

Bioanalytical Services

- FDA Inspected Facility, without 483



Bioanalytical services at WuXi AppTec offers comprehensive and FDA/OECD/SFDA GLP-compliant bioanalysis services to support drug discovery, preclinical and clinical development for pharmaceuticals, biologics, biomarkers and antibodies.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

WX
LISTED
NYSE

GLP Bioanalytical Services

- Method development and validation - LC/MS/MS, ligand binding assay
- Sample analysis - LC/MS/MS, and ligand binding assay
- Synthesis of reference standard and labeled IS - LC/MS/MS
- Immunogenicity - ligand binding assay

Discovery Bioanalytical Services

- Rapid Turnaround Quantitative Analysis
Integrated with DMPK services
- Metabolite Identification
Profiling, structure elucidation, and synthesizing authentic reference standard

Service Features

- Studies
 - Preclinical/Clinical PK and PD
 - Toxicokinetic
 - Immunogenicity
- Instrumentation
 - API 4000/5000 MS
 - UPLC
 - MSD Sector Imager 6000
 - Molecule Devices M2/M5 reader
 - Luminex 200
- Capacity and Experience
 - 13 established clients
 - 15,750 sq. ft.
 - 120 staffs
 - Numerous studies submitted to FDA and SFDA
- Other Features
 - Validated Watson 7.2 LIMS for sample and data management
 - Study-dedicated instrument and scientist
 - Dedicated QC team
 - Strong logistical support for receiving material and biological samples sent from anywhere in the world
 - To synthesize reference standard and stable-labeled internal standards

Nominal Conc.	Rep.	Instrument	Mean Instrument Response	%CV Raw Data	ID	Conc. Found	Status	%Found
31.25	1.0	06050	0.89294177	ST10	N.P.	Active		
31.25	2.0	06745		ST10		Active		
62.5	1.0	12350	0.1277006	ST106	66.179	Active		
62.5	2.0	12775		ST106		Active		
125	1.0	22555	No Value %CV (NA) (0.0)	ST106		Discontinued		
125	2.0	23105		ST106		Discontinued		
250	1.0	48665	0.49225152	ST107	267.00	Active		
250	2.0	49755		ST107		Active		
500	1.0	89845	0.9678148	ST106	489.68	Active		
500	2.0	93135		ST106		Active		
750	1.0	151055	1.45305564	ST105	747.19	Active		

Nominal Conc.	Rep.	Instrument	Mean Instrument Response	%CV Raw Data	ID	Conc. Found	Status	%Found	Adj. R2
62.5	1.0	06025	0.006352450	LI-00-1	N.P.	Active			
62.5	2.0	06745		LI-00-1		Active			
62.5	1.0	48655	0.4813022	LI-00-2	261.83	Active			
62.5	2.0	48655		LI-00-2		Active			
62.5	1.0	20945	0.2032157	LI-00-3	118.57	Active			
62.5	2.0	20945		LI-00-3		Active			
62.5	1.0	28965	0.28495213	LI-00-4	164.51	Active			
62.5	2.0	28965		LI-00-4		Active			
62.5	1.0	48615	2.5352239	LI-00-5	1786.1	Active			
62.5	2.0	48615		LI-00-5		Active			
200	1.0	19605	0.19325205	LI-0-1	112.53	Active			
200	2.0	19605		LI-0-1		Active			

WATSON LIMS

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