IKG PUNJAB TECHNICAL UNIVERSITY, JALANDHAR
M. Pharm. (QUALITY ASSURANCE)
Scheme and Syllabus

FIRST SEMESTER

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Exam. (hr)	Credit
			L	T	P	Int	Ext	Total		
01	PHCQA 131	Pharmaceutical Analytical Techniques	4	1	-	20	80	100	3	5
02	PHCQA 133	Process Validation	4	1	-	20	80	100	3	5
03	PHCQA 135	Product Development	4	1	-	20	80	100	3	5
04	PHCQA 137	Quality Assurance Laboratory-I	-	-	14	20	80	100	8	7
		Total	12	03	14	80	320	400		22

SECOND SEMESTER

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Exam. (hr)	Credit
			L	T	P	Int	Ext	Total		
01	PHCQA 132	Biological Evaluation Techniques	4	1	-	20	80	100	3	5
02	PHCQA 134	Drug Regulatory Aspects & Intellectual Property Rights	4	1	-	20	80	100	3	5
03	PHCQA 136	Pharmaceutical Technology	4	1	-	20	80	100	3	5
04	PHCQA 138	Quality Assurance Laboratory-II	-		14	20	80	100	8	7
		Total	12	03	14	80	320	400		22

THIRD AND FOURTH SEMESTER [Credits 12+12=24]

Research Work for one year
The thesis shall be presented by the candidate at the end of record academic year
The thesis shall be evaluated as under:
Evaluation of written thesis : MM 200
Presentation of seminar on thesis : MM 100 and viva-voce
Total : 300 marks
[Note: L- Lecture – Tutorial, P – Practical]

M. PHARM. (Quality Assurance) SEMESTER-I

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
01	PHCQA 131	Pharmaceutical Analytical Techniques	4	1	-	20	80	100	5

Module 01

UV-Visible Spectroscopy: Introduction, Energy level, choice of solvent and solvent effects and modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward – Fieser rule, Fieser Kuhn and Nelson rules, influence of substituent for calculating absorption maximum, Photometric titrations and its applications.

Flame Emission Spectrometry and Atomic Absorption Spectroscopy: Principle, instrumentation, interferences and applications in Pharmacy.

Module 02

Spectrofluorimetry : Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications in Pharmacy.

Infrared Spectroscopy: Introduction, types of vibrations, characteristics regions of the spectrum, influence of substituent, ring size, hydrogen bonding, vibrational coupling, field effects on frequency, methodology, spectral interpretation with examples, Quantitative IR Applications. FTIR theory & applications.

Module 03

Nuclear Magnetic Resonance Spectroscopy: Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, DEPT, APT, NOE, NOESY, COSY, INADEQUATE and applications in Pharmacy, interpretation of spectra, ^{13}C NMR-Introduction, Natural abundance, ^{13}C NMR Spectra and its structural applications.

Module 04

Mass Spectromery: Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, LC-MS, interpretation of spectra and applications in Pharmacy.

Module 05

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)

X-Ray Diffraction Methods: Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications

Radiochemical Analysis: Instruments used - analytical and screening instruments, isotopic dilution, neutron activation, and Positron Emission Tomography (PET).

Module 06

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange & ion pair chromatography, column chromatography and affinity chromatography, chiral chromatography, size exclusion – techniques and applications.

Gas Chromatography: Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.

High Performance Liquid Chromatography: Principle, instrumentation, solvents used elution techniques, RP-HPLC, LC-MS and applications in Pharmacy.

