GOAUNIVERSITY

P.O TALEIGAO PLATEAU

GOA – 403 206

SYLLABUS FOR M. PHARM (QUALITY ASSURANCE)

APPROVED BY THE BOARD OF STUDIES

FOR THE ACADEMIC YEAR **2014-2015**

PURPOSE

To train a Pharmacist who shall:

- Display talent and competence, backed by reasoning ability to achieve standards in manufacture of quality products in pharmaceutical industry and to lead a company towards achieving global standards through proper inprocess standards.
- Exercise a sense of power and confidence to focus attention on irregularities, errors, exceptions and deviations from standards.
- Articulate a compelling vision to the future by encouraging and implementing ideas, procedures and techniques by thinking out of the box.

PRE-REQUISITES

A candidate who has passed the B. Pharm. Examination of Goa University or an examination of any other Indian University recognized as equivalent thereto with at least **50%** marks in aggregate in one and the same sitting and with **GPAT (Or any other qualifying examination specified by AICTE/PCI/Govt. of Goa)** be admitted to the M. Pharm. Course (partly by papers and partly by thesis) in one of the specialization of Pharmacy mentioned below in which he registers as a post-graduate student. However, if the **GPAT** candidates are not available then the vacant seats shall be filled by admitting the candidates without **GPAT** but who have passed the **B. Pharm**. Examination with at least **50%** marks in aggregate in one and the same sitting.

GOA UNIVERSITY

Syllabus of M.PHARM (QUALITY ASSURANCE)

(2 years course)

SEMESTER I

Sr. No	Code	Subject	Hr/Semester 3hr/Week	Marks	
				Internal Examination	Final Examination
1	MP001T	Modern Pharmaceutical Analysis (Theory)	54	30	70
2	MPQA101T	Product Development-I (Theory)	54	30	70
3	MPQA102T	Quality Management (Theory)	54	30	70
4	MPQA103T	Validation (Theory)	54	30	70
5	MP001P	Modern Pharmaceutical Analysis (Practical)	72 (6 hr)	30	70 (6hr)
6	MPQA101P	Product Development-I (Practical)	72 (6 hr)	30	70 (6hr)
7	MP002	Seminar Evaluation including Journal Club	1hr/week	50	Nil
8	MP003	Entrepreneurship Management	2 hr/week	50	Nil
		TOTAL – 700		**280**	**420**

SEMESTER II

Sr. No	Code	Subject	Hr/ Semester 3hr/Week	Evaluation	
				Internal Examination	Final Examination
1	MPQA201T	Product Development- II (Theory)	54	30	70
2	MPQA202T	Documentation, Quality Appraisal & Quality Audits (Theory)	54	30	70
3	MP004T	Research Methodology (including Biostatistics& Computer Applications) (Theory)	54	30	70
4	MP005T	Drug Regulatory Affairs&Intellectual Property Rights (Theory)	54	30	70
5	MPQA201P	Product Development- II (Practical)	72 (6 hr)	30	70 (6hr)
6	MPQA202P	Documentation, Quality Appraisal & Quality Audits (Practical)	72 (6 hr)	30	70 (6hr)
7	MP006	Seminar Evaluation including Journal Club	1hr/week	50	Nil
8	MP007	Field Activity and Soft Skills	2hr/week	50	Nil
		TOTAL – 700		**280**	**420**

Scheme of Examination for Practicals

Sr. No.	Synopsis	Major Expt.	*Minor Expt.	Viva-voce	Total
1.	10	30	20	10	70

SEMESTER –III & IV

Dissertation	Marks
The examiners will jointly assign the mark for The allotment of marks shall be as under: 1. Methodology 2. Scientific Contents 3. Presentation / Communication 4 .Results & Discussion 5. References/Grammar 6. Viva -voce. **Total**	 25 50 50 50 25 50 **250**
Professional Training*	50

****A candidate shall be required to undergo professional training of four weeks in any industry/research centre/hospital /community pharmacy and submit a completion certificate along with a report for evaluation.***

SEMESTER - I

MODERN PHARMACEUTICAL ANALYSIS

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MP001T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 3 hr

Importance of the following analytical techniques to be elaborated along with their applications in Pharmaceutical Sciences

Sr. No	TOPICS	NUMBER OF HOURS
1	**UV-Visible Spectroscopy**: a) Theory of Interaction of Electromagnetic Radiation with matter and effects, Spectra of isolated Chromophores, Absorption spectrum and its application in qualitative and quantitative studies of drugs, Types of Shifts and their interpretation, Solvent and Substituent effects, b) Woodward-Fischer Rules in predicting absorption maxima in conjugated systems. c) Multicomponent analysis, Derivative spectroscopy,	**3** **1** **2**
2	**Infra-Red Spectroscopy**: a) Theory, Application of Hookes Law in predicting IR absorption frequencies, Force constant, Effect of Mechanical Coupling/ Interaction, Fermi Resonance on absorption frequency, b) Sample preparation and handling, FT-IR and ATR, c) Rules for IR spectra Interpretion, Interpreting spectra of organic compounds and study of spectra in pharmacopoeia, use of IR in polymorph studies.	**3** **2** **3**
3	**Nuclear Magnetic Resonance Spectroscopy:**	**3**

