M.PHARM: PHARMACEUTICAL QUALITY ASSURANCE
SEMESTER-II
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
421	Pharmaceutical Analysis - I	2	---	3	---
422	Natural Product and Biotechnology	3	---	4	---
423	Chromatography	3	---	4	---
424	Validation	4	---	4	---
425	Quality Assurance Practical - II	---	18	---	6
426	Subject Seminar	6	---	---	3
	Total	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
421	Pharmaceutical Analysis - I	3	80	20	---	---
422	Natural Product and Biotechnology	3	80	20	---	---
423	Chromatography	3	80	20	---	---
424	Validation	3	80	20	---	---
425	Quality Assurance Practical - II	12	---	---	80	20
426	Subject Seminar	---	---	---	---	100
	TOTAL		320	80	80	120

SUBJECT : Pharmaceutical Analysis - I
SUBJECT CODE : 421
RATIONALE : Many of the approaches described for characterizing drug substances can be applied to formulations, either by accounting for the presence of excipients in the analyte or by extracting and analyzing the active ingredient. This syllabus devotes a chapter to the technique, focusing on the varied instrumental capabilities, their basic principles of operation and their applicability to pharmaceutical analysis.

COURSE OBJECTIVES: Proposed methods used for separation of drug substances in API and formulations, these methods are also useful for proposed methods used for identification of drug substances in API and formulations understanding their basics. Hyphenated technique used for method development and validation

LEARNING OUTCOMES: Knowledge about DSC and DTA, Particle size analysis, Hyphenated technique

PREREQUISITES : Basic knowledge about principle of analysis and analytical technique like, chromatography, mass spectroscopy, X-ray, thermo-gravimetry

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
421	Pharmaceutical Analysis - I	2	--	2	3	20	--	80	--	100

421. Pharmaceutical Analysis-I:

1	Thermal analysis Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters. Instrumentation of Thermographs and applications.	20
2	Introduction, principle, theory, instrumentation and applications of Scanning Electron Microscope.	10
3	X-ray crystallographic techniques: X-ray absorption and X-ray diffraction methods	10
4	Electrophoresis: Capillary and Gel Electrophoresis- Basic principle, Instrument and application, Advances in electrophoresis	20
5	Hyphenated techniques: LC/MS, GC/MS, MS/MS, LC/MS-MS	20
6	An approach to development of analytical methods for drugs in bulk and in their formulation, recovery studies, stability indicating analytical methods	20

SUBJECT : Natural Product and Biotechnology
SUBJECT CODE : 422
RATIONALE : Natural products-compounds derived from plants, microbes and marine organism. Standardization and authantification technique for natural products covered in the proposed syllabus. In the Quality Assurance and Safety aspect, WHO team aims to assure the safety of medicines by ensuring reliable and timely exchange of information on drug safety issues, promoting pharmacovigilance activities throughout the Organization and encouraging participation in the WHO Programme for International Drug Monitoring .The application of biotechnology can result in (a) new ways of producing existing products with the use of new inputs, and (b) new ways of producing new products. Examples the production of insulin using recombinant DNA technology; the production of hepatitis B vaccine using recombinant DNA technology.

COURSE OBJECTIVES: Pharmacovigilance. (Safety monitoring of medicinal products) used in
1. Drug monitoring
2. Pharmaceutical preparations - adverse effects
3. Adverse drug reaction reporting
4. Product surveillance, Post marketing
5. Legislation, Drug I. Series Pharmacovigilance: To detect and minimize the harm caused by improper dosing and use of medicines.

For Standardization of Natural product drugs/ formulation

LEARNING OUTCOMES: Knowledge about standardization, authantification, fingerprinting of Herbal products, biotechnology product, gene therapy

PREREQUISITES: Basic knowledge about natural products, basic terminology for microbiology related to subject.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
422	Natural Product and Biotechnology	3	--	3	4	20	--	80	---	100

