

Chemistry Service Unit

Integrated Analytical and Purification Services

Discovery Analytical services at WuXi AppTec provides analytical and separation services to support chemistry and drug discovery.

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
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NYSE

Chiral Separation Services

- Quick development of fast assays to evaluate synthetic routes and determine e.e for chiral compounds
- Fast access to pure/enantiopure intermediates or drug candidates with minimal development time and labor

Natural Product Purification

- Analytical reference standard isolation and characterization
- Milligram-to-kilogram natural product purification capability
- Isolation process development
- Quantity analysis of pure natural products or crude extracts

High-throughput Purification and Analytical Services

- MS and UV triggered automatic Prep HPLC
- Standard LC-UV-ELSD-MS platform for QC of isolated compound
- Capability to purify and characterize 1,000,000 compounds annually

High-throughput Physical Property Determination

- Thermodynamic and kinetic solutions solubility by LC-CLND method
- Log P/log D determination utilizing shake-flask
- Pka determination by potential metric titration method

Isolation and Structure Elucidation of Impurities

- Isolation of impurities of regulatory starting materials, intermediates, APIs and drug products using various techniques mainly including preparative HPLC and SFC.
- Structure elucidation of isolated impurities by acquisition and interpretation of comprehensive 1D/2D NMR and LCMS data.
- Isolation and structure elucidation of forced oxidation degradants of APIs.
- Fast purity determination of raw materials, intermediates, APIs and synthetic impurities by quantitative NMR (QNMR).
- Professional document preparation for filings.

Method Development and Verification Methodology Services

- Method validation of API (in accordance with the ICH requirements or other specified standard of customers)
- Residual solvent method validation (in accordance with the ICH requirements)



For more information on WuXi AppTec's services please contact:

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Project Approved by ISO/IEC17025(CNAS)

Residual solvents, atomic absorption spectrophotometry, ultraviolet-visible spectrophotometry, high performance liquid chromatography, heavy metals, loss on drying, residue on Ignition, ash, moisture, optical rotation, melting point, disintegration time limit, minimum, solubility, relative density, pH value etc. (in accordance with Ch.P 2010)

Our Philosophies

- High quality
- Fast turn-around time
- Cost effective
- Flexibility

We Offer

- Chiral separation (mg to multi kg)
- High-throughput purification (1,000,000 compounds annually)
- Natural products extraction, purification, structure identification and quality analysis.
- Physical property determination (Pka, LogP/ LogD, and thermodynamic and kinetic solubility)
- Isolation and structure elucidation impurities of regulatory starting materials, intermediates, APIs and drug products.
- Test items approved by ISO/IEC17025(CNAS): residual solvents, atomic absorption spectrophotometry, ultraviolet-visible spectrophotometry, high performance liquid chromatography, heavy metals, loss on drying, residue on ignition, ash, moisture, optical rotation, melting point, disintegration time limit, minimum, solubility, relative density, pH value etc. (in accordance with Ch.P 2010)



Capabilities

- 2 sets of Agilent LC-TOF Mass
- 20 sets of Bruker and Varian NMR, 400MHz
- 70 sets of Agilent/Shimadzu LCMS
- 50 sets of Agilent /Shimadzu HPLC
- 1 sets of Metrohm IC
- 1 set GC equipped with FID, TCD, ECD and FPD detectors
- 1 set AAS with Flame/Graphite Furnace detectors

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CS-001-08.21.12