

Qualification of analysts Syllabus Rev.1

Day 1 Basic information and equipment

Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Introductions • Course objectives and expectations
GMP at the analytical Laboratory	<ul style="list-style-type: none"> • Laboratory GMP. • Implementation of the GMP requirements at the analytical laboratory. • How to prepare the laboratory and the staff for regulatory inspection
Pharmacopoeias	<ul style="list-style-type: none"> • The implementation of pharmacopeial standards, monographs, and general chapters. Review of examples in USP-NF and EP
Weights and balances	<ul style="list-style-type: none"> • The use of weights and balances according to the general chapters USP-NF <41> and <1251>. • Theory and practice
Volumetric equipment	<ul style="list-style-type: none"> • The correct use of equipment such as: glass and piston pipettes, burettes, calibration flasks, etc. to obtain accurate measurements
Basic equipment at the laboratory	<ul style="list-style-type: none"> • Review of selected items in use at the analytical laboratory including ovens and other heating devices, hoods, centrifuge, sonicators, shakers, dilutors, vortex, reflux, filters, pycnometers. capillary and rotatory viscometers

Day 2 Wet chemistry and other analytical methods

Module	Topics
PH and Conductivity	<ul style="list-style-type: none"> • The principles of pH theory and measurement. Buffer preparation, correct use of pH meter. Pharmacopeial chapters review • The theory and practice of the measurement of Conductivity in water. • Pharmacopeial General Chapters and water monographs review
Total organic content	<ul style="list-style-type: none"> • The principles and practice of the TOC determination in Water. • Pharmacopeial General Chapter review: USP-NF <643> and EP 2.2.44

Titration	<ul style="list-style-type: none"> • Review of the USP -NF Titrations <541> Acid -base, complexometric, Potentiometric, and amperometric titrations. • Direct and residual titrations. Review of theory, examples, and calculations.
Water determination	<ul style="list-style-type: none"> • Water content in pharmaceutical finished products and raw materials. • Principles of LOD and Karl Fischer titration. • Review of the pharmacopeial general chapters.
Spectrophotometry	<ul style="list-style-type: none"> • IR-FTIR-NIR, UV-visible, AA, AES, ICP. • The physical principles and use of spectrophotometers IR-FTIR-NIR, UV-visible, AA, AES, ICP.

Day 3 Chromatography, Identification, limits tests and reports	
Module	Topics
Separation Methods	<ul style="list-style-type: none"> • The physical and chemistry behind HPLC ,UPLC, and GC
Impurities	<ul style="list-style-type: none"> • Review of relevant guidelines regarding Impurities , residual solvents ,Elemental impurities • Detection Limit, Quantitation limits, Reportable Limit
Identifications tests	<ul style="list-style-type: none"> • The chemistry behind multiple USP-EP identification tests method
Limit test	<ul style="list-style-type: none"> • The chemistry behind multiple USP-EP limit tests method
Analytical reports	<ul style="list-style-type: none"> • Feedback • Course summary