422. Natural Product and Biotechnology

1	Pharmacopoeial methods of Analysis by physical test, limit test, microbiological assay, Dissolution tests and miscellaneous tests, tests for effectiveness of antimicrobial preservatives.	25
2	**Standardization of Natural product drugs/ formulation**	35
	Safety monitoring of herbal medicines in pharmacovigilance systems-General Introduction, Pharmacovigilance and WHO International drug monitoring programme, Challenges in monitoring the safety of herbal medicines, safety monitoring of herbal medicines, communication.	
	Determination of physical and chemical constants, extractive values, techniques of separation.	
	HPLC and HPTLC fingerprint identification of raw material and crude drugs.	
3	**Biotechnology in Pharmacy**	40
	System and methods of molecular biology, gene cloning, gene expression, fermentation technology, Prospects in gene therapy, recombinant DNA technology, commercial aspects of biotechnology.	
	Pharmacopoeial methods of Analysis by physical test, limit test, microbiological assay, Dissolution tests and miscellaneous tests, tests for effectiveness of antimicrobial preservatives.	

SUBJECT **: Chromatography**
SUBJECT CODE **: 423**
RATIONALE **:** Subsequent chapters cover the major disciplines of separation sciences. It deals with the techniques that are often necessary for separating the drug from the other components of a pharmaceutical formulation or biological sample.

COURSE OBJECTIVES **:** Due to their versatility and resolution, chromatographic separations of complex mixtures of biologicals are used for many purposes in academic and industry.
Appropriate selection of partitioning mechanism can produce separation of very closely-related molecules.
To understand basic theory and separation science.
To learn instrumentation and troubleshooting of HPLC.
To study various chromatographic techniques.

LEARNING OUTCOMES **:** Expertise in proper handling and operation of instruments like HPLC, HPTLC and also to gain basic idea about latest chromatographic techniques over conventional chromatographic techniques.

PREREQUISITES: Basic knowledge about principles of chromatography, mechanism of chromatography, sample preparation, application of chromatography.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
423	Chromatography	3	--	3	4	20	--	80	--	100

423 Chromatography

	Basic principle, instrumentation and applications in:	
1	Column chromatography: Merits and demerits, short-column chromatography and flash	20
	chromatography, vacuum liquid chromatography (VLC), medium pressure liquid	
	chromatography, High Pressure Liquid Chromatography (HPLC)	
2	HPTLC, Over pressure layer chromatography (OPLC), centrifugal chromatography.	20
3	Ion-exchange Chromatography, Affinity chromatography, Size exclusion and ion-pair	30
	Chromatography.	
4	UPLC and Gas chromatography	15
5	Super critical fluid chromatography	15

SUBJECT **: Validation**
SUBJECT CODE **: 424**
RATIONALE **:** Validation and qualification of analytical methods and equipment are Required by many regulations, regulatory guidance documents, quality standards, and company policies. If executed correctly, they also help to improve the reliability, consistency, and accuracy of analytical data. Methods used in pharmaceutical analysis must be sufficiently accurate, specific, sensitive and precise to conform to the regulatory requirements as set out in the relevant guidelines.
COURSE OBJECTIVES **:** Validation is a basic requirement to ensure quality and reliability of the results for all analytical applications

LEARNING OUTCOMES: perform the analytical and bioanalytical validation of API and formulation

PREREQUISITES **:** Basic knowledge about quality assurance, quality control, regulatory guidelines, instrumentation

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
424	Validation	4	--	4	4	20	--	80	--	100

424. Validation

1	Validation of Analytical Methods (ICH, US FDA, USP, IUPAC, AOAC)	10
2	Calibration of Instruments like Spectrophotometer(UV, IR, Fluorimetry), HPLC,	10
	pH meter, Conductometer.	
3	Validation of process (Sterile and non sterile products). Validation of sterilization methods and equipments like Autoclaves, dry heat sterilizers, Radiation Sterilization, Gaseous sterilization and aseptic membrane filtration.	25
4	Introduction to validation of manufacturing facilities D.Q., I.Q., O.Q., P.Q and certification, preparation of validation protocols.	15
5	Validation of purified water system, distilled water and water for injection.	10
6	Validation of air handling 'system, sterile' and non sterile areas	10
7	Introduction to Cleaning Validation.	10
8	Introduction to computer system validation (21 CFR part 11)	10

SUBJECT : Quality Assurance practical -II
SUBJECT CODE : 425

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
425	Quality Assurance Practical – II	--	18	18	6	--	20	--	80	100

