CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Chemist-Quality Control

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Chemist-Quality Control

CCEK – NSDC course package covers the following Qualification Packs and leads to the following NSDC certifications. The students who successfully completed the course programs are entitled to get NSDC certification after undergoing the assessment process of NSDC as per the rules and regulations stipulated by NSDC from time to time.

SL. NO.	QUALIFICATIONS PACK	QUALIFICATIONS PACK CODE	NSQF LEVEL
1	**Chemist-Quality Control** **Brief Job Description**: Chemist-Quality Control tests samples, reagents from all phases of the manufacturing process to ensure the product quality meets the standards. The individual is responsible for the testing of in-process/input raw materials, packaging materials, product stability of samples, in-process intermediate samples, finished products, preliminary investigation in case of out of specification results, laboratory incidents and handling/preparation of standards. The person is responsible for preparing the documents for reporting the test results and ensures compliance with cGMP, GLP and workplace safety while handling hazardous materials. The role holder also carries out testing of process validation samples and cleaning validation samples.	**LFS/Q1301**	**5**

CENTRE FOR CONTINUING EDUCATION KERALA

COURSE DETAILS

Chemist-Quality Control

EXAMINATION DETAILS

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Chemist-Quality Control	G53	Diploma in Pharmacy (after 12th)/ M.Sc. Chemistry/ UG Diploma in Biochemistry Microbiology	460

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Quality Assurance and Quality Control in Chemical and Physical Analysis	T001	100	50	150
2	Introduction of HPLC, GC, UV & FT-IR	T002	100	50	150
PRACTICAL PAPERS					
1	Quality Control Laboratory investigations and analysis	L001	100	50	150
TOTAL MARKS					
1	Total Examination Marks (Theory Online + Practical Examination)				300
2	Total Internal Marks				150
3	**Total Marks (Total Internal Marks + Total Examination Marks)**				**450**

Chemist-Quality Control

INTERNAL MARK CRITERIA FOR EACH

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Quality Assurance and Quality Control in Chemical and Physical Analysis	T001	100	50	150
2	Introduction of HPLC, GC, UV & FT-IR	T002	100	50	150
3	Quality Control Laboratory investigations and analysis	L001	100	50	150
	TOTAL		300	150	450

ATTENDANCE	GENERAL PERFORMANCE	INTERNAL EXAMINATIONS/ PROJECTS / ASSIGNMENTS	TOTAL MARKS
5	5	40	50

COURSE SYLLABUS

FOR

Chemist-Quality Control

COURSE	Chemist-Quality Control	
TOTAL MARKS	Mark: 450	Internal Mark: 150
TOTAL HOURS	460 Hrs	

DEFENITION OF CREDIT

1 Credit	15Hrs Theory/ 30Hrs Practical
Skill Components	60 – 70 % of Total Credit

MODULES INCLUDED IN THIS SUBJECT

SL NO	MODULE NAME	CREDIT BREAKUP
1	Module 1: Introduction to Life Sciences industry and quality control individual	.5
2	Module 2: Essential concepts for quality control in drug manufacturing	.5
3	Module 3: Pre- analysis checks in Quality Control laboratory	.5
4	Module 4: Laboratory investigations and analysis	.5
5	Module 5: Comply EHS rules in GMP/GLP controlled areas	.5
6	Module 6: Coordination with manager, colleagues and auditors	.5
7	Module 7: Display sensitivity towards all genders and people with disability	.5
8	Module 8: Reporting and documentation	.5
9	Module 9: Process related checks in the quality control process	.5
10	Module 10: Managing Environment Sustainability	.5
11	Module 11: Employability Skills	.5
12	Module 12: Introduction of High-Performance Liquid Chromatography (HPLC)	.5
13	Module 13: HPLC calibration	.5
14	Module 14: HPLC analysis	.5
15	Module 15: Introduction to Gas Chromatography (GC)	.5
16	Module 16: Gas Chromatography (GC) calibration	.5
17	Module 17: Gas Chromatography (GC) analysis	.5
18	Module 18: Introduction to Ultraviolet (UV)- visible spectroscopy	.5

