

Laboratory Service Index

The Quality Control and Development Laboratory at Singota Solutions has a variety of equipment and instrumentation available for formulation, product development, microbiology, testing and analytical activities. Select equipment, methods and instrumentation, listed below, are validated and/or GMP compliant.

Testing Capabilities

- Formulation Development of Parenteral & Lyophilized Products
- Non-Clinical/Reference Standard Formulation & Fill
- Raw Material Testing
- Infusion & Material Compatibility Studies
- API & Medical Device Stability & Thermal Cycle Testing
- Reconstitution Studies
- Cytotoxin Testing
- Water Absorbance Studies
- Container Closure Integrity Testing

Lyophilization & Thermal Analysis

- Lyophilizer (LyoStar II)
- Differential Scanning Calorimeter (DSC)
- Karl Fischer Moisture Content Analyzer
- X-Ray Diffraction (-193 to 450 °C) Vacuum or Inert Gas
- Freeze Dry Microscope (FDM)

ICH Stability & Temp. Excursion Chambers

- -80 +/- 5 °C; Ambient RH
- -15 +/- 5 °C; Ambient RH
- 5 +/- 3 °C; Ambient RH
- 25 +/- 2 °C; 60 +/- 5 % RH
- 30 +/- 2 °C; 65 +/- 5 % RH
- 40 +/- 2 °C; 75 +/- 5 % RH
- 60 +/- 2 °C; 75 +/- 5 % RH

Microbiology

- Microbial Enumeration/Bioburden USP<61>
- Specified Microorganism Testing USP<62>
- Bacterial Endotoxins Testing USP <85>
- Sterility Testing USP <71>

Analytical Instrumentation

- Liquid Chromatography (UHPLC/HPLC)
- UV/Vis Spectrophotometer (UV/Vis)
- Capillary Electrophoresis (CE)
- Fourier Transform Infrared Spectroscopy (FTIR)
- Microplate Spectrophotometer (ELISA)
- Optical Microscope
- Karl Fischer Moisture Content with Compact Oven
- Density Meter
- Osmometer
- TOC Water Analyzer
- Viscometer
- HIAC

Supporting Analytical & Pharma Equipment

- Electronic Laboratory Notebook (ELN)
- Sterility Isolator
- Analytical & Micro Balances
- Laminar Flow Hoods
- Biological Safety Cabinet
- pH & Conductivity Meters
- Fume Hoods, Glove Boxes
- Milli-Q Water System
- Centrifuges
- Vial Sealing Equipment
- Incubators
- Desiccator

Formulation Assistance

- Large & Small Molecule Formulation Studies
- Forced Degradation
- Lyophilization Excipient Evaluation

Singota additionally offers Aseptic Manufacturing, GMP Compliant Material Storage including Hazardous Materials, Sampling & Dispensing Capabilities, Cold Chain Solutions, and Labeling/Kitting Services.

Focused on Faster