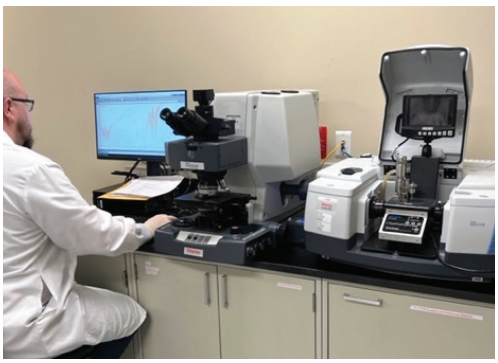
Raw Materials & Container Closure Integrity Testing for Pharma & BioPharma Products

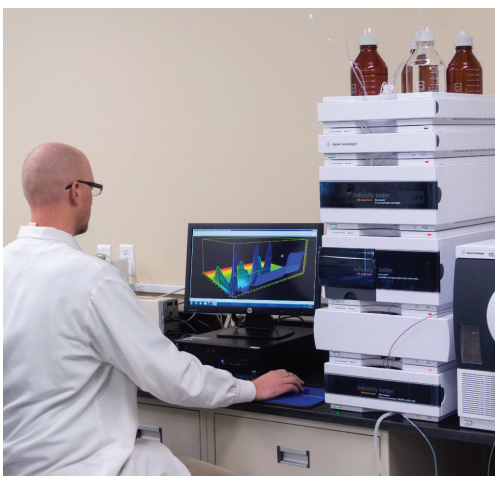
Nelson Labs
A Sotera Health company

Nelson Labs is a global provider of microbiological testing, analytical chemistry, and advisory services, supporting pharma and biopharma companies. We have over 35 years of experience solving challenges that are not typically addressed in routine testing. We have the capabilities and expertise to support the CMC testing needs and lifecycle management of your drug products. We are US FDA registered, cGMP compliant, and ISO17025 accredited and have laboratories located throughout North America and Europe.

The following are some of the services Nelson Labs offers to support your pharma & biopharma products:

- **Container Closure USP & EP**
  - Elastomeric Closure USP <381>
  - Glass USP <660>
  - Plastic USP <661.1>, USP <661.2>
  - Functionality of Prefilled Syringes and Penetrability of Stoppers
- **Raw Materials (Excipients) USP, EP, & JP**
  - Assay
  - Impurities
  - Catalysts and Environmental Contaminants
  - Residual Solvents
  - Moisture
  - Trace Metals
  - Identification: FTIR, UV/Vis., HPLC, TLC
  - Residue On Ignition (ROI)
  - Loss on Drying (LOD)
  - Moisture Determination by KF
  - Viscosity
  - Melting Point
  - Specific Gravity and Density
  - pH and Conductivity
  - Optical Rotation
  - Acid, Base, and Peroxide-Value Determination
  - Microbial Limits
  - Bacterial Endotoxins (BET)
  - Total Organic Carbon (TOC)





Note: Nelson Labs offers method feasibility, verification, and suitability for all compendial procedures.

Contact us today!

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US FDA registered and third-party accredited to ISO 17025 standards