19	Module 19: Ultraviolet (UV)- visible spectroscopy calibrations	**.5**
20	Module 20: Ultraviolet (UV)- visible spectroscopy Analysis	**.5**
21	Module 21: Introduction to Fourier Transform Infrared Spectroscopy (FT-IR)	**.5**
22	Module 22: Fourier Transform Infrared Spectroscopy (FT-IR) calibrations	**.5**
23	Module 23: Fourier Transform Infrared Spectroscopy (FT-IR) Analysis	**.5**
24	Module 24: Introduction to Dissolution Test Apparatus	**.5**
25	Module 25: Routine upkeep Dissolution Test Apparatus	**1.5**
26	Module 26: QC Analysis using Dissolution Test Apparatus	**1.5**
	Total	**15**

Training Outcomes

- Connect Explain the aspects of the life sciences industry and its pertinent regulations.
- Investigate and analyze laboratories in line with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
- Maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, laboratory and area around in conformance with environmental health and safety (EHS) rules by self and subordinates.
- Demonstrate Good Documentation Practices (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP), good laboratory practices (GLP), and Good Manufacturing Practices (GMP).
- Perform process-related checks in the quality control process.
- Conduct quality check for samples using High-Performance Liquid Chromatography (HPLC)/Gas Chromatography (GC)/ Ultraviolet (UV) - visible spectroscopy/Fourier Transform Infrared Spectroscopy (FT-IR)/Dissolution Apparatus as per standard operating procedures (SOP).

MODULES

Module 1: Introduction to Life Sciences industry and quality control individual

THEORY

- Explain the overview of the Life Sciences industry in Indian and global context.
- Discuss the regulatory authorities, regulations, legislation, and good practices (GMP, GLP, GDP) relevant to Quality Control in a life sciences manufacturing facility.
- Explain the impact of non-compliance on the quality of the product and the environment.
- Explain the importance of a Quality Control.
- Explain the basic terminologies used in the quality control process.

Module 2: Essential concepts for quality control in drug manufacturing

THEORY

- Discuss quality principles and concepts applied in the life sciences sector.
- Explain the basic concept of Quality by Design (QbD) and its application in quality control and quality risk management.
- Explain the concepts of organic chemistry and analytical chemistry including measurement, mathematical, and statistical concepts.
- Discuss the types of tests performed in quality control lab in various formulations, Active Pharmaceutical Ingredient (API) and packaging material.
- Recall the procedures for handling, processing, preservation of samples
- Explain the procedures for safe handling of hazardous and poisonous substances.
- Discuss relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines including interpretation of pharmacopoeia and application of its standards.
- Explain the properties of reagents, solvents and hazardous chemicals, and their storage as per Hazard Classification

PRACTICAL

- Demonstrate adherence of safety rules while working in lab
- Perform pipetting and micro pipetting
- Demonstrate safe handling of standards, solvents, reagents and chemicals
- Demonstrate handling of glassware and lab plasticware without contamination
- Perform analytical calculations to measure molarity, normality, percentage concentration and part per million
- Demonstrate how to perform chemistry experiments of electrochemistry, thermal analysis, spectroscopy and chromatography
- Demonstrate how to perform dilution methods
- Demonstrate how to prepare buffer solutions
- Demonstrate the sample processing and preservation
- Prepare a checklist of steps followed in method development and method validation

Module 3: Pre-analysis checks in quality control laboratory

THEORY

- Explain the procedure to check the status and accuracy of instruments used for measurement.
- Discuss the Standard Operating Procedure (SOP), cGMP and GLP guidelines for performing pre-analysis checks.
- Discuss the operation, calibration and common errors for laboratory instruments
- Discuss the Quality parameters of Milli Q Water System.
- Discuss the climatic zones and climatic conditions needed for stability analysis.