	a) ^{1}H NMR, Chemical Shift, Inductive effect, Anisotropic effect, δ scale, Spin-spin coupling, Use of Coupling Constant. b) Instrumentation – NMR spectrometer c) Principles of ^{13}C spectroscopy, Decoupling Techniques, Nuclear Overhauser Effect, Shift reagents, d) Introduction to 2-D NMR techniques e) Applications of NMR technique in Pharmaceutical and Chemical sciences – Fundamental rules for interpreting NMR spectra (Low resolution and High Resolution) with suitable examples	**1** **2** **1** **3**
Sr. No	**TOPICS**	**NUMBER OF HOURS**
4	**Mass spectrometry**: a) Theory and Principles, b) Instrumentation – Ionization sources – Hard and Soft techniques – their relative applications, Analyzers – Single and Double Focus, TOF, Quadrupole, FT-ICR, Ion Trap; Tandem Mass spectrometry, Detectors, c) Applications – Rules for interpreting Mass spectra with relevant examples.	**2** **4** **4**
5	**Optical Rotatory Dispersion**: Principle, plain curves, Cotton effect, Circular dichroism. Measurement of rotation angle in ORD and applications.	**2**
6	**X- Ray Crystallography**: Production of X-rays, X-Ray Diffractometer, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals, Interpretation of Diffraction patterns and applications of X-ray diffraction.	**3**
7	**Separation Science –Techniques of Chromatography and Electrophoresis:** **a) HPLC** - Liquid chromatography, Principles of separation in HPLC, Partition, Adsorption, Ion –pair, Ion exchange, Size exclusion, Supercritical, gel-permeation, flash chromatography; Bonded phase supports, Chiral columns, Criteria for Column and Mobile phase selection,Application of PDA detectors, System suitability, Peak resolution Derivatization techniques, , Applications- Techniques of Quantitative analysis by HPLC. FDA & ICH Guidelines, etc for System suitability & validation. a) **HPTLC** - Stationary phases and their selection, Detection methods – Densitometry, Applications of HPTLC. b) **Gas Chromatography**: Types, Plate theory and Rate theory, Van-Deemter equation, Column types and parameters, Resolution, Pharmacopoeial Stationary Phases, Carrier gases and their properties, Derivatization techniques, Programmed Temperature Gas Chromatography and Applications in solvent and volatile component analysis. c) **Capillary electrophoresis**: Introduction, methods and	**2** **1** **2** **1** **3** **1**

	Applications.	
8	**Hyphenated Techniques:** LC-MS and GC-MS, Instrumentation, Importance of Interface, ESI, APCI, APPI, Applications – Molecular weight determination, Structural Determination, Metabolite and herbicide detection techniques, Impurity profiling.	**2**
Sr. No	**TOPICS**	**NUMBER OF HOURS**
9	**Thermal Methods of Analysis:** Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).	**3**

References:

1. Willard, H.H., Merrit, L.L., Dean, J.A., Settle P.A., Instrumental Methods of Analysis, Van Nostrand.
2. Skoog, D.A., Heller, F.J., Nieman, T.A., Principles of Instrumental Analysis, WB Saunders.
3. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition.
4. Fundamentals of Mathematical Statistics, S.C. Gupta and V.K. Kapoor.
5. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson.
6. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition.
7. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
8. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
9. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
10. Organic Spectroscopy – William Kemp, 3rd Edition.
11. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Spectroscopy of Organic Compounds by P. S. Kalsi.

Journals:

1. Journal of Pharmaceutical Analysis (Elsevier)
2. Journal of Pharmaceutical and Biomedical Analysis (Elsevier)
3. Current Pharmaceutical Analysis (Bentham Science)
4. Journal of Chromatography A and B (Elsevier)
5. International Pharmaceutical Abstracts
6. Journal of Liquid Chromatography (Taylor and Francis)
7. Journal of Chromatography and Separation Techniques (OMICS)
8. Chromatographia (Springer)
9. Analytical Chemistry (ACS Journal)
10. Analytical and Bioanalytical Chemistry (Springer)
11. Journal of Analytical Chemistry (Springer)
12. Journal of Applied Spectroscopy (Springer)

Modern Pharmaceutical Analysis

(Practical)

Semester – I

Subject Code: MP001P

Periods/Week:-1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

List of Experiments

*A minimum of 18 Practical's (Exercises on both Quantitative, Qualitative analyses to be elaborated) shall be conducted from the topics covering **Spectroscopy** (UV, IR, NMR, Mass) and **Separations Science**.

Practical-1 to 2

Calibration of Analytical weighing Balance, UV-Visible spectrophotometer, FT-IR spectrometer, HPLC & HPTLC.

Calibration of Volumetric glassware.

Practical- 3

Plotting of UV/Visible spectrum - Scanning of a simple organic compounds for UV- absorption and correlation with structures

Isosbestic point detection in case of mixtures.

Practical-4 to 6

Effect of solvents and pH on UV spectrum of drugs

Study of Bathochromic and Hypsochromic Shifts, Calculation of Extinction coefficient/ Absorptivity (Qualitative Applications for characterization)

Practical-7 to 9

Estimation of multi component formulation by UV- Spectrophotometry in formulations and Drug mixtures

(Simultaneous equation Method, Absorbance Ratio Method)

Experiments based on the application of derivative spectroscopy.

Practical- 10 to 12

Experiments based on HPLC (Isocratic and Gradient elution) techniques.

- Single and multiple component analysis

- Separation analysis of degradation components
- Calculation of System Suitability Parameters

Practical- 13 to 14

Pharmacopoeial spectra interpretation (atleast 10) for correlation of structural features with absorption frequencies.

Practical- 15 to 17

Problems Solving: (UV, IR, NMR, Mass) structural elucidation of atleast three simple compounds with UV, IR, NMR and Mass spectral data.

