crude drugs and herbal formulations.	(6)
	6 Analysis of a binary mixture by simultaneous equation method and absorption ratio method.	(4)
	7 Interpretation of ORD and CD spectrum.	(2)

Module 2	**Spectrofluorimetry, DSC and electrophoresis**	**1credit**
Contents	**Experiments**	Hrs
	8 Plotting of absorption spectrum	(4)
	9 Plotting of emission spectrum	(4)
	10 Plotting of a standard curve for quinine sulphate	(4)

	11 Analysis of fluorescent compounds such as scopoletin, pigments	(6)
	12 Analysis of proteins using electrophoresis	(4)
	13 Determination of melting point & heat of fusion using DSC.	(4)
	14 Determination of glass transition temperature using DSC	(4)

Module 3	**IR Spectrometry**	**1 credit**
Contents	**Experiments**	Hrs
	17. Calibration of IR spectrometer with polystyrene film	(6)
	18. IR spectrum of a neat liquid	(6)
	19. Preparation of KBr pellet for any one solid sample	(6)
	20. Preparation of a 'mull' for phytoconstituents with different functional groups such as amine, nitro, aldehyde, keto, carboxylic, hydroxyl, etc.	(10)
	21. To identify impurity in the sample	(2)

Assigned Reading/ References	1. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical chemistry, Part 1 & 2, The Athlone Press, London, 2011. 2. Vogel's Textbook of Quantitative Chemical Analysis, 6^{th} Edition, Prentice Hall, 2000 3. Spectroscopic identification of organic compounds. John Dyer, Willy, NY. 4. Spectrometric Identification of Organic Compounds: R. M. Silverstein, Francis X. Webster and David Kiemle, 7th edition, 2005, Wiley Publication, NY. 5. Instrumental Methods of Analysis: S. S. Mahajan, 2010, Popular Prakashan Pvt. Ltd., Mumbai.	

M.Pharm. S1-HDT-2: Advanced Pharmacognosy and Phytochemistry-I (Theory)

Module 1	**Introduction to Pharmacognosy and WHO guidelines**	**1 credit**
Contents	**Topics covered**	Hrs
	• **Adulteration** and methods to encounter adulteration of plant drugs. Evaluation of plant drugs. Organoleptic evaluation of drugs including gross morphology, sampling, preliminary examination and foreign matter.	(2)
	• **Physical evaluation of plant drugs**: Determination of moisture content, foreign organic matter, ash values, extractive values and swelling index. Refractive index, optical rotation and their applications in standardization of plant drugs.	(2)
	• **Microscopic evaluation of plant drugs**: T.S./L.S./Surface views of selected Plant drugs - Use of microtome and preparation of histological slides, Quantitative microscopy, vein islet number, vein termination number, stomatal number, stomatal index, palisade ratio. Micrometry, measurement of fibers, trichomes, starch grains and calcium oxalate crystals. Lycopodium spore analysis. Fluorescence analysis	(4)
	• **Pharmacopoeial evaluation of plant drugs** – Determination of various diagnostic features of identification of different plant drugs as per different herbal pharmacopoeias.	(3)
	• WHO Guidelines for cultivation, collection and quality control of Herbal Drugs	(2)

Module 2	**Cultivation and Extraction of Plant drugs**	**1credit**
Contents	**Topics covered**	Hrs

	• Selection, identification and authentication of herbal materials, drying and processing of herbal raw material	(2)
	• Cultivation technology, post harvest care and processing of medicinal and aromatic plants: Profile of some high trade value plants: Chirata, Giloe, Gudmar, Isapgol, Jatamansi, Kalmegh, Kesar, Mulethi, Sarpagandha and Tulsi, Ashwagandha, Belladona, Ginger, Turmeric, Aloes, Digitalis, Vinca, Ephedra, Senna, etc	(5)
	• Extraction of Herbal Materials, Different methods of extraction- conventional (soxhlet, reflux, decoction, percolation, infusion), and novel/green methods (microwave assisted, ultrasonic assisted, supercritical fluid extraction, pressurized extraction), Choice of solvents for extraction	(5)
	• Safety of herbals/ herbal pharmacovigilance	(1)
	• Herbs as raw materials: Definition of herb, source of herbs, herbal medicine, herbal medicinal product, herbal drug preparation	(2)

Module 3	**Isolation of phytoconstituents**	**1 credit**
Contents	**Topics covered**	Hrs
	• General methods of isolation and separation of phytoconstituents.	(3)
	• **Isolation of Phytoconstituents:** chemical properties, characterization (excluding synthesis) and therapeutic uses of some medicinally important class of Plant Phenolics (Tannins & flavonoids), Alkaloids (Quinine,, Atropine, Solasodine Vincristine, Vinblastine, Strychnine), Glycosides (Sennoside, Digoxin, Diosgenin,), Terpenoides, Steroids and Resinous substances (Podophyllotoxin), Fixed oils, Volatile oils, Carbohydrates, taxol.	(6)
	• Herbal Remedies - Toxicity & Regulations: Importance of Herbal Therapies, Herbal versus Conventional drugs, Efficacy of herbal therapies, safety in herbal drugs, toxicity in Herbals and their interaction, Herbal drug regulations in India	(2)

	• Edible dyes sweeteners, perfumery and cosmetic agents from plants • Enzymes from plant origin. • Marine plants: Introduction, chemistry and biology of marine natural products of plant origin	(1) (1) (1)

Module 4	**Nutraceuticals & Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**
	• Nutraceuticals and herbal health supplements	(4)

Assigned Reading/ References	1. W.C. Evans, 2002. "Trease& Evan's Pharmacognosy". WB.Saunders& co., London. 2. T. Swain, 1963. "Chemical plant Taxonomy". Academic Press, London. 3. C.A Stace, 1985. "Plant Taxonomy and Biosystematics". Edward Arnold, London. 4. C.K. Atal, "Cultivation and Utilization of Medicinal plants". R.R.L. Jammu 5. H.E. Street, 1997. "Plant Cell and Tissue Culture". Blackwell Scientific, London. 6. N. Takashashi, 1986. "Chemistry of Plant Hormones" CRC Press Inc., Florida. 7. A.R. Gennaro, 2000."Remington: The Science & Practice of Pharmacy". Lippincott Williams & Wilkins, Philadelphia. 8. Kaufmann, "Natural products for plants". CRC press New York. 9. K. Nakanishi, 1977. "Chemistry of Natural Products". Kodansha Book Publishing Company, Osaka (Japan). 10. V. Rajpal, 2002. "Standardization of Botanicals", Eastern Publishers,	