	Practical will be based on syllabus to give practical trainings to the students
1.	Test require for tablet dosage form as per IP,BP,USP
2.	To perform test as per monograph of Paracetamol IP'96
3.	To do the calibration of double beam UV visible spectrophotometry
4.	To study monograph of Talc as per IP'96
5.	To determine concentration of Sodium & Potassium given sample of ORS by flame spectrophotometer
6.	To study monograph of Potassium Permanganate as per IP'96
7.	Comparative analysis of uniformity weight test and test for content of active ingredients for two different brands of Atenlolol tablets as per IP'96
8.	Comparative evaluation of different brands of Ibuprofen tablets by dissolution test and assay as per IP'96
9.	Introduction to standard to capsules and ointment as per IP,BP,USP
10.	Comparative evaluation of dissolution profile of Diltiazem Hydrochloride SR tablets of two different brands
11.	Estimation of Zonisamide using reverse phase HPLC method with rhonodyne injection
12.	Simultaneous determination of Potassium Dichromate & Potassium Permanganate in the mixture using simultaneous equation method
13.	Assay of Ephedrine Hydrochloride in given injection using absorbance corrected for interference
14.	Estimation of Nimesulide & Diclofenac Sodium from combined dosage form by simultaneous equation method
15.	Estimation of gliclazide & metformine hydrochloride from combined dosage form by simultaneous equation method
16.	Estimation of Aceclofenac & Paracetamol hydrochloride from combined dosage form by simultaneous equation method
17.	Estimation of Etorocoxib by difference spectroscopy in pharmaceutical preparation
18.	Estimation of Norfloxacin by extractive spectroscopy in pharmaceutical preparation
19.	Spectrophometric estimation of Roxithromycin
20.	To determine dissociation constant of Methyl Red using UV spectroscopy
21.	Assay of Sulpharcetamide sodium eye drops by electrometric & external indicator method
22.	HPTLC fingerprinting of Curcuma Amada Roxx
23.	Simultaneous spectrophotnetrid determination of Amlodipine Bisylate & Atrovastatin Calcium from their mixture by dual wavelength
24.	Estimation of Amlodipine Bisylate tablet by HPLC method

25.	Simultaneous spectrophometric determination of Amlodipine Besylate & Atorvastatin calcium from their mixture by zero absorbance method
26.	Spectrophotometric estimation of Raloxifene Hydrochloride in tablet dosage form
27.	To show the effect of pH upon the absorption spectrum of sulphanilamide
28.	Simultaneous spectrophometric determination of Amlodipine Besylate & Atorvastatin calcium from their mixture by Q- absorbance method
29.	TLC method for paracetamol combine dosage form
30.	Study of linearity response of glass electrode using pH meter.