HPTLC and Super Critical Fluid Chromatography (SFC): Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

Reading Material Recommended

1. Spectrometric identification of Organic Compounds, Robert M Silverstein, 6th Edition, Wiley & Sons Publication.
2. Principles of Instrumental Analysis, Donglass A Skoog, Holler, Nieman, 5th edition, Thomson & Brooks Cole Publication.
3. Instrumental Methods of Analysis, Hobert H. Willard, 7th edition, CBS Publication.
4. Analytical Chemistry, Gary D. Christian, 6th edition, Wiley & Sons Publication.
5. Practical Pharmaceutical Chemistry, Volume I & II, A. H. Beckett, J. B. Stenlake, 4th edition, CBS Publications.
6. Fundamentals of Analytical chemistry, Skoog, west, holler and crouch, 8th edition, Thomson & Brooks Cole Publication.
7. Instrumental Methods of Chemical Analysis, B. K. Sharma, 9th edition, Goel Publication.
8. Organic Spectroscopy, William Kemp, 3rd edition, Palgrave Publication.
9. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, P D Sethi, Dilip Charegaonkar, 2nd edition, CBS Publication.

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
02	PHCQA 133	Process Validation	4	1	-	20	80	100	5

Module 01

Concepts of validation, types of validation, validation & calibration of manufacturing instruments and analytical equipments. Re-validation of validation processes and scale-up and post approval changes (SUPAC)

Module 02

Process validation of pharmaceutical ingredients and production of pharmaceuticals. Validation of Sterilization processes, Biotechnological processes, Transdermal processes, Lyophillization processes and Inhalation aerosols.

Module 03

Equipment and facility qualification, Qualification of water and air handling system. Analytical method validation & its parameters.

Module 04

Packaging validation and Computer system validation. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing.

Module 05 and 06

Biostatistics & its applications in research: Introduction, significance of statistical methods, normal distribution, probability, degree of freedom, standard deviation, correlation & regression coefficient, coefficient of determination, variance, reliability of results, confidence interval, Test for statistical significance – students T-test, F-test, Chi-square test, correlation and regression, analysis of variance (ANOVA), least square methods. Application of statistics in pharmaceutical technology, statistical quality control and control of analytical methods. Biostatics and statistics in clinical research.

Reading Material Recommended

1. Quality Assurance & Quality Management in Pharmaceutical Industry, Y. Anjaneyulu, R. Marayya, Pharma Book Syndicate.
2. Pharmaceutical Process Validation, B. T. Loftus & R. A. Nash, Drugs and Pharm Sci. Series, Vol. 23, 3rd edition, Marcel Dekker Inc.
3. Pharamaceutical Statistics : Practical & Clinical Applications, S. Bolton, Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc.
4. Pharmaceutical Product Development, N K Jain, CBS Publication.
5. United States Pharmacopoeia, USP Convention Inc.

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
03	PHCQA 135	Product Development	4	1	-	20	80	100	5

Module 01 and Module 02

Liquid Dosage forms: Formulation, stabilization and evaluation of liquid dosage forms including suspensions and emulsions, Processing and equipments used in manufacture.

Concepts and Systems design for Rate controlled Delivery: Fundamentals of Controlled Release (CR) Drug Delivery: Rationale of sustained/controlled drug delivery; Physicochemical and biological factors influencing design and performance of CR products, therapeutic status of CDDS. Theory of mass transfer; Fick's first and second laws and their applications in drug release and permeation, Pharmacokinetic/ pharmacodynamic basis of controlled drug delivery; bioavailability assessment of CR systems.

Design and Fabrication of Technology based CR Systems

Module 03

Strategies and design of oral controlled release delivery systems, oral systems based on dissolution, diffusion and dissolution, ion-exchange resins, pH-independent formulations, altered density formulations. Bucco/mucoadhesive systems.

Module 04

Parenteral systems, biopharmaceutic considerations, design and development, polymeric microspheres, dispersed drug delivery.

Implantable therapeutic systems, biocompatibility of polymers and carriers; Intrauterine devices and intravaginal devices.

Module 05

Transdermal therapeutic systems (TTS): Drug absorption through skin, permeation enhancers, basic components of TTS, approaches to development and kinetic evaluation, Testing of transdermal patches, pressure sensitive adhesives; iontophoresis, sonophoresis and electroporation.

Novel ocular drug delivery systems: Ocular therapeutics and constraints to effective delivery, formulation considerations to improve the ocular bioavailability, ocular inserts including insoluble and soluble inserts, non-corneal routes and their use for systemic drug delivery.