New Delhi.
11. J.B. Harborne, 1998. “Phytochemical methods”, Chapman and Hall.
12. K. Paech, 1956. “Modern methods of plant analysis”., Springer-Verlag
13. Guidelines for the Assessment of herbal medicines, 1991,WHO Report, Geneva.
14. Quality Control Methods for Medicinal Plant material, 1992, WHO Guidelines.
15. Indian Pharmacopoeia, 1996, Govt. of India, Ministry of Health and family welfare, Delhi.
16. A.N. Kalia, Textbook of Industrial Pharmacognosy, 2005, CBS Publishers, New Delhi.
17. Dr.C.K. Kokate, Practical Pharmacognosy, 1988, Vallabh Prakashan, Delhi.
18. Dr.P.Mukherjee, Quality control herbal drugs, 2005, Business Horizons,

M.Pharm. S1-HDT-2: Advanced Pharmacognosy and Phytochemistry-I Practical

		1 credit
Contents	**Experiments**	Hrs
	1. Microscopical evaluation of plant drugs (at least five) listed in theory- Vein islet number, vein termination number, stomatal index, stomatal number, palisade ratio, trichomes, starch grains, calcium oxalate crystals) 2. Determination of moisture content, foreign organic matter, ash values, extractive values, swelling index of plant drug. 3. Extraction by different methods - Conventional (Soxhlet, Maceration, Reflux, Percolation, Stirring etc.) & Novel (Microwave Assisted, Ultrasonic method, Supercritical fluid extraction etc) 4. Physico-chemical, phytochemical evaluation of some plant drugs containing alkaloids, terpenoids, glycosides phenolics, steroids. 5. Estimation of total solid content and alcohol content in Asava/Arista 6. Pharmacopoeial evaluation of natural products 7. Determination of vitamin C in some crude drugs	

Assigned Reading/ References	1. W.C. Evans, Trease and Evans Pharmacognosy, 15th edition2002, W.B. Sounders & Co., London. 2. S.S. Handa and M.L. Kaul, Supplement to cultivation and utilization of medicinal plants, 1996, R.R.L Jammu, India. 3. Ram P Rastogi, Compendium of Indian Medicinal Plants, 1998, Vol. I-V, CSIR, Lucknow , New Delhi. 4. T. Fleming, PDR for Herbal Medicine, 2nd edition, 2000, Medical Economics compant, Mountvale, New Jersy. 5. M.J. Cupp, Toxicology and Clinical Pharmacology of Herbal Products, 2000, Humana Press, New Jersy. 6. Wealth of India- Raw Materials, 1985, CSIR Publication, New Delhi. 7. Dr.P.Mukherjee, Quality control herbal drugs, 2005, Business Horizons, New Delhi. 8. V.D.Rangari, Pharmacognosy & Phytochemistry,1st edn.2004,Career Publications, Nasik.	

M.Pharm. S1-HDT-3: TQM, Patent Regulation and Validation (Theory)

Module 1	**I. To understand basic principles of total quality management and quality audits**	**1 credit**
Contents	**Topics Covered**	Hrs
	• Concept of Total Quality Management, Four M's responsible for Quality variation in pharmaceutical products.	(3)
	• Concepts of GMP, GLP and GCP, Quality control laboratory responsibilities, routine controls on instruments and reagents. Standard test procedures, non-clinical testing, controls on animal house, Data generation and storage.	(3)
	• Documentation and its importance, Manufacturing documents, Standard Operating Procedures, Finished product release documentation.	(2)
	• **Quality Audits**: Auditing of manufacturing processes and facilities, Quality Review, Compliance reports and handling of Non –compliance.	(2)
	• **ICH guidelines**: Q1-Q10, Guidelines with special reference to quality by design and risk management.	(3)
	• Sampling plans and methods. Statistical analysis of data generated.	(2)

Module 2	**II. To understand validation of processes and equipment**	**1 credit**
Contents	**Topics Covered**	hrs
	• Qualification, validation and calibration of **equipment**.	(2)
	• **Validation of processes** like mixing, granulation, drying, compression, filtration, filling, etc.	(3)
	• **Validation of sterilization** methods and equipment, dry heat sterilization, autoclaving, membrane filtration.	(3)
	• Validation of manufacturing processes, Equipment, Environment and Water supply systems and analytical methods.	(2)
	• Validation and audits of analytical procedures such as HPLC, UV, GC, HPTLC.	(3)
	• Validation of personnel handling the analytical instruments	(2)

Module 3	III. Regulatory aspects of herbal pharmaceuticals and IPR	1 credit
Contents	**Topics Covered**	hrs
	• Regulatory aspects of herbal pharmaceuticals in India, US, Europe and other countries, US-FDA and WHO Approval, Clinical trial approval, dossier preparation for herbals.	(6)
	• Intellectual Property Rights, Patent search and awareness, Patent applications and filling procedures in India and in other countries	(4)
	• **International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO.	(3)
	• Patent infringement, exploitation of patent, abuse of patent	(2)
Module 4	**To study safety procedures and health hazards & Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**
	• To learn safety procedures of pharmaceutical and herbal industries**.**	(2)
	• Occupational health hazards, fire hazards, safety procedures, Safety exercises and waste disposal and security in plant.	(1)

Assigned Reading/ References	1. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, Inc., New York 2. S. Weinberg, Ed. Marcel Dekker, Good Laboratory Practice Regulations.4th Edition , New York, 2007 3. Andrew A . Signore and Terry Jacobs Good Design Practices for GMP Pharmaceutical Facilities Informa Healthcare 2005 4. ICH Guidelines available at: http://www.ich.org 5. Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes ", 1st edition, New York, Marcel Dekker. 6. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol. 57.New York: Marcel Dekker (993. 7. Malik, V, Drugs and Cosmetics Act, 1940, Eastern Book Co.	

8. S. H. Willig, M.M.Tuckerman and W.S.Hitchings, “Good Manufacturing Practices for Pharmaceuticals”, Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
9. SIGAR. Pharmacovigilance Education and Certification—Report on a Feasibility Survey. Pharmacoepia & Drug Safety. 1995.
10. Talbot JCC. Drug safety—a shared responsibility. Edinburgh: Churchill Livingstone;. Spontaneous reporting,1991
11. Report of CIOMS (Council for International Organisations of Medical Sciences) Working Group III, Guidelines for Preparing Core Clinical-Safety Information on Drugs, Geneva. 1995
12. Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies by Anurag Singh Rathod, Gail Sofer, G.K. Sofer. Informa Healthcare Publisher 2005.
13. Remington’s the science and practice of pharmacy 21st Edition by Alfonso R. Gennaro. Lippincott Williams & Wilkins Publisher 2006.
14. Pharmaceutical Process Validation by Robert A. Nash, Alfred H. Wachter Marcel Dekker Publisher 3rd edition 2003.
15. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
16. CDER Publications and Guidance
17. EMEA Publications and Guidance
18. Orange Book, ICH guidelines, Indian Patents Act
19. Country specific Regulatory Guidelines (available from internet)
20. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
21. J. D. Nally, “Good manufacturing Practice for Pharmaceuticals” Informa Healthcare.
22. I. Kanfer& L. Shargel, “Generic Product Development BE issued” Informa Healthcare.
23. R. A. Guarino, “New Drug Approval Process. The Global challenges”. Informa Healthcare.
24. Watcher and Nash, “Pharmaceutical Process Validation”. Marcel Dekker.