BOOKS RECOMMENDED

1. L. George, N.R. Schmuff, HPLC Methods For Pharmaceutical Analysis, John Willey & Sons, New York, Vol 1-4, 1st Ed., 1996
2. B. T. Lofters, R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, Inc. New York. Volume 23, 2nd edition.
3. Carleton & Agalloco, (Marcel Dekker), Validation of Aseptic Pharmaceutical Processes, 2nd edition.
4. P. C. Sadek, Troubleshooting HPLC Systems :A Bench Manual, John Willey & Sons, New York, 1st Ed., 2000
5. E. Hoftman, A Laboratory Handbook Of Chromatography, New – York, Latest Edition
6. M. Wenland, Thermal Analysis, John Willy And Sons, New-York, Latest Edition
7. F. A. Settle, Handbook Of Instrumental Techniques For Analytical Chemistry, Pearson Education Asia, Delhi, 1st Ed., 2004
8. J. Swadesh, HPLC Practical And Industrial Applications, Crc Press, Baca Raton, New York, 1st Ed., 1996
9. K. Bansal, Chromatography, Campus Books, New Delhi, 1st Ed., 2000
10. P. K. Mukherjee, Quality Control Of Herbal Drugs :An Approach To Evaluation Of Botanicals, Horizons, New Delhi, 1st Ed., 2005
11. G. Currell, Analytical Instrumental Performance Characteristics And Quality, John Willey & Sons, Chichester, 3rd Ed., 2000
12. S. Egon, Thin-Layer Chromatography: A Laboratory Handbook Springer, 2nd Ed., 2005.
13. R. E. Schirmer, Modern Methods Of Pharmaceutical Analysis, CRC Press, Baca Raton, Press, Baca Raton, Vol1&2,2ndEd., 2000.
14. J. Mendham, R.C. Denney, Textbook Of Quantitative Chemical Analysis, Pearson Education Asia,Delhi,6th Ed.,2006
15. K. Danzer, Analytical Chemistry :Theoretical And Metrological Fundamentals, Springer, Heidelberg, 1st Ed.,2007
16. E. Joachim, Method Validation in Pharmaceutical Analysis, Willey-Vch Verlag Gmbh& Co, Kga, 1st Ed., 2005.
17. M. Jahnke, Introduction to the environmental Monitoring of Pharmaceutical Areas, Davis Harwood International Publishing, Latest Edition
18. B. Ljunggvist ,B. Davis, Microbiological Risk Assessment in Pharm. Clean rooms , Harwood International Publishing, Latest Edition
19. R. Prince, Microbiology in Pharmaceutical Manufacturing, Davis Harwood International Publishing, Latest Edition
20. XU, Stability Indicating HPLC Methods for Drug Analysis, Pharmaceutical Press Titles, Latest Edition.
21. Chow, (Marcel Dekker),Statistical Design and Analysis in Pharmaceutical Science, Latest Edition

SUBJECT **: Subject Seminar**
SUBJECT CODE **: 426**
RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: NONE

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
426	Subject Seminar	6	--	6	3	-----	100	-----	-----	100

M.PHARM: PHARMACEUTICAL QUALITY ASSURANCE
SEMESTER - III

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
431	Biological Evaluation and Clinical Research	3	---	3	---
432	Pharmaceutical Product Development	3	---	3	---
433	Food and Cosmetics, Special Analytical Techniques	3	---	3	---
434	Quality Management	3	---	3	---
435	Quality Assurance Practical -III	---	18	---	6
436	Synopsis (Introduction To Dissertation) & Viva Voce	---	---	3	---
437	Subject Seminar	6	---	---	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
431	Biological Evaluation and Clinical Research	3	80	20	---	---
432	Pharmaceutical Product Development	3	80	20	---	---
433	Food and Cosmetics, Special Analytical Techniques	3	80	20	---	---
434	Quality Management	3	80	20	---	---
435	Quality Assurance Practical - III	12	---	---	80	20
436	Synopsis (Introduction To Dissertation)	---	80	20	---	---
437	Subject Seminar	---	---	---	---	100
	TOTAL		400	100	80	120

SUBJECT **: Biological Evaluation and Clinical Research**
SUBJECT CODE **: 431**
RATIONALE **:** In drug development, pre-clinical development is a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data is collected. The main goals of pre-clinical studies are to determine a product's ultimate safety profile. In drug development clinical study is also important to determine a product's ultimate safety profile on humans.
COURSE OBJECTIVES **:** To gain knowledge of the preclinical study of API and Formulations; Clinical research study for API and Formulations

LEARNING OUTCOMES **:** Knowledge about preclinical and clinical study, regulatory guidelines for conducting clinical trials and various immunological assay and bioassay.

PREREQUISITES **:** Basic knowledge about biological assay, Clinical research terminology.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
431	Biological Evaluation and Clinical Research	3	--	3	3	20	--	80	--	100

Contents:

1	Preclinical Drug Evaluation, acute, sub-acute and chronic toxicity, Evaluation of a compound For its biological activity, and ED 50 determination. Special toxicity tests like teratogenicity and mutagenicity	20
2	Pyrogens - chemistry and properties of bacterial Pyrogens and endotoxins, Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogens test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL & other pyrogens tests.	20
3	Clinical research- Clinical research protocol, objective and protocol design, Helsinki declaration, US FDA and ICH guideline for clinical trials for drugs and dosage forms, review and approval of clinical study, GCP, Schedule Y.	25
4	Immunological assays: RIA, ELISA, Immunoblotting, Immunofluorescence, and Immunoaffinity.	20
5	Bioassay _ pharmacological evaluation of drugs in biological fluids, general principle, Scope, limitation, bioassay of some official drugs digitalis, Ach.	15

