

Analytical R&D Services



**EMA-Certified
GMP Analytical
R&D and
Stability Testing
Laboratories
for Regulatory
Filing**

Analytical R&D at WuXi AppTec provides a full range of services including method development and validation, stability services, analytical testing and release, structure elucidation, GMP separation services and CMC authoring services

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**

Method Development and Validation

- **API**
Assay and Impurities; Counter-ion; Water; Chiral Purity; Residual Solvents; Toxic Metals; Particle Size; X-Ray Powder Diffraction; ID; NMR; LC/MS
- **Drug Products**
Assay; Impurities/Degradants; Content Uniformity; Dissolution; Water Activity; Appearance; ID

Analytical Testing and Release

- **Reference Standard Program**
Primary Reference Standard Qualification and Characterization (Purity, Assay, ROI, KF, Residual Solvents, etc); COA Issuance; Establishment of Qualified Reference Standard with Internal Process and Separation Group; Packaging/Storage



- **Confirmation of Structure**
Lab work and documentation for structural elucidation and physicochemical properties including NMR (1H, 13C, 2D), IR, HR-MS, UV, Raman, Elemental Analysis, X-Ray, XRPD, DSC, TGA, Aqueous Solubility, Nonaqueous Solubility, Intrinsic Dissolution, Log P, Log D, Hygroscopicity, Melting Point, pKa, Optical Rotation, etc.
- **Testing and Release of API and Drug Products**
- **Biologic Analysis**

Stability Services

GMP Separation Services



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

U.S.
+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

China
+86 (21) 5046 2477
customer_service@wuxiapptec.com

Fact Sheet

- Passed EMEA audit in November 2009
- Passed client audits from more than dozens of big Pharma and biotech from US, Europe and Japan
- Hundreds of stability-indicating assay/impurities methods developed & validated
- Hundreds of drug substance and drug products on long term stability studies from IND to NDA registration
- Twenty thousand square feet of GMP analytical laboratories
- More than hundred of capable analytical research and development staff
- Proven systematic advanced analytical sciences training and GMP compliance training over years



Instrument Highlight

- **Assay & Impurity, Content Uniformity:** Agilent 1200, Waters 2695, Shimadzu LC20, Aquity UPLC, LC-MS
- **Dissolution and Disintegration:** Sotax AT 7 smart, Varian VK7000, VK 7010, VK7025, Sotax DT2
- **Residual Solvent:** GC, GC-MS
- **Water Content & Water Activity:** Coulometric Karl Fischer Titrator, Metrohm Coulometric Karl-Fischer titrator
- **ID:** HPLC, IR, NMR
- **Counter Ion Detection:** Dionex IC, Potentiometric titrator
- **Mutagen:** LC/MS, GC/MS, LC/MS/MS
- **Toxic Metal:** Thermo ICP-OES
- **Microbial Limit Test:** Incubator, Biosafety Cabinet, Water Bath, Laminar Flow Hood
- **Particle Size/XRPD/Surface Area/DVS**



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

U.S.

+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

China

+86 (21) 5046 2477
customer_service@wuxiapptec.com

www.wuxiapptec.com