Module 06

Colloidal and supramolecular delivery systems: Introduction to Liposomes, Nanoparticles and Microspheres: Method of preparation, Characterization and pharmaceutical applications. Active and passive targeting.

Drug Approval and preparation of documents.

Reading Material Recommended

1. Advanced Pharmaceutical Solids, Jens T Carstenson, Taylor & Francis.
2. Pharmaceutical Product Development, N K Jain, CBS Publication.
3. 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.
4. Y.W. Chien (Ed.), Transdermal Controlled Systemic Medications, Marcel Dekker, N.Y. 1987.
5. S.D. Bruck, Controlled Drug Delivery, Vol.1 (Basic Concepts) CRC Press. Florida, 1983.
6. S.D. Bruck, Controlled Drug Delivery, Vol. II (Clinical Applications) CRC Press. Florida, 1983.
7. L.F. Prescot and W.S. Nimmo, Novel Drug and its Therapeutic Applications, John Willy and Sons Chichester (1990).
8. Targeted and controlled drug delivery by S. P. Vyas and R. K. Khar,2001
9. N.K. Jain, Controlled and novel drug delivery, 1997, CBs, New Delhi.
10. N.K. Jain, Advances in Controlled and novel drug delivery, 2001, CBS, New Delhi.

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
04	PHCQA 137	Quality Assurance Laboratory-I	-		14	20	80	100	7

1. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (at least for 4 compounds each).
2. Calibration and Validation of all the equipments studied in theory such as UV-Visible, IR, Spectrofluorimeter, HPLC, GC, HPTLC, Validation of Autoclave, AHU, Hot air Oven, Machinery related to Pharmaceutical technology, etc.
3. Preparations and evaluation of various novel drug delivery systems & liquid dosage forms.
4. Determination of various analytical method validation parameters for any pharmacopoeial compound.

M. PHARM. (Quality Assurance) SEMESTER-II

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
01	PHCQA 132	Biological Evaluation Techniques	4	1	-	20	80	100	5

Module 01

Microbiological limit tests. Sterility tests: Methodology & Interpretation

Module 02

Tests for effectiveness of antimicrobial preservatives. Preclinical Drug Evaluation acute (LD_{50}), Subacute & chronic toxicity, Evaluation of a Compound for its biological activity and ED_{50} determination, special toxicity tests like teratogenecity and mutagenecity, clinical trials.

Module 03

Biological standardisation: General principles, scope and limitations of bioassay, Bioassays of some official drugs and vaccines.

Radioimmunoassay: General principles, scope and limitation. Radioimmunoassay of some drugs like insulin, digitalis etc.

Module 04

Pyrogens-Production, chemistry and properties of bacterial pyrogens and endotoxins, Mechanism of action of pyrogens, Pharmaceuticals aspects, Pyrogen test of IP compared to that of BP & USP, Interpretation of data, comparison of LAL & official pyrogen tests.

General methods regarding microbial counts, bio-burden &other related determinations.

Module 05 and 06

Analysis of drugs/metabolites in biological fluids like urine, blood and tissues, analysis (Bio-analytical methods). Design and analysis of bioequivalence trials, Crossover designs, bioavailability of oral and non-oral dosage forms, statistical analysis of bioavailability and bioequivalence, pharmacodynamic models, Federal perspectives.

Biochemical analysis of drugs, estimation of enzymes and other endogenous materials.

Reading Material Recommended

1. United States Pharmacopoeia, USP Convention Inc.
2. Indian Pharmacopoeia, Vol. I and Vol. II, The Controller of Publications, Govt. of India.
3. British Pharmacopoeia, Scottish Home & Health Department.
4. ICH guideline for impurity determination and stability studies.
5. Vogel's Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
02	PHCQA 134	Drug Regulatory Aspects & Intellectual Property Rights	4	1	-	20	80	100	5

Module 01

cGMP: Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of raw materials and drug product & finished product release, container and closures.