M.Pharm. S1-HDT-4: Herbal Product Development-I Theory

Module 1	**I. Preformulation, Chemical Kinetics and Herbal Drug Stability**	**Instr. hrs**
Contents	**Topics Covered**	Hrs
	• **Preformulation Studies with respect to herbal pharmaceuticals**: pka and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristics, dissolution, solublization techniques, drug –excipients compatibility studies, protocol for performulation studies..	(6)
	• **Chemical Kinetics & Herbal Drug stability:** Pathways of drug degradation, Rate & order of reactions, Factors affecting reaction kinetics, stability testing, Accelerated studies and shelf life assignment as per ICH guidelines.	(4)
	• **Dosage form consideration in preformulation**: Solid dosage form, solution formulations, emulsion, suspension, freeze dried products, topical, pulmonary, evaluations and its regulatory considerations, antioxidants, chelating agents, impurity, GMP related to drugs from herbal origin.	(4)

Module 2	**II. Principles and Techniques of Solid Dosage Forms and Coating Technology & Study of Pharmaceutical polymers**	**1 credit**
Contents	**Topics Covered**	Hrs
	• **Solid dosage forms**: Recent advances in tablet and capsule technology like double compression, direct compression, capsule filling machine, Excipients (binding agents, super disintegrants, lubricants and diluents) from herbal origin	(4)
	• **Coating of solid dosage forms**:	

	Various types of functional coatings, polymers, Advances in process controls, coating equipments, coating pans, Accela cota, Hi-coater, Driacoater, fluid bed coating equipments, Coating application and metering equipment, particle coating methods, pelletization. Technology. • **Topical drug delivery systems:** Various types of topical drug delivery systems such as creams, gels, nanogels, nanoemulsions, ointments and their evaluation. • **Pharmaceutical polymers:** Biodegradable & non biodegradable polymers block copolymers, stimuli sensitive polymers, mucoadhesive polymers	(2) (2) (2)

Module 3	**III) Drug Dissolution and Diffusion Studies & Study of Pharmacokinetic modeling**	**1 credit**
Contents	**Topics Covered**	Hrs
	• **Dissolution Studies:** Steady state diffusion-procedure and applications, drug dissolution, drug release, diffusion principles in biological systems, thermodynamics of diffusion, Fick's law. Devices for dissolution rate testing viz., forced convection, non-sink devices, and continuous flow through methods; effect of environmental factors in dissolution testing; test apparatus for various drug delivery systems. • **Pharmacokinetics:** Compartmental & Non compartmental analysis, Pharmacokinetic modeling approaches, Biopharmaceutical classification of drugs, absorption, permeability and solubility limited drugs, Biowavers for bioequivalence studies, Concepts of *in vitro & in-vivo* Correlation, One and Two Compartmental Modeling, Statistical Moment Analysis, Non-linear kinetics. • Characterization of biopharmaceutical drugs and phytomedicnes	(3) (6) (3)

Module 4	Project and Seminar Presentation on some recent research /seminars based on the above topics	1 credit

Assigned Reading/ References	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" , Volume 110, Marcel Dekker New York, 2001, CRC 2. Ray and Weller, "Handbook of Pharmaceutical Excipients", Pharmaceutical Press, 2009. 3. Lachman, Lieberman, "Pharmaceutical dosage forms: Dispersed systems", Vol. I, II, Marcel-Dekker New York, 2008. 4. Lisbeth, Illum & Stanley S. Davis, "Polymers in Controlled Drug Delivery", Wright, Bristol, 1987. 5. ICH Guidelines available at: http://www.ich.org 6. Rawlins, E. A., "Bentley's text book of Pharmaceutics" 8th edition, London: Bailliere Tindal.1995. 7. Rubinstein, M. H. M. E. Aulton,"Pharmaceutics: the science of dosage form design", 3rd edition, pp. 304-321, London: ELBS Longman Group Ltd.,1988 8. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy" Philadelphia: Lippincott Williams & Wilkins.2006. 9. Saha, S., & Shahiwala, A. F., "Multifunctional coprocessed excipients for improved tabletting performance" . Expert Opinion on Drug Delivery ,pp 197-208, 2009. 10. David K Platt, Biodegradable Polymers, iSmithers Rapra Publishing, 2006. 11. Catia Bastioli, Handbook of biodegradable polymers, iSmithers Rapra 12. Shaikh R., Sial A., "Stability of pharmaceutical formulations", Pak. J. Pharm. Sci., 2nd edition, pp 83-86 1996,. 13. ICH Q1A (R2), "Stability testing of new drug substances and products", International Conference on Harmonisation, IFPMA, Geneva, 1996 Milo Gibaldi and Donald Perrier, "Pharmacokinetics", Drugs and Pharm. Sci. Series, Vol. 15, Marcel Dekker Inc., N.Y.	

	14. Shargel L, Susanna Wu-Pong, Andrew B. C. Yu. "Applied Biopharmaceutics and pharmacokinetics", 3rd edition, McGraw-Hill, Medical Pub. Division, 2005 15. Malcolm Rowland, Thomas N. Tozer., "Clinical Pharmacokinetics: Concept and Application"; 3rd Edn. B. I. Lea & Febiger, 1989. 16. Shargel, "Generic Drug Product Development Specialty Dosage Form", 1st Edition, 2010.	

Semester II

SEMESTER II

M.Pharm. S2-HDT-1: Analytical Techniques-II (Theory)

Module 1	**Principles and Techniques of planar chromatography**	**1 credit**
Contents	**Topics covered**	Hrs
	General principles, theory and the applications of planar chromatographic techniques • Techniques and instrumentation of thin layer chromatography (TLC) • Techniques and instrumentation of Paper chromatography (PC) • Techniques and instrumentation of High performance thin layer chromatography (HPTLC) Analytical method development and its validation as per ICH guidelines. Quantification using HPTLC. • Applications of TLC, PC, HPTLC for analysis of herbals. • Comparison of planar chromatography and column chromatography	 (4) (2) (5) (2) (1)

Module 2	**Principles and techniques of column chromatography**	**1 credit**
Contents	**Topics covered**	Hrs
	General principles, theory and the application of column chromatographic techniques: • Principle and techniques of conventional column chromatography • Techniques, instrumentation and Applications of High performance liquid chromatography (HPLC) – Theory of HPLC-Van Deemter Equation, various detectors used, derivatisation in HPLC. Analytical method development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Ultra pressure liquid chromatography. • Techniques, instrumentation and Applications of Gas chromatography (GC)-Theory of GC, packed column, Capillary column, carrier gases used.	 (1) (6) (5)

	• Techniques, instrumentation and Applications of Supercritical Fluid Extraction • Techniques, instrumentation and Applications of Flash Chromatography • Techniques, instrumentation and Applications of Size exclusion chromatography and ion pair chromatography	(1) (1) (2)