PRACTICAL

- Demonstrate how to check the status and accuracy of instruments used for measurement.
- Demonstrate performing pre-analysis checks as per SOP, cGMP, and GLP guidelines.
- Demonstrate the operation of laboratory instruments.
- Demonstrate the precautions to be taken while operating lab instruments to eliminate common errors.
- Demonstrate operation of stability chambers.

Module 4: Laboratory investigations and analysis

THEORY

- Explain the concepts of incidents and deviations in context of quality control analysis.
- Recall various statistical concepts used in laboratory investigation and analysis.
- Explain steps to prepare and standardize volumetric solutions and test solutions.
- Explain the concepts of re-standardization and acceptance criteria.
- Discuss the requirement and of importance equipment qualification.
- Discuss the importance of preventative maintenance.
- Explain the procedures for instrument calibration and instrument accuracy test.
- Explain the procedures for laboratory investigations and validation tests performed in the QC lab of the life sciences sector.
- Discuss the concepts of Corrective Action and Preventive Action (CAPA) and change control.

PRACTICAL

- Demonstrate use of statistical methods in laboratory investigation and analysis
- Prepare and standardize volumetric solutions and test solutions
- Perform calibration and accuracy test for lab instruments
- Perform laboratory investigations experiments and tests using various lab
- Perform validation experiments and tests
- Follow change control procedure to manage and document a change in a simulated environment
- Solve a CAPA investigation case study and suggest steps for CAPA strategy investigation in a simulated environment

Module 5: Comply EHS rules in GMP/GLP controlled areas

THEORY

- Explain relevant legislative requirements and company's procedures for environment, health and safety.
- Discuss workplace hazards and their reporting in the laboratory and manufacturing facility in the life sciences sector.
- Explain all the emergency procedures for different emergencies.
- Explain evacuation procedures for employees, contract staff and visitors
- Discuss health, safety and accident reporting procedures.
- Explain different types of breaches in the environment, health, safety and security.
- Discuss how to provide medical assistance and the emergency services of reported accidents.
- Explain the importance of material segregation and 5S system.
- Explain WHO guidelines for personal hygiene, handling and storing hazardous material.
- Discuss the different types of safety gears and how to use them.

PRACTICAL

- Demonstrate how to perform reporting of hazards at the workplace.
- Demonstrate how to evacuate employees, contract staff and visitors as per procedures in case of emergency.
- Demonstrate how to act in case of emergencies as per health, safety and accident reporting procedures.
- Demonstrate how to apply 5S system for handling and storing hazardous material.
- Demonstrate the adherence to WHO guidelines for maintaining personal hygiene.
- Demonstrate how to use different types of safety gears.
- Demonstrate the procedure to douse the fire during lab accidents

Module 6: Coordinate with Manager, colleagues and auditors

THEORY

- Explain the reporting structure of the organization.
- Discuss efficient and clear communication methods for reporting the incidents/ deviations.
- Explain the techniques for collaborating with other groups and divisions.
- Discuss the importance of team management and team building.
- Discuss how to apply emotions and stress management strategies.
- Explain how to apply problem and conflict solving skills in the workplace.
- Discuss how to respond to auditors with integrity.

PRACTICAL

- Demonstrate how to effectively communicate and collaborate with manager and colleagues for multiple scenarios.
- Respond effectively to regulatory audit questions in a mock audit situation.
- Demonstrate how to resolve conflict in multiple scenarios.

Module 7: Display sensitivity towards all genders and people with disability

THEORY

- Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act and the provided penalties for violation.

- Explain the importance of gender-sensitive behavior.
- Explain the procedure to report inappropriate behavior e.g. sexual harassment.
- Describe the importance of an equal opportunity work culture.
- Discuss the importance of respecting other's
- cultures, religion, and caste.
- Explain the need for sensitivity towards people with disabilities.
- Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework.
- Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes.

