METHOD DEVELOPMENT & VALIDATION

Quantex Laboratories provides comprehensive analytical method development and method validation services. Our knowledgeable and experienced scientists develop methods using a wide range of analytical techniques. Analytical methods developed include procedures for active pharmaceutical ingredients (APIs), drug formulations, cleaning agents, and raw materials. We can also provide remediation and validation of methods you're currently using to help improve performance and ensure accuracy and reliability of those analytical methods.

Method validation is designed collaboratively based upon your specific requirements. Protocols employed can be customer supplied or written by Quantex technical staff using our method validation templates. In the development and validation of stability indication methods, we can perform forced degradation studies on your drug substance or drug product to provide stability validation of the analytical procedures. Routine forced degradation is carried out using acid, base, peroxide, heat, and light.

All of our work is carried out under strict compliance with cGMP and ICH requirements, and our analytical operations are based on formal written, detailed SOPs and stringent quality assurance practices. Upon completion, detailed procedures and results for all method development and method validation projects are presented in a comprehensive report. Our standard format includes a copy of the analytical method, a copy of the protocols when applicable, all test results, appropriate graphs and calculations, and sample raw data (such as chromatograms). In addition, reports can be prepared in a customer specified format as well.

Our analytical method development and validation services include support for the following:

- Assay
- Related substances
- Stability indicating assays
- Impurities
- Forced degradation studies
- Method remediation
- Remedial validation
- Residual solvents
- Extractables/Leachables
- Cleaning validation
- Process validation
- Method transfer
- Comparator studies
- Characterization of reference standard & drug substances
- Formulation development
- Product development
- Counterfeit product evaluation
- Raw Materials
- QC & Release testing

Our State-of-the-Art Instrumentation includes:

- HPLC: (UV-VIS, PDA, FL, RI, electrochemical detector, ELSD)
- LC-MS with APCI & ESI
- LC-MS/MS with APCI & ESI
- GC: direct injection, headspace capability, (FID, TCD , NPD & ECD)
- GC-MS: direct injection, headspace capability with EI and CI ionization source
- Flame AA
- GFAA
- ICP & ICP-MS
- Mercury analyzer
- IC
- CE
- Many more additional Instruments

QUANTEX LABORATORIES®

AN EXTENSION OF *YOUR* TEAM℠

For more information on our capabilities please contact our Business Development group at (609) 655-4047, extension 304.

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