SUBJECT **: Pharmaceutical Product Development**
SUBJECT CODE **: 432**
RATIONALE : Pharmaceutical product development deals with development of newer formulation over conventional formulations which have some problems like stability, pharmacokinetic problem.
COURSE OBJECTIVES **:** To acquire basic fundamental knowledge of new formulations like neosomes, liposomes, microspheres, nanoparticles and TDDS
Study of various basic aspects required for preparation of formulations like stability, solubility and preformulation parameters.
LEARNING OUTCOMES **:** Knowledge about newer formulation over conventional formulations like tablets, capsules.
Knowledge about pharmacokinetic models.
PREREQUISITES **:** Basic knowledge about formulation, Solid and liquid's physical properties, pharmacokinetic parameters.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
432	Pharmaceutical Product Development	3	--	3	3	20	--	80	--	100

432 Pharmaceutical Product Development

1.	Preformulation Studies : pKa and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristic, dissolution, compatibility studies, protocol for Preformulation studies.	25
2.	Drug stability: Solution stability, solid state stability, parameters for physical stability testing. Accelerated stability & shelf life assignment of drugs and pharmaceutical	25
3.	Solubilities and solubilization of drugs	10
4.	Pharmacokinetic modeling: two compartment model for IV and extravascular administration, multiple dosing regimens, statistical moment analysis	20
5.	Introduction to neosomes, liposomes, microspheres, nanoparticles and TDDS	20

SUBJECT **: Food and Cosmetics, Special Analytical Techniques**

SUBJECT CODE **: 433**

RATIONALE **:** To acquire knowledge regarding contaminants, trace elements, active ingredients in various food as well as cosmetic products. Various analytical instruments and method available for analysis of various contaminants, major active elements and trace elements. For the study of basic analytical techniques which are used for analysis of these elements

COURSE OBJECTIVES **:** Perform the analysis of major and minor food elements and cosmetics.
To study the regulation requirements for manufacturing and analysis of cosmetics
To learn basic aspects of selected analytical technique.

LEARNING OUTCOME **:** Knowledge of various regulatory aspects of cosmetics.
Knowledge of nutritional requirements at different stages and analysis of different content present in food.
Clarity of basic fundamental aspects of selected analytical technique.

PREREQUISITES **:** Basic knowledge about trace elements, cosmetics and food and its analytical techniques.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
433	Food and Cosmetics, Special Analytical Techniques	3	--	3	3	20	--	80	--	100

Contents:

1.	**Food products:** Concepts of nutritional requirements at different age, sex and in different conditions like normal, diseases, pregnancy etc. Different types of additives used. Regulatory aspects: Introduction, regulations and international standards related to food analysis, nutrition labeling, sampling and sample preparation, compositional analysis of food, chemical properties and characteristic of foods.	25
2.	**Cosmetics:** Information on ingredients used in various products such as creams, powders, lotions, hair products, nail polishes, lipsticks etc. Evaluation of cosmetic products. Regulatory aspects: General concepts and cosmetic legislation, main ingredients in cosmetics, analytical methods for monitoring and quality control, safety and efficacy evaluation.	25
3.	**Emission methods:** Spark emission and plasma emission, Instrumentation and application.	20
4.	**Laser:** Basic principles, classification, instrumentation and application.	15
5.	**Ion selective electrodes:** Classification, instrumentation and applications in drug analysis.	15

SUBJECT : Quality Management
SUBJECT CODE : 434
RATIONALE : For knowledge of basic requirement to set up pharmaceutical manufacturing unit. To get the knowledge of export import policy and requirement of outsourcing policy for the manufacturing of formulation
COURSE OBJECTIVES : To acquire knowledge regarding quality control; and quality management of manufacturing facility.
To have knowledge about current global scenario and requirement of manufacturing unit

LEARNING OUTCOMES : Knowledge of various procedures like export import, loan licenses, quality control, quality audit in the manufacturing unit as per current guidelines