PRACTICAL

- Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc.
- Prepare a list of gender-neutral communication terms.
- Demonstrate through Role-play different workplace situations where gender- sensitive behaviour is required.
- Prepare a report suggesting improvements to promote equal opportunities across gender, race, religion, and ability levels.
- Demonstrate how to communicate and collaborate with people with different disabilities (e.g., visual, hearing, mobility impairments) using proper methods and language

Module 8: Reporting & documentation

THEORY

- Explain the method of reporting and documentation as per Good Documentation Practices (GDP), 21CFR (Code of Federal Regulation) and Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle.
- Discuss guidelines for electronic records & electronic signatures, audit trails, date & time stamps and data integrity in the Life Sciences sector.
- Explain the procedures for reporting any hazards, non-conformance, deviations, OOS
- / OOT, validation results.
- Discuss the documentation requirements in management of controlled documents and change control management
- Explain the procedure for Standardization and validation related documentation
- Explain the procedure to use the manual lab note book as well as e-Lab Note Book (eLNB) for documenting experiments and analysis reports
- Discuss the operating procedure of the lab information management system (LIMS).

PRACTICAL

- Record the quality parameters and investigation results in the sample formats and log book of QC records for experiments done in lab
- Demonstrate adherence of Data integrity and ALCOA+ guidelines during reporting and recording in the lab
- Demonstrate how to report an OOS or OOT incidents or a process deviation.
- Demonstrate documentation of a simulated change control scenario.
- Demonstrate use of manual Lab note book and eLNB in the lab
- Demonstrate the operation of LIMS.

Module 9: Process related checks in the quality control process

THEORY

- Explain how to monitor and conduct regular checks on equipment and instrument conditions by checking precision in instrument calibrations.
- Explain calibrations, installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and techniques for improving instrumental analysis.
- Discuss the methods of handling and storage of reference standard and working standard.
- Discuss potential causes of non- conformities to working standards.
- Discuss the methods of handling and storage of various type of samples
- Explain the requirements and procedures of labelling in a lab

PRACTICAL

- List the routine check points for lab instruments available in the skill lab
- Demonstrate the procedures for routine calibrations and verification of lab instrument precision
- Perform experiments related to IQ, OQ and PQ
- Demonstrate how to identify causes of non- conformities at the workplace.
- Demonstrate the procedures for storing standards and samples
- Perform the labeling inspection of samples used in experiments and label them as per labelling requirements

Module 10: Managing environmental sustainability

THEORY

- Explain the concept and importance of energy conservation.
- Describe the possible actions to optimize energy consumption and minimize energy wastage.
- Explain the concept of environmental pollution and its impact on the health of self, community, and planet.
- Describe the possible actions to minimize environmental pollution at work.
- Explain various guidelines to be followed for hazardous waste management and disposal

PRACTICAL

- Create a checklist of energy conservation practices during and post-work.
- Classify waste into recyclable, non- recyclable, and hazardous.
- Demonstrate the sustainable waste disposal- process.

Module 11: Employability Skills

THEORY

- Outline the importance of Employability Skills for the current job market and future of work
- List different learning and employability related GOI and private portals and their usage
- Research and prepare a note on different industries, trends, required skills and the available opportunities
- Explain the constitutional values, including civic rights and duties, citizenship, responsibility towards society and personal values and ethics such as honesty, integrity, caring and respecting others that are required to become a responsible citizen
- Demonstrate how to practice different environmentally sustainable practices
- Discuss relevant 21st century skills required for employment