Practical-18

Separation of amino acids by Paper chromatography

Practical-19

Separation of alkaloids by TLC/ HPTLC

Practical -20

Impurity profiling – Characterization and determination techniques – use of TLC,HPLC, IR spectroscopy, UV spectrometry to demonstrate presence of impurity and quantification.

Practical -21

Use of IR spectra and DSC curves to study Drug-Excipient interaction in Formulations.

Practical -22

Demonstration – Interpretation of XRD diffractograms.

REFERENCES:

1. Practical Pharmaceutical Chemistry, Part One and Two, A. H. Beckett & J. B. Stenlake – 4th Edition
2. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition.
3. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, DilipCharegaonkar, 2nd Edition.
4. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
5. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia.
6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition.
7. Practical HPLC method development by Lloyd R. Snyder, Joseph J. Kirkland, Joseph I. Glajch, John Wiley and Sons 2nd Edition.

PRODUCT DEVELOPMENT –I

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MPQA101T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Introduction and Perspective** Framework for product development.	1
2	**Preformulation Studies** a) Protocol, Physical-Chemical-Biological Characterization, b) Fundamental –Derived Properties, size-size distribution, surface area, crystal morphology-properties & influence, Solubility & pH solubility profile, Partition coefficient, pKa, drug permeation, dissolution, compatibility studies. c) Selection of excipients d) ICH Q8.	2 7 2 1
3	**Solubilization Techniques** Classification of drugs based on solubility (BCS).Formulation of poorly soluble drugs.	3
4	**Drug Stability** a) Solid state, solution phase physical stability testing, Stability testing general protocol, different stability, climatic zones, reference to regulatory requirements, India, WHO, USFDA, EMA, ICH guidelines [Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C], ASEAN, ANVISA guidelines. b) Kinetic principles applied for stability evaluation and their applications in predicting shelf life, accelerated stability study & shelf life assignment. c) Forced degradation studies.	5 2 1
5	**Tablet Technology** a) Formulation, manufacturing & evaluation, emphasis on unit processes b) Granulation technology, physics of tablet- compression & compression tooling, Advanced granulation techniques (direct compression, compaction, Hot Melt Extrusion)& multi process equipments- single pot, FBP c) Tablet defects & trouble shooting.	2 3 2
6	**Coating of solids & solid dosage forms**: a) Tablet film coating, Aqueous & Non-aqueous systems, polymers, mechanism film formation b) Auto coating equipments, Accelacota, Dria-coater, Glatt coater, Freund Hi coater etc., ancillary devices & gadgets including metering equipment c) Evaluation, film coating defects	2 2 1
Sr. No	**TOPICS**	**NUMBER OF HOURS**
	d) Particulate coating methods, extrusion, spheronization, pelletization. e) Trouble shooting.	1 1
7	**Liquid dosage forms**	

	a) Monophasic, biphasic, formulation development & evaluation, processing &equipments b) Microemulsions. c) Trouble shooting	2 1 1
8	**Semi Solid Dosage Forms** a) Advances in formulation development & evaluation b) Processing & equipment. c) Trouble shooting.	 2 1 1
9	**Sterile Dosage Forms** Formulation review, small volume, large volume, manufacturing facility-design considerations, environmental controls, processing, dry powder injectables-freeze drying	4
10	**Packaging development** a) Types of packages, Flexible packaging, primary, secondary & tertiary b) Quality evaluation as applicable to packages c) Child resistant, tamper evident, advancement in packaging	 2 1 1

REFERENCES:

1. Drug Stability, J.T. Carstensen, Marcel Dekker, New York.
2. Chemical Stability of Pharmaceuticals-A Handbook for Pharmacists, Kenneth Connors, John Wiley and Sons, Inc.
3. Lachmann, L., Lieberman, H.A. &Kanig, J.I.: The Theory and Practice of Industrial pharmacy. Lea and Fibiger, Philadelphia.
4. Banker, G.S. & Rhodes, C.T. : Modern Pharmaceutics, Marcel Dekker Inc. New York and Basel.
5. Turco, S. & King R.E. : Sterile Dosage Forms, Lea and Febiger, Philadelphia
6. Bean, H.S., Backett, A.H. & Carless, J.E: Advances in Pharmaceutical Sciences, Academic Press, London and New york.
7. Jain, N.K.: Controlled and Novel Drug Delivery , CBS, Delhi
8. Jain N. K. Pharmaceutical Product Development, CBS Publisher, Delhi
9. ICH Guideline
10. USP General Chapters

Journals:

1. International Journal of Pharmaceutics
2. International Journal of Pharmaceutical Sciences
3. Indian Journal of Pharmaceutical Sciences
4. Indian Drugs
5. Indian Journal of Pharmaceutical Education
6. Journal of Controlled Release
7. Asian Journal of Pharmaceutical Research
8. Research Journal of Pharmacy and Technolgy
9. Indian Journal of Pharmaceutical Education and Research
10. International Journal of Research in Pharmaceutical Sciences
11. Journal of Advanced Pharmaceutical Technology & Research (JAPTR)

PRODUCT DEVELOPMENT –I

(Practical)

Semester – I

Subject Code:MPQA101P

Periods/Week:-1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

***Minimum of 18 experiments shall be conducted**

Experiments based on following concepts:

1. Formulation of compressed tablets.
2. Evaluation of compressed tablets.
3. Formulation of topical preparations (Cream & Gel) .
4. Evaluation of topical preparations (Cream & Gel).
5. Formulation of oral liquids.
6. Evaluation of oral liquids..
7. Formulation of stable suspensions.
8. Evaluation of stable suspensions.
9. Formulation of dry suspensions.
10. Evaluation of dry suspensions.
11. Formulation of emulsions.
12. Evaluation of emulsions.
13. Formulation of small volume parenterals.
14. Evaluation of small volume parenterals.
15. Formulation of Injectable/ophthalmic preparations.
16. Evaluation of Injectable/ophthalmic preparations.
17. Assessment of stability studies according to ICH guidelines.
18. Evaluation of packaging materials.