Module 02

GLP: Current GLP in manufacturing, responsibilities. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, control of records and reports, Non-clinical testing, Controls on animal house, Application of Computers (ERP systems or SAP technology) in Quality control Laboratory. (As per different guidelines)

Module 03

Documentation: SOPs & protocols for various operations, production and process, packaging and labeling, warehousing, IPQC, Finished product release, Quality review, Quality audit, Audits of quality control facilities, Batch release documents, Distribution and distribution records, Recovered materials and reprocessing, retention sample shandling of returned goods, Complaints and recalls, evaluation of complaints, recall procedures, related records and documents, Waste disposal, scrap disposal producers and records, Loan license (contract manufacture) audits.

Module 04

Recent amendments to Drugs and Cosmetics Act and other relevant rules, Consumer protection Environmental Protection Act, Certification and licensing procedures.

Industrial safety: Industrial hazards due to fire, chemicals, pharmaceuticals, radiation and accidents - mechanical and electrical equipments. Monitoring and prevention systems, Industrial effluent testing.

Drugs Prices Control Order & New Drug Policy

Module 05

Basic Concepts of TQM and ISO 9000 series.

WHO certification, Globalization of drug industry, Introduction to export of drugs and import policy.

Drug Regulatory Affairs: Harmonization of regulatory requirements including ICH guidelines, regulatory requirements of different regions applicable to pharmaceutical developments, bulk manufacturing, quality control on finished products. Filing of INDA, NDA and ANDA for approval and registration. Review and comparison of each guidelines such as OECD, MHRA, WHO, FDA, ICH etc.

Module 06

Clinical trials, GCP & Pharmacovigilance.

Intellectual Property Rights: Concept and fundamentals of IPR, Need and economic importance of IPR, Detail description of various IP Properties, IPR with emphasis on patent regime, registration of patent in India, US and Europe, International registration of patents, factors affecting IP protection, Penalties for violation or infringement, Trade related aspects of IPR. Concepts behind GATT, WTO, TRIPS, TRIMS and GATS.

Reading Material Recommended

1. Good Manufacturing Practices for Pharmaceuticals, S. H. Willig, M. M. Tuckerman and W. S. Hitchings, Drugs and Pharm. Sci. Series, Vol. 16, 5th edition, Marcel Dekker Inc.
2. Good Laboratory Practices, Sandy Weinberg, Drugs and Pharm. Sci. Series, Vol. 129, 3th edition, Marcel Dekker Inc.
3. Quality Assurance & Quality Management in Pharmaceutical Industry, Y. Anjaneyulu, R. Marayya, Pharma Book Syndicate.
4. Law Relating to IPR, M. K. Bhandari, Central Law Publication.
5. Pharmaceutical Product Development, N K Jain, CBS Publication.
6. United States Pharmacopoeia, USP Convention Inc.
7. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
8. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
9. ICH Guidelines, OECD Guidelines, 21 CFR Guidelines, MHRA Guidelines, WHO Guidelines, D & C Act, DPCO Act.
10. www.uspto.gov, ep.espacenet.com, www.patentoffice.nic.in, www.wipo.org

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
03	PHCQA 136	Pharmaceutical Technology	4	1	-	20	80	100	5

Module 01

Pre-formulation Studies: pKa and solubility, kinetic pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristics, dissolution, compatibility studies, protocol for pre-formulation studies.

Solubilisation Techniques: Determination of solubility, solubility parameters, methods of solubilization including addition of co-solvent, surface active agents, complexation, dielectric constant, hydrotrophy, chemical modification.

Module 02

Drug stability: solution stability, solid state stability, parameters for physical stability testing, Accelerated studies and shelf life assignment Degradation Kinetics Studies.

Dissolution Technology: Dissolution testing devices viz forced convection, non sink and sink devices, continuous flow through methods, effect of environmental factors during dissolution testing, dissolution rate test apparatus for suspensions, topical and transdermal products and controlled release products, in-vitro-in-vivo correlations (IVIVC).