- Highlight the importance of practicing 21st century skills like Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn etc. in personal or professional life
- Create a pathway for adopting a continuous learning mindset for personal and professional development
- Show how to use basic English sentences for everyday conversation in different contexts, in person and over the telephone
- Read and understand text written in basic English
- Write a short note/paragraph / letter/e -mail using correct basic English
- Create a career development plan
- Identify well-defined short- and long-term goals
- Demonstrate how to communicate effectively using verbal and nonverbal communication etiquette
- Write a brief note/paragraph on a familiar topic
- Explain the importance of communication etiquette including active listening for effective communication
- Role play a situation on how to work collaboratively with others in a team
- Demonstrate how to behave, communicate, and conduct appropriately with all genders and PwD
- Discuss the significance of escalating sexual harassment issues as per POSH act
- Demonstrate how to conduct offline and online financial transactions, safely and securely and check passbook/statement
- Explain the common components of salary such as Basic, PF, Allowances (HRA, TA, DA, etc.), tax deductions
- Calculate income and expenditure for budgeting
- Discuss the legal rights, laws, and aids
- Describe the role of digital technology in day-to-day life and the workplace
- Demonstrate how to operate digital devices and use the associated applications and features, safely and securely
- Demonstrate how to connect devices securely to internet using different means
- Follow the dos and don’ts of cyber security to protect against cyber crimes
- Discuss the significance of displaying responsible online behavior while using various social media platforms
- Create an e-mail id and follow e- mail etiquette to exchange e -mails
- Show how to create documents, spreadsheets and presentations using appropriate applications
- utilize virtual collaboration tools to work effectively
- Explain the types of entrepreneurship and enterprises
- Discuss how to identify opportunities for potential business, sources of funding and associated financial and legal risks with its mitigation plan
- Describe the 4Ps of Marketing-Product, Price, Place and Promotion and apply them as per requirement
- Create a sample business plan, for the selected business opportunity
- Classify different types of customers
- Demonstrate how to identify customer needs and respond to them in a professional manner
- Discuss various tools used to collect customer feedback
- Discuss the significance of maintaining hygiene and dressing appropriately
- Use various offline and online job search sources to find and apply for jobs
- Discuss the significance of maintaining hygiene and dressing appropriately for an interview

- Role play a mock interview
- List the steps for searching and registering for apprenticeship opportunities

Module 12: Introduction of High-Performance Liquid Chromatography (HPLC)

THEORY

- Explain the working principle and the instrumentation of High-Performance Liquid Chromatography (HPLC) and its various applications in QC analysis.
- Explain the operations of each component of HPLC like stationary phase, chromatographic column, mobile phase, apparatus, and gradient elution.
- Discuss the precautions to be taken while working on HPLC.
- Explain different types of HPLC columns used in the analysis.
- Explain the operating procedure for HPLC and its software system.
- Explain the protocols to be followed for the HPLC method development and validation
- Explain the documentation process for HPLC analysis

PRACTICAL

- Identify and locate the different parts/ components of the HPLC on a schematic diagram or in a simulated module
- Demonstrate the safe handling of a HPLC system
- Demonstrate how to operate HPLC.

Module 13: HPLC calibration

THEORY

- Discuss the need for and importance of HPLC instrument calibrations.
- Discuss the principles and procedure of calibration and validation of HPLC instrument.
- Discuss different techniques/inspection methods used to identify defects.

PRACTICAL

- Demonstrate how to perform HPLC calibrations.
- Demonstrate the inspection of HPLC for its state of calibration and, validation in QC laboratory.
- Perform troubleshooting and rectification of the minor issues of HPLC instrument

Module 14: HPLC analysis

THEORY

- Explain the properties of different chemicals, reagents and reference standards and working standards used for HPLC analysis.
- Recall the safety measures to be taken while operating the HPLC instrument.
- Discuss the analytical calculations required in a HPLC analysis
- Discuss the procedures of sample preparation for HPLC test analysis.
- Explain the scientific principles behind the HPLC test performed.
- Explain the methods of recording and analysis of HPLC chromatogram.
- Explain the concepts of HPLC data deviations in case of deviations in the results.

PRACTICAL

- Prepare a checklist of different chemicals, reagents and working standards required for HPLC analysis.
- Demonstrate safety measures to be taken while handling chemicals, reagents, working standards and reference materials.
- Demonstrate how to perform sample preparation for HPLC analysis considering stability and storage requirement.
- Demonstrate how to perform sample analysis by HPLC method in a QC lab.
- Record the observations of test results and analyse the chromatogram.
- Identify data deviations in case of deviation in results and raise/log an incident in the system.

