Department of Higher Education, Govt. of M.P.

Post graduate semester wise syllabus

As recommended by Central Board of studies and approved by the governor of M. P.

उच्च शिक्षा विभाग, मध्यप्रदेश शासन

स्नातकोत्तर कक्षाओं के लिए सेमेस्टर अनुसार पाठ्यक्रम

केन्द्रीय अध्ययन मण्डल द्वारा अनुशंसित तथा म. प्र. के राज्यपाल द्वारा अनुमोदित

Session (सत्र) - 2015-16

Scheme of Marks

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management

(P.G.D.P.Q.C.Q.A.M.)

SEMESTER- I

Paper	Comp/ Opt	Paper Title	Code (MCH)	Max. Marks
I	Compulsory	General Pharmaceutical Laws and Guidelines	101	70+30 (CCE) = 100
II	Compulsory	IPR, Patents and ICH Guidelines	102	70+30 (CCE) = 100
III	Compulsory	Information Systems in industry	103	70+30 (CCE) = 100
IV	Compulsory	Documentation and Planning in pharma industry	104	70+30 (CCE) = 100
V	Compulsory	Quality Management Systems	105	70+30 (CCE) = 100
		TOTAL		**500**

Govt. Madhav Science P.G. College, Ujjain

Syllabus

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Semester 1

Paper-101 General Pharmaceutical Laws and Guidelines

U. S. Federal Food & Drugs Laws-
Historical Perspective Function and Organization of the FDA
Laws Governing Evaluation of New Drug Products
Law Covering Preparation and Distribution of Existing Products

U.S. Legal Agencies Involved with Manufacturing of Pharmaceutical Products
Occupational Safety and Health Administration (OSHA)
Environmental Protection Agency (EPA)
Maximum Allowable Cost (MAC)

WHO Guidelines
Introduction
Essential Drugs and medicine Policy
Counterfeit drugs Guidelines
Effective Drug Regulation
Regulatory Assessment of medicinal products for use in self-medication
Who Model System SIAMED – Computer Assisted Drug Registration
National Regulatory Policy
Review of international conference of Drug Regulatory Authorities (ICDRA)
WHO Certification Scheme on the Quality of Pharmaceutical
Product Moving in International Commerce
Exchange of Drug Regulatory Information
Pharmacovigilance
WHO Programme for International Drug Monitoring

7/7/15

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-102 IPR, Patents and ICH Guidelines

International conference on harmonization (ICH) Guidelines

I. Quality Topics
Stability testing
Photo stability testing of new drug substances and products
Validation of analytical procedures
Impurities in new drug substances
II. Safety Topics
Carcinogenicity studies of pharmaceuticals
Toxicity and Pharmacokinetic studies
III.Efficasy Topics
Preclinical safety Evaluation of biotechnology-Derived pharmaceuticals
Medical dictionary for regulatory Activities (MEDDRA)

Patents and Other intellectual Property rights in drug delivery

History of intellectual property
IPR in India
Patents Act
What is a copyright?
Trademark

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-103 Information Systems in industry

Data transfer and Data Bases

Introduction
Local Networking
Spread Sheet
Remote Access
Local Networking
Databases
Internet as a source of Pharmaceutical Information

Industrial Documentation

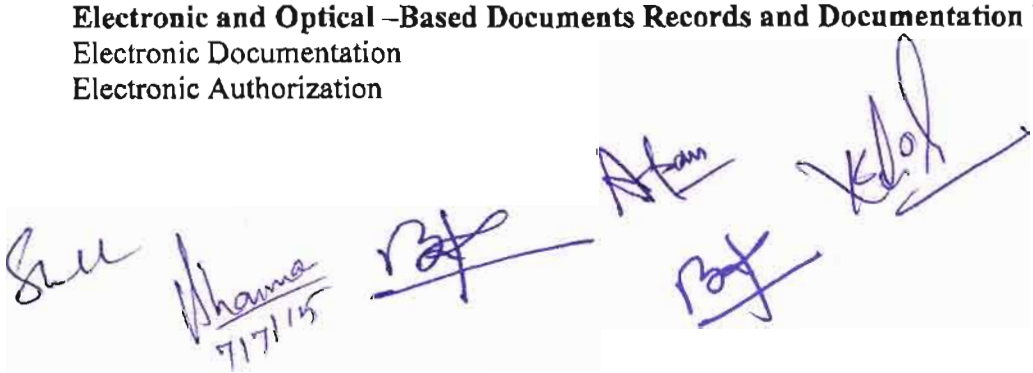
Documentation and Information Management
Pharmaceutical information Systems
Electronic Submissions
File Format for Electronic Documents
File Format for electronic Datasets
Procedures for sending electronic Submissions for archive
Preparation of the media for Electronic Submissions for Archive
Procedure for Processing Electronic Submissions for archive

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-104 Documentation and Planning in pharma industry

Document Management in Pharmaceutical Industry
Documentation and Document Systems
Document Organization Purpose
Quality Documentation
Quality Assurance
Document System Basics
Document Systems

