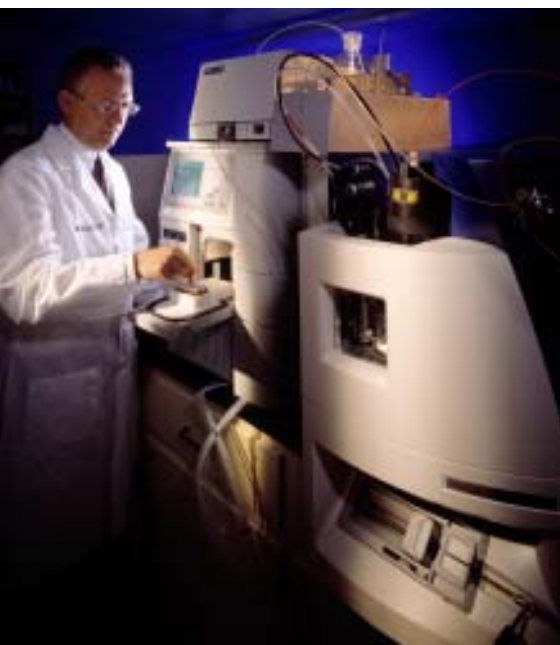


Analytical Method Development and Validation

Lancaster Laboratories offers comprehensive analytical method development and method validation services through a specialized staff of experienced pharmaceutical scientists. We're available for analytical consulting as required, and we can develop methods using a wide range of analytical techniques and assist in the design of validation protocols based upon your requirements. We can also validate methods you're presently using to help ensure accuracy and reliability in your analytical processes. The protocol for validations can be client supplied or written by us using our validation templates. All of our work is performed under strict compliance with cGMP requirements, and our analytical operations are based on written, detailed SOPs and stringent quality assurance practices.



We specialize in the development and validation of analytical methods in support of:

- Stability testing.
- Impurities.
- Raw materials testing.
- Method remediation.
- Extractables/leachables.
- Biopharmaceuticals.
- Formulation development.
- Release testing.
- Residuals.
- Process validation.
- Cleaning validation.
- Comparator testing.
- Materials characterization.
- Product development.

We can perform forced degradation studies on your drug substance or drug product to provide stability validation of the analytical procedures. Routine forced degradation at Lancaster Laboratories is done using acid, base, peroxide, heat, and light.

The analytical techniques we use to develop and validate methods are:

- HPLC and UPLC using diode array, variable wavelength UV, refractive index or fluorescence detection.
- Ion chromatography for anionic and cationic separations.
- GC using flame ionization or thermal conductivity detection with direct injection or static headspace analysis.
- LC/MS and GC/MS to determine molecular weight and to elucidate chemical structure.
- Flame Atomic Absorption, Graphite Furnace Atomic Absorption, ICP, and ICP/MS.
- UV/VIS spectroscopy.

The 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, protocols when applicable, all test results, appropriate graphs and calculations, and sample raw data (such as chromatograms). The report can also be prepared to client specifications and format. In addition, we can deliver the report on diskette, along with the standard bound copy, using common PC word processing software programs.

For more information on our method development and validation capabilities or any of our pharmaceutical capabilities, please contact your project manager or Pharmaceutical Business Development at 717-656-2300.



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