Module 15: Introduction to Gas Chromatography (GC)

THEORY

- Explain the working principles and instrumentation concepts of GC instrument.
- Discuss the types of columns and detectors used in GC instrument.
- Discuss the applications of GC instrument in QC testing.
- Explain the application of GC instrument in various type of analysis
- Explain the operating procedure for GC instrument and its software system
- Explain the standard protocols to be followed for GC method development and validation.

PRACTICAL

- Identify and locate the various parts of the GC instrument on a schematic diagram.
- Demonstrate how to operate GC instrument.
- Identify the various types of columns and detectors used in the GC instrument on a schematic diagram or in a simulation module

Module 16: Gas Chromatography (GC) calibration

THEORY

- Explain the principles of GC instrument calibration and validation.
- Discuss the importance and need of GC instrument calibrations.
- Explain the process of GC instrument calibration

PRACTICAL

- Demonstrate how to perform GC instrument calibrations.
- Perform troubleshooting and rectification of the minor issues of GC instrument operations

Module 17: Gas Chromatography (GC) analysis

THEORY

- Explain the properties of different chemicals, reagents and standard solutions used for GC analysis.
- Recall the safety measures to be taken while operating GC.
- Discuss the procedures of sample preparation for GC analysis.
- Explain the scientific principles behind the GC test performed.
- Explain methods of recording and analysis of GC chromatograms.

- Explain the concepts of GC data deviations in case of deviation in the results

PRACTICAL

- Prepare a checklist of different chemicals, reagents and standard solutions used for GC analysis.
- Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials.
- Demonstrate how to perform sample preparation considering stability and storages requirement.
- Demonstrate how to perform QC sample analysis by GC method.
- Record the observations of test results and analyse the chromatogram.
- Identify data deviations in case of deviation in results and raise logs in the system.

Module 18: Introduction to Ultraviolet (UV)- visible spectroscopy

THEORY

- Explain the working principles of Ultraviolet (UV)- visible spectroscopy.
- Discuss the instrumental components of Ultraviolet (UV)- visible spectrophotometer.
- Explain the measurement principles of UV/VIS spectrophotometry.
- Discuss the application of Ultraviolet (UV)- visible spectroscopy in QC testing.
- Explain the operating procedure for Ultraviolet (UV)- visible spectroscopy its software system.

PRACTICAL

- Identify and locate the various parts/components on the schematic diagram of Ultraviolet (UV)- visible spectroscopy.
- Demonstrate how to operate (UV)-visible spectroscopy.

Module 19: Ultraviolet (UV)- visible spectroscopy calibrations

THEORY

- Explain the scientific principle behind the calibrations of UV- visible spectroscopy.
- Explain the procedures to be followed for calibrations of UV- visible spectroscopy.

PRACTICAL

- Perform calibration and performance qualification of UV spectrophotometer.
- Perform troubleshooting and reconciliation of the minor issues of UV- visible spectroscopy instrument operations.

Module 20: Ultraviolet (UV)- visible spectroscopy Analysis

THEORY

- Explain the properties of different chemicals, reagents and standard solutions used for Ultraviolet (UV)- visible spectroscopy analysis.
- Recall the safety measure to be taken while handling Ultraviolet (UV)- visible spectroscopy.
- Discuss the procedures of sample preparation for Ultraviolet (UV)- visible spectroscopy analysis.
- Explain the principle behind the Ultraviolet (UV)- visible spectroscopy test methods.
- Explain methods of recording and analysis of UV- visible spectroscopy test results

PRACTICAL

- Prepare a checklist of different chemicals, reagents and standard solutions used for (UV)- visible spectroscopy.
- Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials.
- Demonstrate how to perform sample preparation for UV- visible spectroscopy analysis.
- Demonstrate how to perform QC testing by (UV)- visible spectroscopy.
- Record the test observations and analyse the results.

