Affiliated to Shivaji University, Kolhapur &
UGC sponsored under NSQF

# Analytical Instrumentation for Quality Control and Assurance

2020-21










## DEPARTMENT OF CHEMISTRY
## JAYSINGPUR COLLEGE, JAYSINGPUR

- Affiliated to Shivaji University, Kolhapur
- Reaccredited at 'A' Grade (NAAC)
- Jain Minority College
- DST - FIST [Level - I] Sponsored

# Analytical Instrumentation for Quality Control and Assurance

**STRUCTURE OF SYLLABUS:**

**To be implemented from the academic year 2020-21**

**1. Title of the course: Analytical Instrumentation for Quality Control and Assurance**

**2. Skills to be acquired after completion of Course:**

After successful completion of the Course, the student shall be able to acquire the following skills.

1) Basic knowledge of different departments and work culture in pharmaceutical company.

2) Prepare a design of outlay of work performed in pharmaceutical company.

3) Independent handling of different instruments.

4) Basic knowledge of terms used in submission to the different regulatory agency.

**Duration:**

The duration of the Analytical Instrumentation for Quality Control and Assurance course will be of six months.

**Medium of Instruction and Exam:**English

The suggested credits for each of the years are as follows:

| AWARD | | Duration | Credits | | |
|---|---|---|---|---|---|
| | | | Theory | Practical | Total |
| 1 | Certificate course in Analytical Instrumentation for Quality Control and Assurance | Six months | 12 | 18 | 30 |

Credits can be defined as the workload of a student in

1. Lectures

2. Practical's

The Syllabus of six month **"Certificate course in Analytical Instrumentation for Quality Control and Assurance"** has been prepared as per half yearly system, which will be implemented from Academic Year 2020-21. It has been prepared taking into consideration its importance in gettingjobs in the industries as well as the guidelines of the syllabus of other Universities.

The Theory and Practical syllabus of the certificate course in Analytical Instrumentation in Chemistry is as follow:

1) Duration of course: Six-monthJanuary to June

2) Eligibility of course: students studying in B.Sc. or M. Sc.

4) Theory papers: One paper of 50 mark

5) Practical: One practical of 50 marks.

**6) Nature of question paper**

| | | | |
|---|---|---|---|
| Question 1 | Multiple Choice | 10 questions | 10 marks |
| Question 2 | Solve any 4 out of 6 | 10 marks each | 40 |
| | | **Total** | **50** |
| OR | | | |
| Objective type | Solve 25 out of 25 | 2 marks each | **50** |

**Practical:** 50Marks: Based on Experimental; Assignment; Oral; and task

**Standard of Passing:**

To pass the examination a candidate must obtain at least 40% (i.e 40 marks out of 100) in Theory and practical subjects.

**Paper – I [Total periods: 24]**
**Fundamentals in Quality guideline and Regulatory affairs**

**UNIT 1. Pharmaceutical Industry (5)**

Applications of chemistry in Pharmaceutical industry, Global view of pharmaceuticalindustry, Indian Pharmaceutical industry, Departments in pharmaceutical industry, Role of chemist in different departments.

**UNIT 2. Regulatory affairs (RA) (07)**

Introduction, Importance of RA and quality, responsibility of RAprofessional, Regulatory agencies, List of agencies, Indian Regulatoryagency.

**UNIT 3. ICH and ICH Quality guideline (07)**

Introduction about ICH (Members and administrative authorities), ICH topics,List anddescription of each guideline, ICH Multidisciplinary guideline. Introduction ICH M4 (CTD), CTD module, ICH Q3 and ICH Q6 overview

**UNIT 4. Submission to regulatory agency (Terms used for USFDAsubmission)(5)**

GMP and GLP, Indian Pharmacopoeia, British Pharmacopoeia, US Pharmacopoeia, Regulatory Inspection, Reference guidance (21 CFR, WHO, warning letter)

## Paper- II [Total periods: 24]

## Instrumental Methods in Pharmaceutical Industry

**UNIT 1. General Introduction: (05)**

Sampling of solids, liquids and gases, sample registration and storage. WET Analysis, Instrumental methods of analysis, their classification and advantagesof instrumentalmethods, the limitations, sensitivity and detection limits,precision and accuracy.