Planning Documents: Master Plans and Work Plans
The Planning Process
Master plan format and Content
Plan Management
Regulatory Submission Documents
What Documents
Format and Content
Submission Processing Control
Document Management
Files and Archives
Electronic and Optical –Based Documents Records and Documentation Practices
Electronic Documentation
Electronic Authorization



Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-105 Quality Management Systems

Quality Management Systems
Introduction
International Organization for Standards
Quality Management in the pharmaceutical Industry: Guidelines
Quality Assurance
Sanitation and Hygiene
Qualification and Validation
Product Recalls
Self-Inspection and Quality Audits
Personnel, Premises, Equipment, Materials and Documentation
Good Practices in Production
Process Quality Control and Quality Audits
In process quality control
Sterile preparations
Non-sterile preparations
Quality control of capsules
Liquid Formulations for Internal Use
Liquids for External Use
Quality Control of Emulsions, Suspensions and Ointments
Objectives of Auditing
Mechanisms of Auditing
Standard Operating Procedures for auditing
Gap analysis and Corrective Action System
Analytical Methods Quality Auditing
Standard Operating Procedures
Process Design and Process Control Fundamentals
Process Design
Draft and Procedure
Process Control
Sop Content
Sop Format Management

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Session (सत्र) - 2015-16

Scheme of Marks

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management

(P.G.D.P.Q.C.Q.A.M.)

SEMESTER- II

Paper	Comp/ Opt	Paper Title	Code (MCH)	Max. Marks
I	Compulsory	Principles & Practice of Pharmaceutical Management	201	70+30 (CCE) = 100
II	Compulsory	Quality Requirement – Job Responsibility of Quality Control Department	202	70+30 (CCE) = 100
III	Compulsory	Functions of quality control department	203	70+30 (CCE) = 100
IV	Compulsory	GMP and Quality Control	204	70+30 (CCE) = 100
V	Compulsory	ISO-9000 and Evaluation of Packing Material	205	70+30 (CCE) = 100
		TOTAL		**500**

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
II Year Course

Semester II

Paper-201 Principles & Practice of Pharmaceutical Management

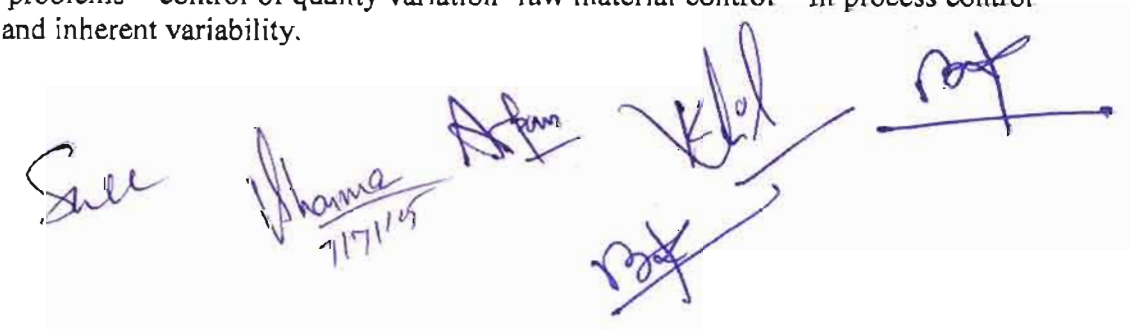
Management- Differentiation b/w management, administration, organization- concept of management- various definitions- management as art, Science.

Profession – Functions of Management – planning – organizing – staffing- motivating – controlling- time management – behavioral management – assertiveness- How to become successful in pharma profession.

Importance of pharmaceutical quality control and quality assurance management.

Meaning of Quality Control and Quality Assurance-

Introduction- Differentiation b/w Q.A. & Q.C.
What is quality? Quality cost? Quality objective? Quality assurance? Quality audit? Results of Q.C. objective.
Total quality control and product quality – Purpose of total quality control – meaning of quality in industry- Challenges of product quality in pharmaceuticals- how to set quality control.
The concepts of Total Quality control in pharmaceuticals- The basis of Quality Control- Quality Control in Pharmacy and pharmacy Curriculum.
The principles of quality control – product reliability- reliability and cost- quality cost process- definition and measurement of reliability- risk analysis and quality decision.
Approach of quality control through research and development – production – marketing requirements.
Factor controlling quality – sources of quality variation – factors affecting quality – modern quality control problems – control of quality variation- raw material control – In process control – quality level and inherent variability.



Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
11 Year Course

Paper 202- Quality Requirement – Job Responsibility of Quality Control Department

Quality control department – Principal duties for different position in Q.C. dept. – Job and responsibility – Qualification – scope and potential – Organization structure- coordination with other department.
flow chart of raw material – packing material-final product retesting – in process quality control finished product release – packing material – good laboratory practices as per GMP requirements – sampling – sampling plans – sampling procedure for raw material, packing material for microbial count.
Analytical procedures – instruments handling – spectrophotometer, balance, PH meter, melting point apparatus , karl fisher , polarimeter , HPLC, IR, DT dissolution , friability calibration of instruments – volumetric solutions and reagents – preparation and recording as per GMP concept instrumental calibration.
Training and development – responsibilities of Q.C. training , various phases – personal selection – time cost benefit analysis – use of PERT – CPM methods in quality control department.
Approval in quality control department – FDA rules and regulations – questions answers for FDA interview – role of FDA approval and its importance.

