



Analytical Development

The BioDuro Advantage

BioDuro's analytical team is well-integrated into the formulation and manufacturing programs to facilitate and accelerate the development of the analytical methods and testing of prototypes, raw materials and drug products. Sharing knowledge of the formulation and the manufacturing process results in analytical data that is scientifically sound and project support that is well-coordinated and timely. Experienced and dedicated development and QC chemists at BioDuro are committed to the highest levels of technical quality and GMP compliance.

Analytical Services:

- Method evaluation/transfer
- Method development
- Method qualification/validation
- API physical and chemical characterization
- Raw material & API testing/release
- Product-specification support
- Cleaning verification
- In-process testing
- Formulation prototype testing
- Stability storage
- Finished product release testing
- Drug excipient compatibility studies
- ICH stability testing

Testing Capabilities:

- Chromatography (HPLC, UPLC, and GC)
- Spectroscopy (FTIR, UV)
- X-ray powder diffraction
- Dissolution
- Karl Fischer
- Physical testing
- Particle analysis
- Thermal analysis



	Equipment	Manufacturer
Liquid Chromatography	<ul style="list-style-type: none"> • Corona CAD (Detector) • UV/Vis, PDA (Detector) • HPLC • UPLC 	<ul style="list-style-type: none"> • Dionex • Waters • Waters, Agilent • Waters
Gas Chromatography	<ul style="list-style-type: none"> • G6890 Gas Chromatograph, G1888 Headspace Sampler 	<ul style="list-style-type: none"> • Agilent
Spectrometry	<ul style="list-style-type: none"> • Cary 60 UV-Vis Spectrophotometer • Spectrum 100 FTIR • SpectraMax 	<ul style="list-style-type: none"> • Agilent • Perkin-Elmer • Molecular Devices
Particle Sizing	<ul style="list-style-type: none"> • Mastersizer 3000 	<ul style="list-style-type: none"> • Malvern
Thermal Analysis	<ul style="list-style-type: none"> • MDSC w/Autosampler • Pyris TGA 	<ul style="list-style-type: none"> • TA Instruments • Perkin-Elmer
Dissolution and Disintegration	<ul style="list-style-type: none"> • Dissolution Test Station w/Autosampler • QC-21 Disintegration Test Systems • Enhancer Cell • Ointment Disk 	<ul style="list-style-type: none"> • Agilent • Hanson Research • Vankel • Hanson Research
Stability Chambers	<ul style="list-style-type: none"> • 25°C/60% RH Chamber • 30°C/65% RH Chamber • 40°C/75% RH Chamber • 2-8°C Chamber • -20°C Chamber 	<ul style="list-style-type: none"> • Environmental Specialties • Environmental Specialties • Environmental Specialties • Environmental Specialties • Thermo Fisher Scientific
Other	<ul style="list-style-type: none"> • Fluorescence Detector • Karl Fischer Titrator • Polarizing Light Microscope • Hardness Tester • Friability Tester • Savant High Speed Solvent Evaporator • X-Ray Powder Diffraction Analyzer 	<ul style="list-style-type: none"> • Waters • Mettler Toledo • Leica • Varian/Vankel • Erweka • Thermo Scientific • Rigaku