**UNIT 2. Introduction to pharmacopeia and software's (07)**

Preparation of indicators, reagents and standard solutionsas per pharmacopeia, General introduction to computer, different software's and their functions, advantages and practical applications.

**UNIT 3. Theory and applications of following techniques of analysis(05)**

pH metry, Conductometry, Potentiometry, Colorimetry, Spectrofluorimetry, Dissolution etc.

**UNIT 4. Thermal and chromatographic methods of analysis: (07)**

Introduction, theory, and applications to DTA, TGA, DSC, HPLC, GC, HPLC-MS, Particle size analysis,AAS/ICP etc.

**Practical's:**

1. Complexometric titration of aluminium and magnesium from different commercial antacids
2. Analysis of milk of magnesia by acid base titration
3. HPLC-Determination of caffeine from coffee beans
4. HPLC- Effect of flow rate on the retention time
5. HPLC- Effect of mobile phase composition on resolution
6. Determination of theoretical plates, HETP, S/N ratio, Retention volume and resolution
7. Uniformity of weight of tablets or capsule
8. Qualitative determination of methanol percent in ethanol by FTIR techniques
9. Structural determination of primary or secondary or tertiary alcohols
10. Preparation of solutions and standardization as per IP/BP/USP
11. Technical and nontechnical group discussion
12. Interview skill and CV preparation
13. Calibration of pH meter
14. Calibration of Analytical Balance
15. Calibration of glassware's

## Board of Studies:

Dr. R. R. Kumbhar : Chairman, Jaysingpur College, Jaysingpur

Dr. S. R. Sabale : Member, Jaysingpur College, Jaysingpur

Dr. R. S. Dhabbe : Member, Jaysingpur College, Jaysingpur

Dr. A. R. Supale : Member, Dr. P. K. Mahavidyalaya, Sangli

Mr. P. B. Diwan : Member, Director, Assura Pharma, Sangli

Mr. Anand Potdar : Member, QC Head Unichem Laboratories, Kagal MIDC

**Reference Books:**

1. Introduction to Instrumental Analysis; R. D. Braun,
2. Instrumental Methods of Analysis; Willard, Merritt, Dean and Settle
3. Standard Methods of Chemical AnalysisVol.3, Part A & B F. J. Welcher:
4. Instrumental Methods of Analysis, 4th &5th editions; G. W. Ewing,
5. Instrumental Methods of Analysis; Chatwal and Anand.
6. Electroanalytical Chemistry, Ed. H. W. Nurnberg.
7. A Textbook\k of Electrochemistry, Kortum and Bockris,

8. Principles of Electrochemistry; D. A. Maclines,

9. Analytical Chemistry – G. D. Christain

10. Introduction to Chromatography, Bobbit.

11. Instrumental Methods of Analysis. Chatawal and Anand

12. Instrumental Methods of Inorganic Analysis (ELBS): A.I.Vogel

13. Chemical Instrumentation: A Systematic Approach, H.A. Strobel

14. Physical Chemistry, P. W. Atkins.

15. Principles of Instrumental Analysis, D. Skoog & D. West

16. Treatise on Analytical Chemistry, Vol. I to VII- I. M. Kolthof

17. Analytical Chemistry (J.W ) G. D. Christian

18.Introduction to Chromatography: Bobbit

20. Instrumental Methods of Analysis: Chatwal and Anand

21. Instrumental Methods of Inorganic Analysis (ELBS): A.I. Vpge;

22. Physical Chemistry; P.W.Atkins.

23. Principles of Instrumental Analysis- D. Skoog and D. West

24. Treatise on Analytical Chemistry; Vol. I to VII I, .M. Kolthoff.

25. Computer' Fundamentals: P. K. Sinha.

26. ICH Quality Guidelines: An Implementation GuideAndrew Teasdale, David Elder,Raymond W. Nims.

27.Drug Regulatory Affairs by Dr. N. S. Vyawahare.

28. DRUG REGULATORY AFFAIRS by PAPIYA BIGONIYA

29 https://www.pharmaguideline.com/p/pharma-sops.html

30 Quality assurance ofpharmaceuticalsA compendium of guidelinesand related materialsVolume 2, 2nd updated editionGood manufacturing practicesand inspection, WHO.