

Quantex Laboratories performs comprehensive analytical testing of raw materials, active pharmaceutical ingredients, excipients and finished pharmaceutical products. Our services can assist you in the qualification of your vendors or in the release of raw materials for production and manufacturing purposes. Compendial testing is performed in accordance with USP/NF, BP, EP, JP, ACS and FCC methodologies and monographs, as well as with client-supplied or vendor-specified methods.

Quantex's highly trained scientists, in conjunction with our considerable investment in laboratory resources, can handle the analysis of significant quantities of samples. We maintain well equipped state-of-the-art laboratories that routinely support the analysis of raw materials including actives, fillers, binders, colors, and other excipients. All our laboratory operations and procedures are based on written, detailed SOPs and stringent quality assurance practices. And, as you would expect from your own laboratories, all our work is performed under strict compliance with cGMP requirements.

Some of the USP Raw Materials & Compendial tests we perform:

Chemical Tests & Assays

<181> Identification – Organic
Nitrogenous Bases

<191> Identification Tests - General

<193> Identification - Tetracyclines

<197> Spectrophotometric Identification Tests

<201> TLC Identification Test

<206> Aluminum

<211> Arsenic

<216> Calcium, Potassium, and Sodium

<221> Chloride and Sulfate

<231> Heavy Metals

<241> Iron

<251> Lead

<261> Mercury

<271> Readily Carbonizable Substances

<281> Residue on Ignition

<291> Selenium

<341> Antimicrobial Agents Content
Benzyl Alcohol
Chlorobutanol
Phenol
Methylparaben and Propylparaben

<401> Fats and Fixed Oils
Specific Gravity
Melting Temperature
Acid Value
Ester Value
Hydroxyl Value
Iodine Value
Peroxide Value
Saponification Value
Fatty Acid Composition

<461> Nitrogen Determination

<466> Ordinary Impurities

<467> Residual Solvents

<591> Zinc

Physical Tests & Determinations

<611> Alcohol Determination

<631> Color and Achromicity

<641> Completeness of Solution

<643> Total Organic Carbon

<645> Water Conductivity

<651> Congealing Temperature

<698> Deliverable Volume

<731> Loss on Drying

<741> Melting Range or Temperature

<781> Optical Rotation

<785> Osmolarity

<786> Particle Size Distribution

<788> Particulate Matter in Injections

<791> pH

<831> Refractive Index

<841> Specific Gravity

<911> Viscosity

<921> Water Determination

Microbiological Testing

<61> Microbial Limit Tests

<71> Sterility

<85> Bacterial Endotoxins

Other

- Monograph-specific Chemical, Microbiological, and Physical Tests
- FCC Monograph-specific Chemical, and Physical Tests
- European Pharmacopeia Testing Physical and Physio-chemical Methods, Identification, Limit Tests, Assays, Biological Tests
- General Tests and Monographs
- Testing per Client/Vendor Methods



Our capabilities includes:

- Assay (HPLC, GC).
- Organic volatile impurities (USP<467>).
- Residual Solvents (USP<467>).
- 1,4-Dioxane testing.
- Ethylene Oxide testing.
- Spectroscopic analysis (FTIR and UV/VIS)
- Water (Karl Fischer, volumetric and coulometric).
- Heavy Metals.
- Arsenic, Lead, Mercury.
- Metals by Flame, Cold Vapor & Graphite Furnace Atomic Absorption spectroscopy
- Metals by ICP and ICP-MS.
- Physical-chemical (pH, viscosity, specific gravity, refractive index, optical and specific rotation, melting point, loss on drying, residue on ignition and congealing temperature)
- Titrimetry (potentiometric and visual end points).
- Purified water and sterile water for injection testing.
- USP microbial limits



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