

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.
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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.
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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

