BHARATHIAR UNIVERSITY: COIMBATORE-641 046
CENTRE FPR COLLABORATION OF INDUSTRY AND INSTITUTION(CCII)
POST GRATUATE DIPLOMA IN PHARMACEUTICAL QUALITY ASSURANCE
(For the CCII students admitted from the academic year 2014-15 and onwards)

SCHEME OF EXAMINATIONS

Paper	Course Title	Dur. Hrs	Total Marks
	SEMESTER-I		
I	Quality control and Quality Assurance in Pharmaceuticals	3	100
II	Practical –I (Quality control and Quality Assurance in Pharmaceuticals)	3	100
III	Quality Control Checks and Documentation	3	100
IV	Practical –II (Quality Control Checks and Documentation)	3	100
	SEMESTER-II		
V	Pharmaceutical Validation	3	100
VI	Practical –III(Instrument Validation protocol)	3	100
VII	Practical-IV (Standard Operating Procedure and handling of equipments)	3	100
VIII	Project		100
	TOTAL		800

SEMESTER-I

PAPER I: Quality control and Quality Assurance in Pharmaceuticals

Unit: 1

Definition - Quality control and Quality assurance, concept and philosophy of Total quality management (TQM)

Unit: 2

Good manufacturing practices (GMP) for pharmaceutical products, biological products and investigational pharmaceutical products for clinical trials in humans

Unit: 3

International Conference on Harmonisation (ICH) for pharmaceutical quality system and ISO-9000.

Unit: 4

Organization and personnel responsibilities, training and hygiene to establishment and maintenance of a satisfactory system of quality.

Unit: 5

Scope and principle of GLP, Quality assurance unit, SOP, protocols for conduct clinical & non clinical testing, report preparation and documentation.

References books

1 Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vo. 69, Decker Series.
2 ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
3 A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
4 How to practice GMPs – P. P. Sharma.
5 ICH guidelines

PAPER II: Practical – I Quality control and Quality Assurance in Pharmaceuticals

Name of the Experiments

1. Calibration of glassware and volumetric flask
2. Determination of acid value.
3. Handling and calibration of micropipette
4. Leakage test for strip and blister packing
5. Handling and calibration of digital balance

Reference books

1 The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
2 Essentials and applications of microbiology: Judy Kandal
3 ICH & Food and Drug Administration (FDA) guidelines

PAPER III: Quality Control Checks and Documentation

Unit: 1

Equipment and raw material: selection, purchase specification and maintenance of equipment and raw materials

Unit: 2

Purchase specifications, Maintenance of stores, Selection of vendors, Controls and maintenance of Raw materials

Unit: 3

Manufacturing Documents, Master Formula, Batch Formula Records, Standard operating procedure, Quality audits of manufacturing processes and facilities

Unit: 4

In process quality control and finished products quality control for following formulation in pharma industry: tablets, capsules, ointments, creams, modified release products (controlled release, sustained release products, etc), parenterals, ophthalmic and surgical products.

Unit: 5

Quality control of radio pharmaceutical and radio chemical methods in analysis

REFERENCES BOOKS

1 Quality Assurance Guide by Organisation of Pharmaceutical products of India.
2 The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005
3 QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000

PAPER IV: Practical –II Quality Control Checks and Documentation

Name of the Experiments

1. Sterility testing of liquids.
2. Sterility testing of solids.
3. Sterility testing of equipments.
4. Sterility testing of area.
5. Microbiological evaluation of water.

References books

1. Microbiology. A laboratory manual. 7th edition: James G Cappuccino
2. Mackie & McCartney Practical Medical Microbiology

SEMESTER II

PAPER V: Pharmaceutical Validation

Unit-1
Scope of Validation, Organization for Validation, Validation Master Plan, Installation Qualification, Operational Qualification & Performance Qualification of facilities.

Unit-2
Validation of Water (Demineralised, Distilled and Water for Injection), Facilities & Cleaning Validation

Unit-3
Validation of facilities in sterile and non sterile plants. Cleaning validation of equipments and facilities.

Unit-4
In process quality control and finished products quality control, quality review and quality audits for formulations in pharma industry.

Unit-5
Conducting and Handling of internal/Domestic/International Regulatory Audits and general guidelines.

References books

1 Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials. Vol. I-WHO Publications.
2 The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
3 Controller of Publication, Govt. of India - Indian Pharmacopeia, Vol. I and II, 1996. 9.
4 Burn, Finiey and Godwin: Biological Standardisation, 2nd Edition, Oxford University Press, London.
5 Dr. A. Patani: The Drugs and Cosmetics Act 1940, Eastern Book Company, Lucknow.
6 Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition

PAPER VI: Practical –III Instrument Validation Protocol

Name of the Experiments

1. Instrumentation and calibration of UV spectrophotometer.
2. Instrumentation and calibration of IR.
3. Instrumentation and calibration of HPLC.
4. Preparation of Standard Operating Procedure (SOP) for UV spectrophotometer.
5. Preparation of Standard Operating Procedure (SOP) for IR.

Reference books

1 The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
2 Essentials and applications of microbiology: Judy Kandal
3 ICH & Food and Drug Administration (FDA) guidelines

PAPER VII: Practical –IV Standard Operating Procedure and handling of equipments

Name of the Experiments

1. Preparation of bio-analytical validation protocol and report
2. Preparation of Standard Operating Procedure (SOP) for HPLC.
3. Preparation of Standard Operating Procedure (SOP) for Nitrogen evaporator.
4. Preparation of Standard Operating Procedure (SOP) for digital pH meter.
5. Preparation of Standard Operating Procedure (SOP) for Centrifuge.

Reference books

1 The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
2 Essentials and applications of microbiology: Judy Kandal.
3 ICH & Food and Drug Administration (FDA) guidelines.

PAPER VIII: PROJECT