REFERENCES:

1. Drug Stability, J.T. Carstensen, Marcel Dekker, New York.
2. Chemical Stability of Pharmaceuticals-A Handbook for Pharmacists, Kenneth Connors, John Wiley and Sons, Inc.
3. Lachmann, L., Lieberman, H.A. &Kanig, J.I.: The Theory and Practice of Industrial pharmacy. Lea and Fibiger, Philadelphia.
4. Banker, G.S. & Rhodes, C.T. : Modern Pharmaceutics, Marcel Dekker Inc. New York and Basel.
5. Turco, S. & King R.E. : Sterile Dosage Forms, Lea and Febiger, Philadelphia
6. Bean, H.S., Backett, A.H. & Carless, J.E: Advances in Pharmaceutical Sciences, Academic Press, London and New york.
7. Jain, N.K.: Controlled and Novel Drug Delivery , CBS, Delhi
8. Jain N. K. Pharmaceutical Product Development, CBS Publisher, Delhi

QUALITY MANAGEMENT

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MPQA102T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	a) Quality Management System and its importance to improve business performance. b) Quality Models in business, Six Sigma Concept, Six Sigma tools, Continuous improvements and its applications, Lean Concept for	2 3

	Process improvements. c) Introduction to statistical tools like Fish bone diagram, Process Flow diagram, Pareto analysis, 5why analysis, etc.,	2
2	(a) Change Controls: Types of change controls, Handling of change controls, Personnel to be involved, Impact assessments. (b) Incident Handling and Deviations,Corrective Actions and Preventive Actions	3 2
3	Personnel Training and its Evaluation, Development of Job responsibilities, Competency Matrix, RACI Matrix. Environmental monitoring. Control of contamination and cross contamination	2
4	Risk Analysis: ICH Q9, HACCP, FMEA, Principles of QbD.	4
5	1. Control on starting materials, Vendor approval and monitoring	3
6	Sampling Techniques, Sampling Plans	2
7	In- process quality control on various dosage forms- Sterile and non-sterile. Line clearances	2
8	Packaging and labeling controls,	2
9	Control on Finished Products. Regulatory requirements by different countries. ICH Q6A-Q6B, USP General Chapters on different test requirements (Disintegration, Dissolution, Uniformity of dosage units etc;) for control of different dosage forms (tablets, injections, transdermal etc;) and drug substances, vaccines, biotechnology products. Storage, handling and transportation	3
10	Quality Planning in Product Life cycle. Product Quality Life cycle implementation (PQLI). ISPE guideline. APQR	4
11	Good Practices in QC laboratory, Schedule L1, standardization of reagents, labeling of reagents, control samples, controls on animal house, data generation and storage, QC documentation, LIMS	4
12	Out of Trend and Out of specification handling and evaluation.	3
Sr. No	**TOPICS**	**NUMBER OF HOURS**
13	Good warehousing practices. Pest and rodent controls. Temperature mapping and monitoring of warehouses.	3
14	Environment Protection Act, Factories Act Waste disposal, disposal procedures and records, current regulations for waste disposal.	4
15	Technology Transfers	3
16	Complaints handling, Recall and recall procedures. Mock recalls.	3

REFERENCES:

1. Drugs & Cosmetics Act 1940 and rules there under.

2. Drugs Laws by Hussain.

3. Indian Patent Act.

4. Quality assurance & GLP by Y. Anjaneyulu.

5. Quality control & Application by Bentrand L. Hanser.

6. Guidelines of various countries like MCA, TGA, ICH.

7. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series

8. GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.

9. I.P., B.P., U.S.P. International Pharmacopoeia

VALIDATION

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MPQA103T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	(a) Introduction to Pharmaceutical validation definition, scope of validation, manufacturing process model, advantage of validation, organization for validation, ICH Q2. Validation Master Plan, User Requirement Specifications Technical Specifications, Design qualification, Factory Acceptance Tests, Site Acceptance Tests, Installation qualification, Operational qualification,	5

	Performance qualification. Requalification (b) Calibration of instruments. (c) USFDA, EMA, WHO Regulatory requirements on Process Validation and Method Validation. (d) Preparation of Protocols and reports	1 2 1
3	Facility Qualification and Area Qualification	2
4	HVAC System Qualification / Validation	4
5	Water System Qualification / Validation	4
7	Qualification of Compressed Air System and Pure Steam Generator	4
9	Performance Qualification of Sterilizing Equipment. Performance Qualification of Steam Sterilizers, Dry heat sterilizers, Dry heat sterilizer tunnels, ETO sterilizers and Gamma radiation sterilizers.	5
10	Cleaning Validation and validity, Equipment and Area cleaning and monitoring.	3
Sr. No	**TOPICS**	**NUMBER OF HOURS**
11	Process validation: prospective, concurrent, retrospective and revalidation. Process Validation of Solid Dosage Forms including Aerosols Process Validation of Liquid Dosage Forms Process Validation of Semisolid Dosage Forms Process validation of Sterile Products, Media Fills	**5** **2** **1** **1** **1**
12	Computer system Validation, Regulatory Guidelines.	**3**
13	Packaging Process validation	**2**
14	Analytical Method Validations, Analytical Method Transfers, Direct Transfers and Indirect Transfers. Microbiological Method Validations.	**4**
15	Product Transfers from Development lab, Site transfers of Products.	**2**
16	Process Analytical Technology (PAT).	**2**