Module 3	**Structure elucidation of organic compounds- Theory and Problem solving**	**1 credit**
Contents	**Topics covered**	Hrs
	General principles, theory and the application of techniques for structure elucidation of organic compounds • Theory, principle, instrumentation of Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API, ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications for pharmaceuticals and herbals, different types of Mass spectrometry • High Resolution 1H &13C Nuclear magnetic resonance (NMR) Spectrometry Theoretical calculation of chemical shifts of various carbon atoms..Theory, principle of NMR spectroscopy, instrumentation, Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR, INADEQUATE, HSBC, HMQC etc. Use of this technique in determination of absolute configuration.	(7) (7)

Module 4	**Problem solving in structure elucidation & Project and Seminar Presentation on recent research /seminars based on above topics**	**1 credit**
	• Problem solving in structure elucidation of phytosterols, flavonoids and terpenoids. organic compounds using UV, IR, NMR, 1HNMR, 13CNMR and Mass spectroscopy	(7)

Assigned Reading/ References	1. E. Stahl, Thin-Layer Chromatography, A Laboratory Handbook. 2nd Edition Springer-Verlag Berlin–Heidelberg–New York 1969. 2. Wagner & S. Bladt, Plant Drug Analysis by H., 2nd Edition, Springer 2001. 3. Jiri Gasparic and Jaroslav Churacek, A Laboratory Handbook of paper and thin layer chromatography, Ellis Horwood limited 1979. 4. P.D. Sethi, HPTLC Quantitative Analysis of Pharmaceutical Formulations. CBS Publishers and. Distributors, New Delhi, 1996. 5. F. James Holler, Stanley R. Crouch Douglas A. Skoog. Principles of Instrumental Analysis, , Publisher: Brooks/Cole Pub Co; 6th edition, 2006 6. Analytical Chemistry by open learning series, Wiley Publisher, 2nd Edition 7. David G. Watson Pharmaceutical analysis: a textbook for pharmacy students and pharmaceutical chemists Elsevier/Churchill Livingstone, 2005 8. Bernard Fried, Joseph Sherma, Thin-layer chromatography 4th Edition Marcel Dekker 2005 9. Instrumental methods of Analysis by Higuchi, CBS Publishers. 1997 10. High Performance Liquid Chromatography: Analytical Chemistry by open learning series, Wiley Publisher, 2nd Edition 1992. 11. W. John Lough, High performance liquid chromatography: fundamental principles and practice Blackie Academic & Professional Publisher, 1995 12. HPLC: High Performance Liquid Chromatography: Volume 2, by P.D. Sethi and Rajat Sethi CBS Publisher, 2008 13. F. James Holler, Stanley R. Crouch Douglas A. Skoog. Principles of Instrumental Analysis, , Publisher: Brooks/Cole Pub Co; 6th edition, 2006 14. Frank A. Settle , Brian D. Lamp , David L. McCurdy, Mark F, Vitha , Brian W. Gregory, Yinfa Ma Instrumental Methods of Analysis Wiley-Interscience; 8th edition, 2011 15. R.M. Silverstein, G.C., Bassler, T.C. Morrill Spectroscopic identification of organic compounds John Wiley and Sons, New York, 5th Edition. 1991. 16. William. Kemp Organic Spectroscopy 3 edition . W.H. Freeman & Company; 1991	

17. J.R. Dyer, Applications of absorption Spectroscopy of Organic compounds Prentice Hall,London 2009
18. Pavia D. L., 2009. “Introduction to spectroscopy”. 4th, Belmont CA
19. Munson & Munson, “Pharmaceutical analysis: modern methods”. edited by James W. Munson, New York : M. Dekker
20. Kenneth A. Connors, 2007. “A Textbook Of Pharmaceutical Analysis” 3rd Ed. Wiley India-wse
21. Jens Thuro Carstensen, 2001. “Advanced pharmaceutical solids” Marcel Dekker, New York
22. Joseph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham Cooks, 2010.
23. “Organic structural spectroscopy”, 2nd Ed. Pearson Education, Limited.

M.Pharm. S2-HDT-1: Analytical Techniques II Practical

Module 1	**Techniques of planar chromatography- TLC, PC, HPTLC.**	**1 credit**
Contents	**Experiments**	Hrs
	1. Development of suitable solvent system for the separation of mixtures of organic compounds by TLC.	(6)
	2. Development of suitable solvent system for the separation of herbal extracts by TLC.	(6)
	3. Quantitative separation of phytoconstituents from herbal extracts by Preparative thin layer chromatography.	(4)
	4. Use of various derivatising agents for detection of phytoconstituents by TLC and PC.	(4)
	5. Separation of sugars/ amino acids by TLC and PC.	(4)
	6. Demonstration and hands on training on High performance thin layer chromatography.	(2)
	7. Analytical method development for three component mixture using HPTLC	(4)
Module 2	**Techniques of column chromatography- HPLC, GC, Flash chromatography, Super critical fluid chromatography.**	1credit
Contents	Experiments	Hrs
	8. Demonstration of High performance liquid chromatography (HPLC).	(2)
	9. Plotting of a standard curve for caffeine / betaine/ catechin by HPLC.	(6)
	10. Quantitative estimation of caffeine in cola drinks and tea extract by HPLC.	(6) (4)
	11. To check the effect of alteration of various parameters on retention times (RT) of compounds by HPLC.	(6)
	12. Determination of HETP value, selectivity factor, resolution, tailing factor by HPLC.	(4)
	13. Demonstration of Gas liquid chromatography/ Flash chromatography/ Supercritical fluid extraction.	(2)

Module 3	**Structure elucidation of organic compounds- Problem solving**	**1 credit**
Contents	**Experiments**	Hrs
	14. Identification of various functional groups (amine, nitro, aldehyde, keto, carboxylic, hydroxyl, etc.) by UV and IR	(6)
	15. Identification of different functional groups by PNMR.	(6)
	16. Identification of different types of carbons and carbon containing groups by 13 CNMR	(4)
	17. Identification of Molecular ion peak, base peak in a mass spectrum of small molecular weight phytoconstituents .	(6)
	18. Structure elucidation of some small molecular weight phytoconstituents by UV, IR, NMR and MS spectral data.	(6)

Assigned Reading/ References	6. Thin-Layer Chromatography, A Laboratory Handbook by E. Stahl, Second. Edition, Springer-Verlag Berlin–Heidelberg–New York 1969. 7. Plant Drug Analysis by H. ***Wagner*** & S. Bladt, Second Edition, Springer. 8. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited. 9. Manual of HPTLC applicator, scanner and photodocumentation system by CAMAG 10. HPLC: High Performance Liquid Chromatography: Volume 2, by P.D. Sethi and Rajat Sethi CBS Publisher, 2008	

M.Pharm. S2-HDT-2: Advanced Pharmacognosy and Phytochemistry-II (Theory)