Module 21: Introduction to Fourier Transform Infrared Spectroscopy (FT- IR)

THEORY

- Explain the working principles of Fourier Transform Infrared Spectroscopy (FT-IR).
- Discuss the instrumental components of Fourier Transform Infrared Spectroscopy (FT-IR).
- Discuss the application of Fourier Transform Infrared Spectroscopy (FT-IR) in QC testing.
- Explain the operating procedure for Fourier Transform Infrared Spectroscopy (FT-IR) and its software system

PRACTICAL

- Identify and locate the various parts/components on the schematic diagram of Fourier Transform Infrared Spectroscopy (FT-IR).
- Demonstrate how to operate Fourier Transform Infrared Spectroscopy (FT-IR)

Module 22: Fourier Transform Infrared Spectroscopy (FT-IR) calibrations

THEORY

- Explain the scientific principles behind the calibrations of Fourier Transform Infrared Spectroscopy (FT-IR).
- Explain how to check the resolution performance of the instrument.
- Explain the procedures for calibrations of Fourier Transform Infrared Spectroscopy (FT-IR).

PRACTICAL

- Demonstrate how to perform calibration of Fourier Transform Infrared Spectroscopy (FT-IR) instrument.
- Perform troubleshooting and rectification of the minor issues of Fourier Transform Infrared Spectroscopy (FT-IR) instrument operations.

Module 23: Fourier Transform Infrared Spectroscopy (FT-IR) Analysis

THEORY

- Explain the properties of different chemicals, reagents and standard solutions used for Fourier Transform Infrared Spectroscopy (FT-IR) analysis.
- Recall the safety measures to be taken while handling Fourier Transform Infrared Spectroscopy (FT-IR) instrument.

- Explain analysis procedure for solids, liquids and mineral oil dispersion.
- Discuss the procedures of sample preparation for Fourier Transform Infrared Spectroscopy (FT-IR) analysis.
- Explain the principles of Fourier Transform Infrared Spectroscopy (FT-IR) test analysis.
- Explain methods of recording and analysis of Fourier Transform Infrared Spectroscopy (FT-IR) test results.

PRACTICAL

- Prepare a checklist of different chemicals, reagents and standard solutions used for (FT-IR) test analysis.
- Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials.
- Demonstrate how to perform sample preparation for Fourier Transform Infrared Spectroscopy (FT-IR).
- Demonstrate how to perform sample analysis by (FT-IR).
- Record the test observations and analyse the results.

Module 24: Introduction to Dissolution Test Apparatus

THEORY

- Explain the fundamental concepts of Dissolution test apparatus.
- Explain the purpose of Dissolution test and types of dissolution apparatus used for testing.
- Explain the process of Dissolution method development and validation.

PRACTICAL

- Identify different components of the dissolution test apparatus on a schematic diagram.
- Demonstrate the working of dissolution test apparatus in the QC lab

Module 25: Routine upkeep Dissolution Test Apparatus

THEORY

- Explain the procedures to be followed for preventive maintenance of dissolution test apparatus.
- Discuss methods used for cleaning of dissolution test apparatus

PRACTICAL

- Demonstrate the routine upkeep of the dissolution test apparatus.
- Inspect the cleaning status of the dissolution test apparatus.

Module 26: QC Analysis using Dissolution Test Apparatus

THEORY

- Explain the properties of different dissolution medium.
- Recall the safety measures to be taken while handling the dissolution test apparatus.

- Explain the procedures of sample preparation for dissolution test.
- Explain the sample withdrawal procedures for dissolution testing.
- Explain the principle behind QC analysis using a dissolution test apparatus

PRACTICAL

- Demonstrate safety measures to be taken while handling the dissolution test apparatus.
- Demonstrate how to perform sample preparation for dissolution test.
- Demonstrate the testing methods for QC analysis using a dissolution test apparatus.