PREREQUISITES : Basic knowledge of GMP, TQM

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
434	Quality Management	3	-	3	3	20	--	80	--	100

434 Quality Management

1.	Quality control laboratory, responsibilities, routine controls, instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, data generation and storage, quality control documentation, retention samples, records.	30
2.	Quality Audits: Raw Materials, Finished Products & Analytical Procedures.	20
3.	Distribution and distribution records. Handling of returned goods. Recovered materials and processing.	10
4.	Complaints and recalls, evaluation of complaints, recall procedures, related records and documents	10
5.	Waste disposal, scrap disposal procedures and records	10
6.	Loan licenses (contract manufacture)	10
7.	Globalization of drug industry. Introduction to export of drugs and import policy.	10

SUBJECT : Quality Assurance Practical - III
SUBJECT CODE : 435

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
435	Quality Assurance Practical - III	--	18	18	6	---	20	--	80	100

435 Quality Assurance Practical-III

Practical based on syllabus to give practical trainings to the students.
• Standard Operating Procedure report format.
• To measure the amount of iron in common foods by UV visible spectroscopy
• To perform calibration of UV spectrophotometer
• To perform the analysis of milk.
• To perform assay of chloramphenicol eye ointment by UV vis. spectroscopy as per IP'96
• Estimation of calcium in milk powder
• To carry out assay of Diltiazem Hydrochloride using ion pair extraction method
• Estimation of phosphorus in milk powder by colorimetric.
• To perform assay of losartan tablets by UV visible spectroscopy &first derivative Method
• To perform recovery study of Paracetamol tablets as per IP '96
• To perform the Hydrolytic resistance of Glass Containers for Injectable preparation
• To perform assay of Ketoconazole by UV visible spectroscopy from shampoo formulation
• To perform Zinc content from syrup formulation.
• To perform assay of **Ambroxol** Hydrochloride Tablets using by Spectrophotometric method
• To perform assay of Ascorbic acid in lemon and orange juice.
• To perform assay of Vitamin – C by Iodimetry.
• To identify the given sample of sugar with the help of ascending paper Chromatography and calculate R_f value.
• To perform assay of Ambroxol Hydrochloride by Potentiometer
• Estimation of ascorbic acid tablet using UV-Visible spectrophotometer
• Estimation of Ascorbic acid by titrimetry
• Extractive Spectrophotometric analysis of Amlodipine and methyl orange (ion pair colorimetry)
• Assay of Acetaminophen and Caffeine tablet by High Pressure Liquid Chromatography
• To study metal binding ratio of salicylic acid and Ferric chloride.
• Estimation of Pantoprazole by Thin Layer Chromatography
• To estimate Metformin Hydrochloride and Glibenclamide in a combination tablet by spectrophotometry
• To determine the concentration of copper using spectrophotometric titration.
• Simultaneous RP-HPLC method for estimation of Nimesulide & Diclofenac sodium
• To Perform HPLC method for determination of Paracetamol

BOOKS RECOMMDNED

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4. S. Suzanne Nielsen, Food analysis Springer science and business media, 3rd Edition, 2005.
5. Janet Gough, Hosting a compliance Audit, Davis Harwood International Publishing, Latest Edition
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11. K. Manoranjan, Food analysis and quality control, Kalyani publications, Latest Edition.
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15. S. C. Itakar, Pharmaceutical Management, Nirali Prakashan,Pune,1st Ed.,2006
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25. Marcel Dekker, Cosmetic analysis- Selective methods and Techniques, Latest Edition.
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28. S. C. Itakar, Pharmaceutical Management, Nirali Prakashan,Pune,1st Ed.,2006
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31. Brown (Marcel Dekker), Handbook of Polymer testing, by, Latest Edition.
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SUBJECT : Subject Seminar
SUBJECT CODE : 437

RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
437	Subject Seminar	6	-	6	3	-----	100	-----	-----	100

SPECIALISATION: PHARMACEUTICAL QUALITY ASSURANCE
SEMESTER-IV

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK	CREDITS
441	Dissertation (Project Work)	36	12
442	Viva- Voce	----	12

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	UNIVERSITY LEVEL EVALUATION
441	Dissertation	100
442	Viva- Voce	100
	TOTAL	200