REFERENCES:

1. Pharmaceutical Process Validation, B. T. Loftus and R. A. Nash, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., New York.
2. Validation of Aseptic Pharmaceutical Processes, Carleton and Agalloco, Marcel Dekker Inc., New York.
3. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries by Syed ImtiazHaider and Erfan Syed Asif
4. Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance, Second Edition by Guy Wingate

5. Pharmaceutical Process Scale-Up", Michael Levin, Drugs and Pharm. Sci. Series, Vol. 157, Marcel Dekker Inc., New York.
6. Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter
7. Process Validation in manufacturing of biopharmaceuticals: Guidelines – Anurag Singh Rathore, Gail Sofer, G. K. Sofer
8. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO

Journals:

1. Journal of pharmaceutical quality assurance
2. International Journal of Pharmaceutical Quality Assurance
3. The Quality Assurance Journal
4. Journal of Pharmaceutical Innovation (Springer)

ENTREPRENEURSHIP MANAGEMENT

(Theory: 36Hr – 18 weeks)

Semester - I

Subject Code: MP003 Sessional exam: 30

Period/Week :2hr Uni. Examination: 70

Examination : Theory (Internal) Exam Duration : 1hr

Course Objectives:

- To provide conceptual inputs regarding entrepreneurship management.
- To sensitize and motivate the students towards entrepreneurship management.
- To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.
- To develop management skills for entrepreneurship management.

Sr. No	TOPICS	NUMBER OF HOURS
1	**CONCEPTUAL FRAME WORK** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy Types of enterprise – Merits and Demerits An introduction to laws governing establishments like Factories Act, Shops and Establishment Act, Labour Act, etc; Government policies and schemes for enterprise development Institutional support in enterprise development and management	**5**
2	**THE ENTREPRENEUR** 4 hr Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding	**5**

	the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role	
3	**LAUNCHING AND ORGANISING AN ENTERPRISE** 5 hr Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	**6**
Sr. No	**TOPICS**	**NUMBER OF HOURS**
4	**GROWTH STRATEGIES AND NETWORKING** 4 hr Performance appraisal and assessment Profitability and control measures, demands and challenges Need for diversification Future Growth – Techniques of expansion and diversification, vision strategies Concept and dynamics Methods, Joint venture, co-ordination and feasibility study	**7**
5	**PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE** Project work – Feasibility report; Planning, resource mobilisation and implementation.	**6**
6	State owned industrial zones, SEZ, EOU, Bond Sale, High Sea Sales, Custom, Excise	**4**
7	Business Ethics	**3**

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

SEMESTER II

PRODUCT DEVELOPMENT – II

(Theory: 54 Hr – 18 weeks)

Semester - II

Subject Code: MPQA201T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1.	**DISSOLUTION TECHNOLOGY** a) Dissolution testing devices viz forced convection, non sink and sink devices, continuous flow through methods, effect of	3

	environmental factors during dissolution testing b) Dissolution test apparatus official-USP 1 to 7, Performance verification of Dissolution apparatus c) Disso testing of suspensions, topical and transdermal products, suppositories and controlled release products, recommended apparatus, in-vitro in-vivo correlations. Different Pharmacopoeia (Ph. Eu. JP) requirements on Dissolution, ICH Q4B.	1 2
2.	**CONCEPTS AND SYSTEMS DESIGN FOR RATE CONTROLLED DELIVERY** a) Rate pre-programmed, activation modulated and feed back regulated drug delivery systems. b) Effect of system parameters on controlled release drug delivery	3 3
3.	**ORAL 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-Gastro retentive	4
4.	**MUCOSAL DRUG DELIVERY SYSTEMS** a) Mechanism of transmucosal permeation and mucosal membrane models b) Buccal, Nasal, pulmonary, rectal and vaginal drug delivery systems, delivery of peptide based pharmaceutical.	4 2
5.	**OCULAR DELIVERY OF DRUGS** Ocular delivery of drugs-constraints, development of ocular controlled release therapeutic systems including sol-gel & gel-sol phase transition systems.	4
Sr. No	**TOPICS**	**NUMBER OF HOURS**
6.	**TRANSDERMAL DRUG DELIVERY** a) Permeation through skin, mechanistic analysis, permeation enhancers b) Technologies for developing transdermal drug delivery systems, gels, patches and evaluation there of.	2 2
7.	**PARENTERAL DRUG DELIVERY SYSTEMS** Injectable controlled released formulations, long acting contraceptive formulations, implantable drug delivery systems.	4
8.	**INTRAVAGINAL / INTRAUTERINE DRUG DELIVERY SYSTEMS** Design of devices, rational in design, Medicated IUDS, copper IUD, Homone releasing IUD.	4
9.	**SITE SPECIFIC DRUG DELIVERY** Active and passive targeting, monoclonal antibiodies for drug targeting, particulate carrier systems, microspheres, Liposomes, Niosomes.	4

