Sannova Analytical

cGMP Analytical Testing

Trace impurity identification specialists with a full release and stability laboratory

Sannova Analytical has completed more than 3,500 cGMP analytical studies for pharmaceutical, generic, and contract manufacturers. We specialize in high-sensitivity impurity assays. Our services include method development and validation, release testing, and stability testing for clinical and commercial material.

Nitrosamine & NDSRIs

- Product-specific methods at FDA acceptable intake limits
- Nitrosamine risk assessment and testing
- Other genotoxic impurities (ICH M7)
- Drug substance and drug product
- LC-MS/MS and GC-MS

Extractables & Leachables

- Container closure systems, single-use components, and delivery devices
- Controlled studies designed to USP <1663> and <1664>
- Identification of unknowns
- LC-MS/MS, GC-MS, and ICP-MS

Elemental Impurities Testing

- ICP-MS testing to ICH Q3D and USP <232>
- Drug substance, excipients, and drug product
- Method validation to USP <233>

Method Development and Validation

- Identity, assay, impurities, and dissolution
- Validated to ICH Q2(R2) and USP <1225>
- IND-enabling characterization through commercial QC

Release and Stability Testing

- cGMP lot release and QC testing
- APIs and drug products, clinical and commercial
- On-site stability storage and scheduled pull testing

14 LC-MS/MS, 21,000sq.ft. facility | FDA-inspected under cGMP and GLP | DEA-registered, Schedules II-V

155 Pierce St., Somerset, NJ 08873 www.Sannova.com