Module 03

Improved tablet production and coating systems: Benefits, process design considerations; Tablet production equipment, layout and design of facilities, materials flow, quality assurance procedures including in-process quality control, construction, equipment and environmental considerations, Advances in coating process, fluid-bed coating, particle coating.

Module 04

Processing of parenteral and related sterile products: Manufacturing including various aspects of preparing SVP solutions, suspensions, powders/ freeze dried powders for reconstitution, filling, sealing, inspection and labeling, raw materials include water, stability. Environmental factors in the design of parenteral production facilities.

Capsulation Technology: Hard gelatin capsules: Development of hard geletin capsules as a dosage form. Manufacturing process and material used in the shell and the steps used in its manufacturing such as sorting, printing, size and shapes, sealing and self locking closures. Different materials used for automatic filling based on auger, vibratory and piston tamp fill (Dosing Disk and Dosator Machines) principles. General considerations in the design of hard gelatin capsule for formulations, storage, packaging and stability consideration.Soft gelatin capsules: General considerations of the

development of soft gelatin capsules as a dosage form composition of shell, formulation strategies and carriers of the drug used & their manufacturing devices.

Module 05 and 06

Packaging Materials and its regulations

Glass, Plastic and metal containers for Pharmaceuticals: Glass types, their manufacture, chemical performance, testing and quality control. Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties; Additives and fabrication processes. Plastic container for parentrals and transfusion sterile drip kits. Quality control testing and biological toxicity. Aluminium and timplate, Drums, collapsible tubes and Aerosol containers, Lacquering, coating and lining.

Paper and paper board: Types of paper, folding cartons, quality control testing of paper and paper board. Corrugated and solid fibre boards and boxes and type of corrugation methods, Labels and labelling, types of labels, adhesives, inject and bar coding.

Caps and Closures: Types caps closure liners, child resistant caps. Elastomeric closures for parenterals, classification of elastomers, physical, chemical and biological properties and their quality control. Tamper evident packaging systems.

Flexible Packaging and Packaging Machinery.

Product-Package compatibility and Transit worthiness of package. Cosmetics Preparations and evaluation

Reading Material Recommended

1. A Martin, Physical Pharmacy, 3rd Edition. B. I. Waverly Pvt. Ltd., New Delhi, India 1995.
2. Pharmaceutical dosage forms Lachman et al.,: Tablets, volume I,II,III.
3. Pharmaceutical dosage forms Lachman et al. : Parenterals, volume I,II.
4. Remington, Science and practice of Pharmacy, Vol.1, 2000, Lippincot williams and wilkins.
5. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.
6. N.K. Jain, Pharmaceutical product development. CBS publication and distributors, New Delhi.
7. G.S. Banker and C.T.Rhodes, Modern Pharmaceutics, IInd edition, Marcel Dekker, INC, NewYork.
8. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
10. Good and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G. Hardman, Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., 2006.

S. No.	Subject Code	Subject Title	Teaching Load Allocation			Marks Distribution			Credit
			L	T	P	Int	Ext	Total	
04	PHCQA 138	Quality Assurance Laboratory-II	-	-	14	20	80	100	7

1. Microbiological limit tests & Sterility testing, Pyrogen testing
2. Determination of analytes in biological fluids.
3. LD_{50} and ED_{50} determination.
4. Bioassays of some official drugs and vaccines.
5. Drafting of patent & SOPs & Protocol preparation
6. To perform pre-formulation studies & to perform stability studies.
7. Pharmacopoeial methods for quality control testing of glass, metal, plastic containers & quality control testing of papers and corrugated boxes.
8. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.

THIRD AND FOURTH SEMESTER [Credits 12+12=24]

Research Work for one year
The thesis shall be presented by the candidate at the end of record academic year
The thesis shall be evaluated as under:
Evaluation of written thesis : MM 200
Presentation of seminar on thesis : MM 100 and viva-voce
Total : 300 marks