10.	**NANOTECHNOLOGY AND NANOMEDICINES** Insight of Nanoparticulate drug delivery systems ,Fundamentals of Drug Nanoparticles, Manufacturing of Nanoparticles – Milling, Homogenization , Supercritical fluid Technology, Emulsion process, Characterization of Nanoparticles, Drug delivery applications of Nanoparticles, Clinical, Ethical & Regulatory issues.	4
11.	**CHRONOPHARMACEUTICAL DRUG DELIVERY SYSTEM** Introduction and basis of drug delivery. Approaches and Classification of Chronopharmaceutical DDS. Chronogenetics, Chronopharmacokinetics, Chronotherapy CR systems triggered by physical and/or chemical activation, Chronopharmacodynamics, chronomics.	4
12.	Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD.	4

BOOKS RECOMMENDED

1. P. Tyle and B. Ram, Targeted Therapeutic Systems, Marcel Dekker, N.Y., 1990.
2. N.K. Jain, Advances in Controlled and novel drug delivery, 2001, CBS, New Delhi.
3. Advanced Pharmaceutical Solids, Jens T Carstenson, Taylor& Francis.
4. J. R. Robinson & V.H.L. Lee (Eds), Controlled Drug Delivery, Fundamentals and applications, Vol 29 &Vol 31, 2nd Edition, Marcel Dekker, N.Y. 1987
5. International Journal of Pharmaceutical Sciences and Nanotechnology
6. Encyclopedia of Nanoscience and Nanotechnology (New 15-Volume Set)
7. Nanomedicine and Nanobiotechnology Editor- Logothetidis, Stergios
8. Chronopharmaceutics: Science and Technology for Biological Rhythm Guided Therapy and Prevention of Diseases By Bi-Botti C. Youan
9. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.
10. N.K. Jain, Pharmaceutical product development. CBS publication and distributors, New Delhi.
11. Novel drug delivery systems by Chien
12. Oral mucosal drug delivery by M J Rathbone

13. G.S. Banker and C.T.Rhodes, Modern Pharmaceutics, IInd edition, Marcel Dekker, INC, NewYork.
14. Specialized drug delivery systems by Praveen Tyle.
15. Pharmaceutical Dissolution Testing By UmeshBanakar

Journals:

1. International Journal of Pharmaceutics
2. International Journal of Pharmaceutical Sciences
3. Indian Journal of Pharmaceutical Sciences
4. Indian Drugs
5. Indian Journal of Pharmaceutical Education
6. Journal of Controlled Release
7. Asian Journal of Pharmaceutical Research
8. Research Journal of Pharmacy and Technolgy
9. International Journal of Biopharmaceutics
10. Biopharmaceutics & Drug Disposition
11. Drug Development and Industrial Pharmacy
12. Indian Journal of Pharmaceutical Education and Research
13. International Journal of Research in Pharmaceutical Sciences
14. Journal of Advanced Pharmaceutical Technology & Research (JAPTR)
15. Pharmaceutical Statistics

PRODUCT DEVELOPMENT II

(Practical)

Semester – II

Subject Code:MPQA201P

Periods/Week:-1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

1. Preparation of a SOLID DISPERSION - two methods
2. Evaluation of a SOLID DISPERSION - two methods
3. Preparation of a Transdermal patch.
4. Evaluation of a Transdermal patch.
5. Preparation of a topical Gel.
6. Evaluation of a topical Gel
7. Preparation of matrix SR Tablets
8. Evaluation of matrix SR Tablets
9. Preparation of Gastro Retentive Drug delivery System

10. Evaluation of Gastro Retentive Drug delivery System
11. Preparation of Microspheres
12. Evaluation of Microspheres
13. Preparation of a hydrodynamically balanced drug delivery system
14. Evaluation of a hydrodynamically balanced drug delivery system
15. Preparation of Buccal Patches
16. Evaluation of Buccal Patches

DOCUMENTATION, QUALITY APPRAISAL& QUALITY AUDITS

(Theory: 54 Hr – 18 weeks)

Semester - II

Subject Code: MPQA202T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	Regulatory affairs aspects that influence documentation requirements	5
2	Documentation related to a) Facilities, Location, Design, Plant layout, construction, b) Maintenance, sanitation, environmental control, utilities & services like gas, water, electricity c) Maintenance of sterile areas, control of contamination (Site Master File, Quality Manual)	 3 3 2
3	Good Documentation Practices, Document Format and Controls Documents & Records: a) Standard Operating Procedures: Preparation, Approvals, Control, distribution, review & revisions b) Log Books, c) Master Formulas d) Batch Manufacturing Records& Batch Packing Records e) Protocols, Reports f) Cleaning & Disinfection records g) Training Records Approvals, Control, retention, review and disposal of documents and records. QC Documents - Specifications- Raw Material, QC Reports, Stability Records, Record of Reference / Working Standards. Instruments/ Machine related records – IQ, OQ, PQ, calibration etc;	1 4 2 2 2
4	Electronic Data Management System	2
5	Risk management and mapping Overview of Risk management FMEA Risk identification, assessment ,prioritization and mitigation.	5

6	Audits and Self Inspection: Types of audits,Systemsaudit,Productaudit,Process audit, Audit of Drug Product manufacturing facility Audit of Drug substance manufacturing facility and ICH Q7	 3 1 1
Sr. No	**TOPICS**	**NUMBER OF HOURS**
	Audit of Excipients manufacturing facility and IPEC guidelines Audit of Packaging material manufacturing facility Audit report preparation Internal audits Audit Compliance report , Closure report Case Studies on audit observations	1 1 1 1 1 2 1
~~7~~	Quality Appraisal Standards for (a) Solid Dosage Forms (b) Semi Solid Dosage Forms (c) Sterile Dosage Forms	 4 3 3