Setting Quality Control Laboratory.

FDA rules and regulations – list of schedules – Different sections – Min. sq. feet area – facility design – planning – selection – selected design criteria's – facility monitoring.

Chemical section – instrument section – microbiology and sterility – pyrogen and toxicology – pharmacology section – animal house – control room library I.P.Q.C

Equipment's used-operating procedures-cost-maintenance-make in different section- installation protocol of instruments in Q.C. department.

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-203 Functions of quality control department

Implement of total quality control – selling QC – step in selling-attitude development – use of illustrations and char-internal education - quality midness-professional nature of work- product quality and its impact on sales

Quest of quality-informative gap creating confidence-sound QC policy vendor development and its advantages.

In process quality control-quality assurance – quality control system-IPQC for parenterals-tablets solutions-emulsions-suspensions-topical applications-capsules-powers-automated process control.

Process validation – control and assurance of finished product – validation protocol.

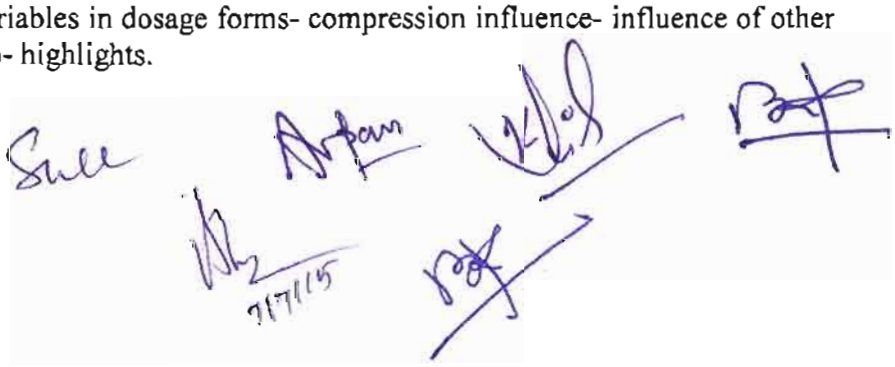
Analytical methodologies – electrometric methods- spectrophotometric methods-chromatographic methods-solvent extraction methods – stability indicating methods- titrimetric method – automated systems for assay procedures.

Stability studies, product identification system, adulteration, misbranding, counterfeiting, maintenance, storage, retrieval of records, complaints and its handling, return of goods, recall procedures, adverse effects.

Expiry dates – Mfg dates – shelf life – use before- shelf life of formulations- pre formulation and stability studies- stability system, ICH guidelines.

Bulk drug substance and purity- testing against specifications- factors affecting stability-environmental factors- purity- storage- crystallization methods.

Quality controls role in bio-availability- disintegration- dissolution- history- compressed tablets-mfg of compressed tablets- variables in dosage forms- compression influence- influence of other agents- dissolution- vivo- vitro- highlights.



Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-204 GMP and Quality Control

Philosophy, concept, rationale for GMP in pharmaceuticals- GMP.
Evaluation of validating quality elements related to product specifications.
Regulations- organization, personnel, building, facilities, control of components, drug product container, closures, I.P.Q.C.
Control and assurance of production and process control – production procedure control- manufacturing control- packaging control- process validation – labeling control- laboratory control.
Record and reports – Raw material records – Master formula records – Batch processing records – Labelling and packaging records – Quality control records – Stability study records – Distribution records – complaint records – Drug recall record – personnel record – Self appraisal record – cGMP record – Air and water quality control – change controls – Deviations and reporting – Out of specifications.
Personal training - Assessment of training – Hygienic and safety training.
Guidelines for storage of drugs.
Water for pharma use which shall include treatment, purification and inspection.
Role of W.H.O. – International biological standard- international

requirement- organization of W.H.O. activities- international pharmacopoeia- international chemical reference standard- W.H.O. requirement of biological substances.

Post Graduate Diploma in Pharmaceutical Quality Control and Quality Assurance Management (P.G.D.P.Q.C.Q.A.M.)–
1 Year Course

Paper-205 ISO-9000 and Evaluation of Packing Material

Introduction to ISO 9000 and its applicability to pharmaceuticals-
ISO 9000 revised norms.

Testing procedure for different types of packing materials.
Auditing the Function of Total Quality Control

Assurance function- product reliability- system reliability- audits and inspections- tasks vs systems- periodic vs continuous- specific vs general- elements of system- std procedures- instruments methods- facilities- controls- personnels.
Job responsibilities of auditor, internal and external audit- auditing procedure- conduct of auditing- qualification of auditor.
Preparing for an inspection.
Types of GMP inspection.
Microbiological control of non- parenteral formulations- environment – atmosphere- materials- equipment- testing methods and precautions useful in pathogen testing and its requirement as per I.P.- microbial testing of purified water as per GMP requirement- lal test, microbial testing of steam and compressor, due point test of compressor, sanitization of drains.
Validation which includes VMP, clearing, process and QC related