Module 1	**Standardization of Herbal drugs**	**1 credit**
Contents	**Topics covered**	Hrs
	• **Chemotaxonomy**: Significance in classification of medicinal plants, distribution of chemotaxonomic groups of constituents in plant kingdom like alkaloids, glycosides, terpenoids etc.	(2)
	• **Phytochemical evaluation of plant drugs**: Qualitative and Quantitative evaluation of phytoconstituents such as Alkaloids, steroids, terpenoids, flavonoids, glycosides, tannins etc. Chemoprofiling, TLC & HPTLC fingerprinting of crude drugs.	(2)
	• Bioactivity guided fractionations, Cytotoxicity tests	(2)
	• Drug discovery and development from natural products with special emphasis on drugs derived from some of the following Plants: Ashwagandha, Digitalis, Artemesia, *Atropa belladonna, Catharanthus roseus*, Podophyllum,Taxus species.	(6)

Module 2	**Plant Biotechnology**	**1 credit**
Contents	**Topics covered**	Hrs
	• Historical perspectives, prospects for development of plant biotechnology as source of medicinal agents. Applications in pharmacy and allied fields.	(1)
	• Types, techniques, nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenisis. Protoplast fusion and cultures, artificial seeds, micropropogation of medicinal and aromatic plants. Genetic stability of tissue cultures.	(2)
	• Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Screening and selection of high yielding cell lines. Effect of cultural practices, precursors and elicitors on production of biomedicinals.	(2)
	• Plant finger print analysis: Methods used in gene identification, localization and sequencing of genes. Application of PCR to plant genome analysis	(2)
	• Biotransformation, bioreactors, industrially potential tissue culture systems for pilot and large scale cultures of plant cells, cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.	(2)
	• Immobilized plant cell culture systems, immobilization techniques, effect of immobilization on secondary metabolism and realization of chemosynthetic potential in immobilized cells. Genetic transformation methods, Hairy root cultures and their applications.	(2)
	• Basic metabolic pathways and techniques employed in elucidation of biosynthetic pathway.	(2)
	• Biogenesis of tropane, quionoline, Imidazole, Isoquinoline and Indole alkaloids; Sterols, Anthraquinone and Saponin glycosides; Flavanoids; and Isoprenoid compounds of pharmaceutical significance	(2)

Module 3	**Regulatory aspects of herbals**	1credit
Contents	**Topics covered**	Hrs
	• Recent Methods (UV, HPLC, HPTLC, etc.) of assay of Andrographolide, Amarogenin, Asiaticisides, Atropine, Solasodine, Bacoposide, Caffeine, Cubebol, Citral, Curcumin, Digitoxin, Diosgenin, Embelin, Emetine, Ergometrine, Eugenol, Gingerol, Gycerrhetinic acid, Hesperidine, Kutkosides, Piperine, Plumbagin, Quinine, Quinidine, Recinolic acid, Sennosides, Taxol, Vinca alkoloids, Withaferin, etc. in extract / formulations.	(4)
	• Qualitative and quantitative estimations exemplified by the method of preparation of at least two standardized extracts. Single and multi components herbal formulations	(2)
	• Stability studies for extracts (Predictable chemical and galenical changes)	(2)
	• Pharmaceutical aids: Profile for manufacture and commerce of Papain, Pectin, Pharmaceutical gums, Starch, Absorbent cotton and Gelatin. Methods of preparation of different conventional solid and liquid dosage forms incorporating herbal extracts.	(2)
	• GMP and other regulatory and safety requirements (ICH,OECD), Schedule Y, Drug and Cosmetic Act and Rules for Herbal, Ayurvedic and other Drugs of traditional origin	(4)

Module 4	**Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**

Assigned Reading/	1. W.C. Evans, 2002. “Trease& Evan’s Pharmacognosy”. WB.Saunders & co., London.	

References	2. T. Swain, 1963. "Chemical plant Taxonomy". Academic Press, London. 3. C.A Stace, 1985. "Plant Taxonomy and Biosystematics". Edward Arnold, London. 4. C.K. Atal, "Cultivation and Utilization of Medicinal plants". R.R.L. Jammu 5. H.E. Street, 1997. "Plant Cell and Tissue Culture". Blackwell Scientific, London. 6. N. Takashashi, 1986. "Chemistry of Plant Hormones" CRC Press Inc., Florida. 7. A.R. Gennaro, 2000."Remington: The Science & Practice of Pharmacy". Lippincott Williams & Wilkins, Philadelphia. 8. Kaufmann, "Natural products for plants". CRC press New York. 9. K. Nakanishi, 1977. "Chemistry of Natural Products". Kodansha Book Publishing Company, Osaka (Japan). 10. V. Rajpal, 2002. "Standardization of Botanicals", Eastern Publishers, New Delhi. 11. J.B. Harborne, 1998. "Phytochemical methods", Chapman and Hall. 12. K. Paech, 1956. "Modern methods of plant analysis"., Springer-Verlag 13. Guidelines for the Assessment of herbal medicines, 1991,WHO Report, Geneva. 14. Quality Control Methods for Medicinal Plant material, 1992, WHO Guidelines. 15. Indian Pharmacopoeia, 1996, Govt. of India, Ministry of Health and family welfare, Delhi. 16. A.N. Kalia, Textbook of Industrial Pharmacognosy, 2005, CBS Publishers, New Delhi. 17. Dr.C.K. Kokate, Practical Pharmacognosy, 1988, Vallabh Prakashan, Delhi. 18. Dr.P.Mukherjee, Quality control herbal drugs, 2005, Business Horizons,	

M.Pharm. S2-HDT-2: Advanced Pharmacognosy and Phytochemistry-I - Practical

		1 credit
Contents	**Experiments**	Hrs
	1.Isolation and separation of phytoconstituents by Column chromatography 2.Isolation and Chemical Evaluation of Phytochemical Constituents: Curcumin, Caffeine, Quinine, Strychnine, glycyrrhizin and sennosides 3.Isolation of volatile oils from various plant drugs and their TLC Characterization 4. Isolation of piperine from pepper. 5. Isolation & TLC of reserpine from Rauwolfia root. 6.Isolation of Hespiridine from orange peel. 7.Isolation & TLC of Menthol from mentha oil 8.Qualitative and quantitative estimation of phytoconstituents in crude drugs & commercial herbal formulations. 9.Preparation of detailed monograph of at least one plant drug covering Pharmacognosy and Phytochemical investigation with its use in traditional system of medicine. 10. Preclinical studies of some herbal extracts like analgesic anti-inflammatory and antianxiety.	

Assigned Reading/ References	1. W.C. Evans, Trease and Evans Pharmacognosy, 15th edition2002, W.B. Sounders & Co., London. 2. S.S. Handa and M.L. Kaul, Supplement to cultivation and utilization of medicinal plants, 1996, R.R.L Jammu, India. 3. Ram P Rastogi, Compendium of Indian Medicinal Plants, 1998, Vol. I-V, CSIR, Lucknow , New Delhi. 4. T. Fleming, PDR for Herbal Medicine, 2nd edition, 2000, Medical Economics compant, Mountvale, New Jersy. 5. M.J. Cupp, Toxicology and Clinical Pharmacology of Herbal Products, 2000, Humana Press, New Jersy.	