BOOKS RECOMMENDED

1. Juran's Quality Handbook, 5th Ed, by J M Juran, A B Godfrey, McGrawHill International Edition
2. ISO 9001 and Total Quality Management – Sadhank. G. Ghosh.
3. A guide to Total Quality Management – KaushikMaitra and SedhanK.Ghosh.
4. ICH Guidelines, OECD Guidelines, 21 CFR Guidelines, MHRA Guidelines, WHO
5. Guidelines, D & C Act, DPCO Act
6. United States Pharmacopoeia, USP Convention Inc.
7. ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard, Sixth Edition: Using the standards as a framework for business improvement by David Hoyle

Journals:

1. International Journal of Pharmaceutics
2. International Journal of Pharmaceutical Sciences
3. Indian Journal of Pharmaceutical Sciences
4. Indian Drugs
5. Indian Journal of Pharmaceutical Education
6. Journal of Controlled Release
7. Asian Journal of Pharmaceutical Research
8. Research Journal of Pharmacy and Technolgy
9. Drug Development and Industrial Pharmacy
10. Indian Journal of Pharmaceutical Education and Research
11. International Journal of Research in Pharmaceutical Sciences
12. Journal of Advanced Pharmaceutical Technology & Research (JAPTR)
13. Pharmaceutical Statistics
14. Journal of pharmaceutical quality assurance
15. International Journal of Pharmaceutical Quality Assurance
16. The Quality Assurance Journal
17. Journal of Pharmaceutical Innovation (Springer

DOCUMENTATION, QUALITY APPRAISAL& QUALITY AUDITS

(Practical)

Semester – II

Subject Code:MPQA202P

Periods/Week:-1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

1. Sterility testing of devices/sterile products / immunological products.Test for microbiological screening of environment.
2. Analysis of pharmaceutical and cosmetic raw materials with the help of instruments.
3. Dissolution studies of solid dosage forms including calibration and validation. (2 experiments)
4. Stability testing of pharmaceutical dosage forms. (minimum three months)
5. Patch test for semi solid dosage forms. (subject to Animal Ethics Committee Clearance)
6. Evaluation of marketed cosmetic preparations like shampoo, creams, dentifrices, lipsticks etc.
7. Determination of LOD – API and excipients.
8. Testing containers, closures, liners, glass, plastics used for packing.
9. Microbiological limit test on excipients/non sterile products.
10. Test for effectiveness of preservatives.
11. Demonstration of statistical software's as applicable.
12. Preparation of SOP
13. Preparation of Protocols.
14. Case studies

RESEARCH METHODOLOGY
(including Biostatistics and Computer Applications)

(Theory: 54 Hr – 18 weeks)

Semester - II

Subject Code: MPP004T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
I	**Research Methodology**	
1	Introduction: Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research), Approaches to research, Criteria for good research, qualitative & quantitative research methods.	3
2	Literature survey: Using library, book and journals, online data bases like MEDLINE, Science direct, use of internet for procuring patents and reprints of articles as sources for literature survey	4
3	Methods and tools used in research: Selection of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work. Qualitative studies, quantitative studies. Simple data organization, descriptive data organization. Limitations and sources of errors. Enquiries in forms of questionnaire, opinionaire and interviews	6
4	Research report/paper writing/thesis writing / poster presentation: Different parts of research report or paper Title-title of project with authors name Abstract-statement of the problem, background list in brief, purpose and scope, Key words , Methodology-subject, apparatus/instrumentation and procedure. Results-tables, graphs, figures and statistical presentation Discussion-support or non-support to hypothesis. Practical and theoretical implications. Acknowledgements, References , Errata , Importance of spell check, Use of foot notes, Bibliography, referencing styles.	8
Sr. No	**TOPICS**	**NUMBER OF HOURS**
5	Principles of validity and reliability of research work, Ethical aspects of research methodology, special emphasis on plagiarism.	4
7	Cost analysis of the project Cost incurred on raw materials, Procedure, instrumentations	2
8	Industrial-institution interaction- Industrial projects, their, feasibility reports.	2
9	Writing projects for various funding agencies	2
II	**Biostatistics& Computer Applications**	
1	Introduction, Concept of Statistics in Quality Control (SQC), its role and uses. Collection, organization, measurement of central tendencies & dispersion; degree of freedom, standard deviation, standard error, Coefficient of variation, Probability, Sample and Sampling method.	4

	Process capability study. Statistical process control Charts.	
2	Estimation and Hypothesis testing: Null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student 't' test, Chi-Square test	4
3	Linear regression and Correlation: Analysis of variance (one way & two way), Factorial design	3
4	Brief review of non parametric tests, experimental design in clinical trials, statistical test for bioequivalence, Dose-Response study, statistical quality control; validation, optimization techniques & screening design, significance of coefficient of correlation, non-linear regression, Application of software for statistical calculations.	6
5	Designing and development of databases , information storage and retrieval, report Generation.	2
6	Statistical data Analysis using statistical software /Data Analysis Tool pack-MS Excel Descriptive statistics, Hypothesis Testing Regression and Correlation Formation of linear regression equation.	4

REFERENCES:

