MRSPTU PG SKILL CERTIFICATION COURSE IN PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL 2017 BATCH ONWARDS

PG Skill Certification Course in Pharmaceutical Analysis and Quality Control

Total Contact Hours = 28 **Total Marks = 450** **Total Credits = 18**

		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
SCPQ 101	Pharmaceutical Analytical Techniques	4	-	-	40	60	100	4
SCPQ 102	Quality Control	4	-	-	40	60	100	4
SCPQ 103	Practical	-	-	12	50	100	150	6
SCPQ 104	Seminar/Assignment	-	8	-	100	-	100	4
Total		8	8	12	250	250	450	18

Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	**Crdits**
SCPQ 101	Pharmaceutical Analytical Techniques	4	-	-	25	75	100	4

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are the basic knowledge of all the commonly used analytical techniques in academia and industry.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

UNIT-1

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

UNIT-2

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, Interferences and Applications.

UNIT-3

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

UNIT-4

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

Method development and Validation: Analytical and bioanalytical method development, method validation as per ICH Guidelines, Documentation of analytical testing and validation.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Subject Code	Subject Name	L	T	P	Int.	Ext.	Total	Credits
SCPQ 102	Quality Control	4	-	-	25	75	100	4

Scope

MRSPTU PG SKILL CERTIFICATION COURSE IN PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL 2017 BATCH ONWARDS

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QC departments**.**

UNIT-1

Introduction:

a. Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q Series guidelines.

b. Good Laboratory Practices: Scope of GLP, Definitions, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT-2

Quality control of raw and finished product

a. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

b. In process quality control, finished product quality control and stability testing for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: solid dosage forms and parenterals (How to refer pharmacopoeias).

UNIT-3

Operations and controls:

a. Packaging operations, process deviations, drug expiry date calculation, calculation of yields, change control.

b. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents etc.

c. Roles and responsibility of QA/QC personnel in pharmaceutical industries.

UNIT-4

Validation and Documentation:

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

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, CoA, QRM documentation.

MRSPTU PG SKILL CERTIFICATION COURSE IN PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL 2017 BATCH ONWARDS

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. 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.
6. ICH guidelines
7. ISO 9000 and total quality management
8. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
9. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

Subject Code	Subject Name	L	T	P	Int.	Ext.	Total	Credits
SCPQ 103	Practical	-	-	12	50	100	150	6

PRACTICAL

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry or AAS.
7. Development of Stability study protocol.
8. In process and finished product quality control tests for solid dosage forms, parenterals and other dosage forms.
9. Assay of raw materials as per official monographs.
10. Testing of related and foreign substances in drugs and raw materials.
11. Quality control tests for Primary and secondary packaging materials.
12. Accelerated stability studies.
13. Determination of pKa and Log p of drugs.
14. Analysis of drugs/metabolites in simulated and biological fluids like gastric, urine, blood and tissues, analysis.
15. Analytical and bioanalytical method development and validation

16. Representative documentation for batch processing of various dosage forms for e.g. SOP, CoA, BMR, QRM Sheet etc.

Subject Code	Subject Name	L	T	P	Int.	Ext.	Total	Credits
SCPQ 104	Seminar/Assignment	-	8	-	100	-	100	4

SEMINAR/ASSIGNMENT

- Introduction, Information and Retrieval Systems.
- Writing Assignments and Term Papers
- Reading Research Papers
- Organization & Presentation of Scientific Material etc.
- Skills in Oral and Technical Presentations
- Tutorials related to subject taught

Each student has to present at least three seminars during the course and also submit three assignments.