	6. Wealth of India- Raw Materials, 1985, CSIR Publication, New Delhi. 7. Dr.P.Mukherjee, Quality control herbal drugs, 2005, Business Horizons, New Delhi. 8. V.D.Rangari, Pharmacognosy & Phytochemistry,1st edn.2004,Career Publications, Nasik.	

M.Pharm. S2-HDT-3: Herbal Product Development-II Theory

Module 1	**To study concepts of rate controlled and site specific drug delivery systems and particulate carrier systems**	**1 credit**
Contents	**Topics Covered**	Hrs.
	• **Concepts and systems design for rate controlled delivery:** Rate preprogrammed, Activation modulated and Feedback regulated drug delivery systems.	(3)
	• **Particulate carrier systems:** microspheres, liposomes and nanocarriers.	(3)
	• **Site specific drug delivery:** Active and passive targeting, monoclonal antibodies for drug targeting.	
	1 **Ocular delivery of drug:** Anatomy & physiology of eye, development of ocular controlled release therapeutic systems, safety & toxicity evaluation.	(3)
	2 **Transdermal drug delivery:** Permeation through skin, permeation enhancers, technologies for developing transdermal drug delivery systems like gels, patches and sprays and evaluation thereof.	(3)

Module 2	**Advances in Oral, Mucosal, Intrauterine & Parenteral with respect to Herbal Drug Delivery Systems**	**1credit**
Contents	**Topics Covered**	Hrs
	• **Oral Herbal Drug Delivery Systems:** Osmotic pressure controlled, membrane permeation controlled, pH controlled, Ion-exchange controlled, gel diffusion controlled and hydro dynamically balanced systems, modulation of gastro intestinal transit time and release kinetics and evaluation thereof.	(3)
	• **Mucosal herbal drug delivery systems:** Mechanism of transmucosal permeation and mucosal membrane models, Buccal, Nasal, Pulmonary, Rectal and Vaginal drug delivery systems.	(3)
	• **Intrauterine drug delivery systems:** Medicated IUDS, copper IUD,	(3)

	Hormone releasing IUD, long acting contraceptive formulations. • **Parenteral drug delivery systems:** Injectable controlled release formulations, long acting depot formulations, implantable drug delivery	(3)

Module 3	**III. Packaging materials for herbal dosage forms**	**1 credit**
Contents	**Topics Covered**	Hrs
	• .Glass containers for Herbal Pharmaceuticals**:** Glass types, their manufacture chemical composition, Performance testing and quality control, Defects.	(2)
	• Plastics containers for Herbal Pharmaceuticals: Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties, Quality control testing and biological toxicity.	(2)
	• Metal containers: Aluminum and tinplate drums collapsible tubes. Aerosol containers, Lacquering, coating and lining.	(2)
	• Flexible packaging: Types of films, Co-extruded films, foils, coating and laminates, shrink and stretch films, blisters and Strip Packaging.	(2)
	• Paper and paperboard: Types of paper, folding cartons, quality control testing of paper and paperboard and their common defects	(1)
	• Corrugated and solid fibre boards and boxes: Types of corrugation, methods, types of box design and Quality control.	(1)
	• Caps and Closures: Types of caps, closures, liners, child resistant caps. Elastomeric closures for parenterals, classification of Elastomers, physical chemical and biological properties and their quality control.	(1)
	• Labels and labeling: Types of labels, adhesives, inject and bar coding and printing of labels, Quality control and common defects in printing of labels.	(2)

Module 4	**IV. Study of Product package compatibility & Project & Seminar**	**1 credit**

Contents	Topics covered	hrs
	• Product–Package compatibility: Stability of product, package selection and development criterion, Line clearance and packaging operation in pharma and herbal industry. • The Seminar topic will be given to the student based on the above content & they have to present the same	(4) (8)

Assigned Reading/ References	1. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y,1992. 2. Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc. , ***New York*** , 1987. 3. S.D. *Bruck, "Controlled Drug Delivery"*, Vol.1 (Basic Concepts) CRC Press.1983. 4. Davis, S.S. and Illum, L., "Colloidal delivery systems- opportunity and challenges, in site specific drug delivery cell biology", John Wiley and Sons, Chichester, , 1986. 5. Vyas, S.P. and Khar, R.K., "Targeted and controlled drug delivery novel carriers", CBS, 1st edition, 2002. 6. Micheal Roberts, "Dermal Absorption & Toxicity Assessment", 2nd Edition, Vol 177, 2007. 7. G.S.Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y. 1994. 8. Jain S., Jain N., "Liposomes as drug carriers", In: Controlled and novel drug delivery", CBS Publishers and Distributors, 1997. 9. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001. 10. Lachman, L., Lieberman, H. A., & Kanig, J. L. "The Theory and Practice of Industrial Pharmacy" 3rd edition, Mumbai: Varghese Publishing House,1991 11. Rawlins, E. A. (1995). Bentley's text book of Pharmaceutics, 8th edition, London: Bailliere Tindal. 12. Micheal Rathbone, "Modified Drug Release Drug Delivery Technology", 2nd Edition, Vol 1, 2008. 13. Chilukuri D.," Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007. 14. Rubinstein, M. H.,. Aulton M. E., "Pharmaceutics: the science of dosage form design", pp. 304-321., London: ELBS Longman Group Ltd. 1988. 15. Rolland A., "Pharmaceutical Particulate Carriers",. New York: Marcel	

Dekker, Inc.1993

16. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy",Philadelphia: Lippincott Williams & Wilkins.2006.
17. Saha, S., & Shahiwala, A. F. "Multifunctional coprocessed excipients for improved tabletting performance", 2nd edition, 2009
18. K.E.Avis, "Pharmaceutical Dosage Forms: Parental Medication", Vol. I Marcel Dekker Inc., N.Y, 2008.
19. S. Turco and R.E. King, "Sterile Dosage Forms", 2nd edition,1998.

M.Pharm. S2-HDT-4: Ayurveda and Allied systems of medicine

Module 1	**Principles of Ayurvedic system of medicine**	**1 credit**
Contents	**Topics Covered**	Hrs.
	• Basic principles of treatment in Ayurvedic System of medicine	(2)
	• Plants used in Ayurveda for various disorders.	(2)
	• Preparation of Ayurvedic formulations like Asava, Arista, Bhasma, Churna, Ghrita, Vati /Gutika/pills, Avaleha, Kshar, Kashaya, Taila etc as per Ayurvedic Pharmacopoeia and texts	(4)
	• Introduction to Ayurvedic Pharmacy, some aspects of standardization of Ayurvedic formulations	(4)
	• Clinical trials, introduction to "Reverse Pharmacology" and other models	(3)

Module 2	**Principles of Allied systems of medicine**	**1 credit**
Contents	**Topics Covered**	Hrs.
	• Basic principles of treatment in Unani system of medicine - Common plants used and types of formulations.	(3)
	• Basic principles of treatment in Homeopathic systems of medicine - Common plants used and types of formulations.	(4)
	• Basic principles of treatment in Siddha systems of medicine - Common plants used and types of formulations.	(3)
	• Ethnoplants, plants used in folklore and tribal medicines	(3)

Module 3	**Monographs of plants in various pharmacopoeias**	**1 credit**
Contents	**Topics Covered**	Hrs.