1. Research in education – John W. Best Jems V. Kahn
2. Research methodology – C. R. Kothari
3. Methodology and techniques of social research – Willkinson and Bhandarkar
4. Presentation skills – Michel Halton – Indian society for institute education
5. Practical introduction to copyrights – Gavin Mofariane
6. Thesis projects in sciences and engineering – Richard M. Devis
7. Scientist in legal system – Ann Labor Science
8. Thesis and assessment writing – Janolthon Anderson
9. Writing a technical paper – Donald Manzel
10. Effective business report writing – Lel and Brown
11. Protection of industrial property rights – Purshottam Das and Gokul Das
12. Spelling for millions – Edna Furmess

13. Preparation for publications – King Edwards hospital foundation for London
14. How to write and publish a scientific paper – Robert A. Day Cambridge University Press 4th Edition, 1994
15. Introduction to Statistical Methods- C. B. Gupta
16. A first course in Mathematical Statistics- C. E. Weatherborn
17. Introduction to Biostatistics-Mahajan
18. Experimental Pharmacology by S K Kulkarni.
19. Fundamentals of Science & Technology Communication – N R Rajagopal, NISCAIR (CSIR)

DRUG REGULATORY AFFAIRS&INTELLECTUAL PROPERTY RIGHTS

(Theory: 54Hr – 18 weeks)

Semester - II

Subject Code: MP005T Sessional exam: 30

Period/Week : 3 hr Uni. Examination: 70

Examination : Theory Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	Regulatory aspects that influence drug product design in India	2
2	Understanding of D&C Acts and rules, DPCO and NDPS and related laws with reference to license requirements for new drug development and approval, Import, manufacturing license, BE/CT approval. D&C Act: Schedule Y and related forms. D& C Act: Import and registration, Schedule D1 & D2.	5
3	Regulation in developed countries, USA, Europe, Australia, etc; e.g. NDA, ANDA, dossier filings Regulation in developing countries – Brazil, Asia Regulation controlling batch release, GMP, Quality systems Regulations and laws on Counterfeit products and Not of Standard Quality drug products ICH M4& M8: CTD structure and contents for dossier, granularity ACTD Requirements Module 1 of CTD requirements for EU, USA & ASEAN	5
4	Regulatory aspects applicable to bulk drugs manufacturing	2

5	Regulatory aspects applicable to packaging and medical devices	2
6	Product filing and responding to regulatory queries	2
7	Post approval procedures	2
8	Case Studies involving regulatory recalls	2
9	Other guidelines – ISO, WHO GMP, Pharmacopoeias, ICH Guidelines Q, S, E & M. Focusing impurities, stability, development, specifications.	2
10	Laws governing ethical practices, pre-clinical and clinical studies including OECD guidelines. Focusing on toxicological studies, good clinical practices, clinical trials, CTD, eCTD.	4
11	Laws governing neutraceuticals and dietary supplements	2
Sr. No	**TOPICS**	**NUMBER OF HOURS**
12	Laws governing alternative medicines (AYUSH)	4
13	Environmental regulations and laws governing Waste management	4
14	**PATENTS AND INTELLECTUAL PROPERTY RIGHTS (IPR)** Definition, scope, objectives, sources of patent information, patent processing & application, patents, copyrights, trademarks, salient features. Supplementary Protection Certificates (SPC), Patent term among different countries. Exclusivity: Implications of exclusivities, different types of Data Exclusivity in Europe, USA and Japan Market Exclusivity, Orange Book, compulsory licensing.	6
15	**GATT AND WTO** GATT – Historical perspective, objectives, fundamental principles, impact on developing countries. WTO – objectives, scope, functions, structure, status, membership & withdrawal, dispute settlement, impact on globalization, India – tasks & challenges. Hatch Waxmann Act, Trade related aspects (TRIPS), international & regional agreements, Indian Patent Laws, Commitment.	6
16	**Documents related to IPR** Protection of geographical indication of total intellectual rights	2
17	Case Studies on Patents (Neem, Turmeric, Basmati, drug cases, etc;)	2

REFERENCES:

1. Good manufacturing practices for pharmaceuticals, SH Willing, Vol. 78, Marcel Dekker, NY.

2. Protection of industrial property rights, P Das and Gokul Das.

3. Law and drugs, las Publ. S.N. Katju

4. Original laws published by Govt. of India

5. Laws of drugs in India, Hussain

6. New drug approval process, RA Guarino, Vol 100, Marcel Dekker, NY

7. Fda.org.wipo.int.patentlawlinks.com, hc-sc.gc, inch.org.cder.org.

8. WIPO website.

Field Activity & Soft Skills

Semester – II

Subject Code: Sessional exam: 50

Period/Week :2hr

Examination: Internal

A) Field Activity

Involvement in celebration of days of importance, Participation in CEP/Seminar/Conference, Health camps, Blood donation camps and such community centric activities.

Field surveys on drug, disease and social and health management.

Fund raising /Application for grants/ Project submission Indian funding agencies Application to foreign Universities.

Visit to research centres, NGO's, effluent treatment plants, forest department, etc;

B) Soft Skills

1. ETIQUETTE & ETHICS ON THE JOB

Understanding Body Language, Social & Business Etiquette, Netiquette Communication Ethics.

Telephone/Mobile Etiquette

2. GROUP DISCUSSION SKILLS & SPOKEN ENGLISH

Interacting and working in a group.

Analyzing a case study working in a Group & presenting a Case Study.

3. PRESENTATION SKILLS

Essentials of Effective Presentation Oral skills in Presentation, Putting together PowerPoint Presentations use of Laptops, LCD, Multimedia.

Writing resume, preparation for interviews.