	• Monographs of various medicinal plants and products as per Indian Herbal Pharmacopoeia (IHP) • Monographs of various medicinal plants and products as per Ayurvedic Pharmacopoeia of India • Monographs of various medicinal plants and products as per Indian Pharmacopoeia • Monographs of various medicinal plants and products as per British Herbal Pharmacopoeia, Comparison of IHP,IP,BHP and Ayurvedic Pharmacopoeia • Monographs of various medicinal plants and products as per Homeopathic Pharmacopoeia of India and American Homeopathic Pharmacopoeia • Monographs of various medicinal plants and products as per Siddha Pharmacopoeia of India • Monographs of various medicinal plants and products as per Unani Pharmacopoeia of India	(2) (2) (3) (2) (2) (1) (1)

Module 4	**Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**

Assigned Reading/ References	1. Indian Herbal Pharmacopoeia (IHP), Revised edition 2002, published by Indian Drug Manufacturers Association. 2. Ayurvedic Pharmacopoeia of India, Vol. 1-6, 2007,Government of India, Ministry of Health and Family Welfare, CCRAS, Department of AYUSH, New Delhi, 3. Indian Pharmacopoeia, 6th edition Vol.1-3, 2010, Government of India, Ministry of Health and Family Welfare 4. British Herbal Pharmacopoeia, 1996, published by Scientific Committee of the British Herbal Medicine Association. 5. Homeopathic Pharmacopoeia of India, Vol. 1-7, 1986, Government of India, Ministry of Health and Family Welfare 6. American Homeopathic Pharmacopoeia, 1882, Boericke and Tafel, Kessinger Publishing's Legacy. 7. Siddha Pharmacopoeia of India, Part - 1, vol. 1, first edition, 2008, published by Department of AYUSH, Government of India 8. Unani Pharmacopoeia of India Part - 1, vol. 1-6, Part - 2, vol. 1-2, 2008, published by Department of AYUSH, Government of India	

Semester III

SEMESTER III

M.Pharm. S3-HDT-2: Biological evaluation – (Theory)

Module 1	**Pre-clinical drug evaluation**	**1 credit**
Contents	**Topics Covered**	Inst. hrs
	• New Drug Discovery and development process- Leads from plants. • Pre-clinical drug evaluation for biological activity as per Schedule Y, ICH and OECD guidelines: Safety studies in animals- for acute, sub-acute and repeat dose toxicity studies, ED50 and LD50 determination, Special toxicity tests like teratogenecity, mutagenicity, carcinogenicity and reproduction toxicity studies, genetic toxicology, • Clinical Trials, Phase I, II & III • Screening of drugs, Transgenic and Knockout animals, Biostatistics and calculation of doses in experimental pharmacology	(3) (5) (3) (3)
Module 2	**II. Biological standardization and Molecular biology**	**1 Credit**
Contents	**Topics Covered**	Hrs
	• General principles, scope and limitations of bioassay, bioassay of official drugs • Molecular biology of receptors such sodium, calcium and potassium ion channels as well as GPCR. • Biological evaluation of drugs- Screening and evaluation (including principles of screening, development of models for diseases: *in vivo* models/ *in vitro* models/ cell line study) techniques of the following: 1.Cardiovascular drugs(antihypertensive, antiaarythmic ischemic heart diseases, atherosclerosis, cardiotonic) 2.Drugs acting on CNS(anesthetics, sedatives, hypnotics, antiepileptics, antiparkinsonism, 3.Drugs used in metaboliic syndrome- diabetes	(3) (2) (8)

	4.Analgesic drugs and anti-inflaamatory drugs 5.Gastro intestinal(peptic ulcers, IBS, hormone and endocrine disorders) 6.Adrenegric and cholinergic drugs 7.Drugs used in respiratory disorders 8.Antifertility drugs and diuretics	
Module 3	**Microbiological evaluation and Pyrogen Science**	**1 credit**
Contents	**Topics Covered**	
	1.Microbiological limit tests with special emphasis on Crude drugs 2. Bacterial, fungal, microbial counts – Principle & Methodology 3. Sterility tests: Methodology & Interpretation 4. Tests for effectiveness of antimicrobial preservatives. 5.Sources, chemistry and properties of bacterial Pyrogens and endotoxins, 6.Official Pyrogen tests- IP, BP & USP, Interpretation of data, and comparison of LAL. 7.Microbiological assay of antibiotics and vitamins.	(2) (2) (2) (2) (2) (2) (3)
Module 4	**Project and Seminar Presentation on some recent research /seminars based on the above topics**	**1 credit**

M.Pharm. S3-HDT-2: Biological evaluation – (Practical)

Module 1	**Introduction to Animal Models**	**Credit 1**
Contents	**Experiments**	**Practical hrs**
	1.To Study Effect of diazepam on locomotor activity by actophotometer.	**(**4)
	2.To Study Effect of diazepam on muscle grip by rota-rod apparatus	(4)
	3.To Study Effect of diazepam on behavioral activity by hole-board technique and elevated plus maize.	(6)
	4.To Study of chlorpromazine induced catatonia.	(4)
	5.Effect of analgesic by hot plate technique	(6)
Module 2	**Microbiological testing of various formulations.**	**Credit 1**
Contents	**Experiments**	
	1.Effectiveness of antimicrobial agent by cup plate method	(4)
	2. Effectiveness of antimicrobial agent using Ditch plate method	(6)
	3. To perform Sterility test of given sample.	(4)
	4.To determine minimum inhibitory concentration of given antibiotic	(6)
	5. To perform the Microbial limit tests of Crude drugs	(4)
Module 3	**Demonstrations**	**Credit 1**
Contents	**Experiments**	
	1. Demonstration of animal handling techniques.	(4)
	2. Demonstration of various routes of administration	(4)
	3. Demonstration of Bioanlayser	(6)
	4. Demonstration of Blood Cell Counter	(4)
	5. Demonstration of Water Maize Apparatus	(6)

M.Pharm. S3-HDT-3: Computing & Statistics (Theory)

Module 1	**I. Basics of computers**	**1 credit**
Contents	**Topics Covered**	hrs
	• Application of computers in pharmaceutical sciences, stores management, inventory control, drug information systems and hospital information systems	(3)
	• Access to and retrieval of information: Smart search using internet, use of search engines and web sites, drug information sources.	(3)
	• Computer applications in pharmacy, with special reference to formulation development, production, quality assurance, and validation.	(3)
	• Modeling and simulation of data with application in pharmacokinetics	(3)

Module 2	**II. Applications in Pharmacy**	**1credit**
Contents	**Topics Covered**	
	• Introduction to computer-aided drug design (CADD), QSAR various software's and molecular modeling in CADD	(3)
	• Importance and generation of physico-chemical descriptors using various software's.	(3)
	• Correlation methods and generation of molecular models using computer software's. Interpretation and statistical significance of molecular models developed using softwares.	(3)
	• Structure based and pharmacophore based drug designing using CADD. Importance of docking studies in drug development.	(3)

Module 3	**III. Concept of Statistics**	**1 credit**
Contents	**Topics Covered**	Hrs

	• Probability: Laws of probability, types of distribution. • Hypothesis testing: Types of errors, tests for significance: one-tailed and two- tailed tests, t test, z test, chi-square test. • Correlation and regression: definition and calculation of correlation coefficient, regression coefficient, least square, method, linear regression.	(4) (4) (4)

Module 4	**IV. Application of Statistics**	**1 credit**
Content	**Topics Covered**	Hrs
	• Analysis of variance: Completely randomized design randomized complete block design, Factorial design, and response surface graphs. • Non-parametric tests: The sign test, The Mann-Whitney U test, The Runs test, Spearman's rank correlation. • Role of statistics in design of pharmaceutical and biomedical experiments specially controlled clinical trials.	(4) (4) (4)

M.Pharm. S3-HDT-3: Computer & Statistics I (Practical)

Module 1	**1. Basics of computers**	**-**
Contents	**Experiments**	(20)
	• Major Commands For Windows Operating System	(6)
	• Introduction To Word Processing (MS word)	(4)
	• Presentation Tool: Introduction to presentation tool, features and functions, Creating presentation, Customizing presentation, Showing presentation. Tools used may be Microsoft Power Point, Open Office or similar tool.	(6)

Module 2	**II. Use of internet & application of softwares in data interpretation**	**-**
Contents	**Experiments**	(20)
	• Introduction to Internet, Use of Internet and www	(6)
	• Applications of Software-QSAR, CADD, Pharmacokinetics, Factorial design.	(6)
	• Using search engines like Google, Yahoo etc, Using advanced search techniques. Literature search using various search engines like google, pubmed, science direct, freepatentsonline.	(6)

Module 3	**III. Statistical Data Analysis & Application of Spreadsheet to Pharmacy**	**-**
Contents	**Experiments**	(20)
	• Spreadsheet Tool: Introduction to spreadsheet application, features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features. Tools used may be Microsoft Excel, Open office or similar tool.	(8)
	• R-Project: Statistical package.	(6)

M.Pharm. S3-HDT-4: Research Methodology

1. **Objective:** To inculcate an understanding of research methodology and study various aspects and ethics associated with it.
2. To study principles of Instructional design through active and collaborative learning.
3. To understand problem identification, its implementation and evaluation and also introduce various research funding agencies for pharmacy.
4. To introduce different methods of assessment and concepts of basic research and give a brief overview of formation of research problem.
5. To study in detail concepts of mathematical modeling and types involved in processes of formulation of model based on simulation.
6. To understand experimental modeling, general model of process and introduce risk assessment and uncertainty associated with experimental modeling.
7. To inculcate an understanding of research deliverables in form of various publications, thesis writing and presentations.
8. To develop a learning of principles on ethical consideration involving research and issues related to plagiarism.

Module 1	**Introduction of Research Methodology**	**1 credit**
Objectives	1. To inculcate an understanding of research methodology 2. To understand various principles of learning & theory based on it. 3. To know various government & other research funding agencies. 4. To understand various methods and sources of literature	
Contents	**Topics Covered**	**15**
	Learning and instruction Principles of Instructional design and learning theory, Merrill's five principles and Gagne's	**5**

	condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.	
	Basics of Research Definition, objectives, motivation, types of research and approaches: descriptive research, conceptual, theoretical, applied and experimental.	**6**
	Literature review Important methods and sources to search for literature (Primary and secondary sources), referencing and search from Journals and Patents, Literature search using internet and web based interfaces, suitable search engines, advanced search techniques & data bases. Review and compilation of the collected matter	**3**
	Funding & Scholarship Agencies funding research in pharmaceutical sciences, Scholarship, types of scholarships in education.	**1**
Module 2	**Basics of Research**	**1credit**
Objectives	1. To learn about various assessment techniques. 2. To understand basics of research. **3.** To study various research problems & develop research plan **4.** To learn planning, execution and implementation of the schedule	
	Assessment Definition and methods, Georges Millers pyramid, Assessment, measurement and tests, Types of numbers, Formative and summative assessment.	**3**

	Formation of Research Problem Research Process: To determine what type of research to be done, plan of research work Selection of research area, prioritization of research. Objectives and scope of work, Developing Research Plan and Schedule: Scheduling Constraints, steps, problems in scheduling, limitations.	**6**
	Implementation and Documentation Collecting the requisites of the experiments to be performed, maintaining the records of all the experiments, maintenance of equipments/instruments and log books for all the instruments, to come out with innovative ideas.	**6**
Module 3	**Mathematical Modelling & Analysis of Data**	**1 credit**
Objectives	**1.** To acquaint research students with various mathematical & experimental modeling techniques used to draw conclusions in Experimental Research. **2.** To be able to identify, analyze and solve problems related to research using software. **3.** To study the various software used in pharmacy for data analysis.	
	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	**5**

	formulation of model based on simulation. Variables and measurement	
	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.	**5**
	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 regression, 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.	**5**
Module 4	**Ethics In Pharmacy & Research Deliverables**	**1 credit**
	• To learn techniques used in the professional presentations. • To learn about research publications, thesis writing and presentations.	

	• To understand ethical consideration involving research and issues related to plagiarism.	
	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	**6**
	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.	**6**
	Plagiarism Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.	**3**

Assigned Reading/ References	**1.** B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press. **2.** J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education*", 7th Ed*. Boston: McGraw-Hill. **3.** 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. **4.** N. Peter, 2009. "Leadership: Theory and Practice.*" 3rd Ed.* Thousand Oaks: Sage Publications. **5.** G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. *Medical Education, 37*(4): 376-385. **6.** B.J. Avolio, F.O. Walumbwa, T.J. Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*: 421-449. **7.** C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers. **8.** D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience. **9.** K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd Ed. Himalaya publishing, Mumbai. **10.** Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill. **11.** D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons.	

S3-HDT5: Research Seminar

SEMESTER		SUBJECT			
III		Research Seminar			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
2	--	2	--	50	--

S3-HDT-6: Research Project

SEMESTER		SUBJECT			
III		Research Project			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
	24	-	8	200	--

S3-HDT-1: Industrial Training

SEMESTER		SUBJECT			
III		Industrial Training			
ONE MONTH		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
		2		50	

Semester IV

S4-HDT-1: Research Project

SEMESTER		SUBJECT			
III		Research Project			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
32	--	24	--		600