SK pharmteco

Small Molecule Analytical Testing Services

Accurate, Timely, Reliable Analytical Solutions

In today's evolving regulatory landscape, staying ahead of compliance demands and advancements in small molecule analysis is crucial. Robust and accurate analytical data are essential at every stage of drug development and manufacturing under CGMP guidelines. Partnering with a CDMO for small molecule analytical development, API contract testing, and other services unlocks deep expertise and testing capacity to accelerate your path to market and empower continued commercial success.

At SK pharmteco, we offer flexible, phase-appropriate analytical services tailored to your project needs. From method development and validation to release testing and stability studies for active pharmaceutical ingredient (API) drug substances, intermediates, registered starting materials (RSMs), and various drug product formulations, our team guides you in selecting and developing the right analytical approach for your product.

With a comprehensive portfolio of capabilities, an experienced team, and a proven track record, SK pharmteco ensures confidence at every step of the product lifecycle.

Services:

- Drug Substance & Drug Product Analytical Development & Testing
- Analytical Development, Tech Transfer, Validation
- Nitrosamines
- Extractables & Leachables
- Stability Studies
- Release Testing
- Raw Materials & Excipients
- Material Science
- Reference Standard Characterization

Your Seamless Partnership Begins Here

In the fast-paced pharma and biotech industries, efficiency is key. As a consolidated contract analytical laboratory, we offer a comprehensive range of services under one roof. This helps simplify your lab management, save time, and reduce sample volume requirements, translating into cost and resource efficiency.

From initial contact to final delivery, our team is committed to making your experience as smooth and efficient as possible.

Easy to Work With:
Streamlined onboarding with straightforward contracts, transparent terms, and a clear sample submission process. We aim to deliver accurate and thorough proposals and begin processing samples immediately upon receiving a purchase order.

Strong Communication:
Benefit from having direct access to the technical lead driving your project. This agile approach ensures your needs are communicated and addressed quickly and effectively.

Prioritized Delivery:
Our team is committed to on-time, in-full delivery to ensure that your project progresses smoothly without unnecessary rush or delays.

Integrated Sample Management:
Manage and track your sample transfers with advanced temperature-controlled supply chain solutions, ensuring secure, reliable, and precise transportation for your samples.

Highlights

Proven Track Record: With experience across 650+ commercial APIs and drug products, we serve as a reliable partner to drive your success.

Commitment to Safety: With our stellar safety record, you can trust that your project will be managed with the highest safety standards.

Regulatory Excellence: Our 100% adherence to global regulatory agencies offers you confidence in our compliance and quality standards to accelerate your path to the market. Our CGMP laboratories have been successfully inspected by global regulatory agencies, including the FDA (U.S.), PMDA (Japan), and EU QP.

100%
Inspections passed at all facilities

9
Recent PAIs waived

1,500+
Raw Materials tested and released

>230
FDA personnel trained on-site

Our Capabilities

Whether you require analytical services through our manufacturing partnership, or independent contract analytical services, our laboratories deliver accurate, reliable, and timely solutions.

Analytical Development

Complex method development across all testing platforms along with phase-appropriate validation/ qualification/transfer

Raw Material & Excipients Testing

Testing against established internal specifications and/or pharmacopoeia for all modalities. We have tested and released over **1,500** raw materials.

Nitrosamines & Genotoxic Impurities

Development and testing for nitrosamines, drug-specific nitrosamines, and other genotoxic impurities down to ppm or ppb levels

Material Science & Characterization

Characterization for filings and extensive solid state characterization capabilities including particle size, polymorph and beyond

Extractables & Leachables

E&L testing and validation for product packaging, storage, and delivery systems assessed against our MS libraries

Reference Standard Management & Characterization Testing

Dedicated team to manage qualifications, inventory, storage and distribution of reference standards

Stability Studies & Storage

ICH stability studies across the range of storage conditions, along with photostability and forced degradation studies

Elemental Impurities

Testing your products for elemental impurity control in compliance with USP <232>, <233>, and ICH Q3D regulations

Release Testing

CGMP release for RSMs, intermediates, drug substance, and drug product from a dedicated QC and QA team

Residual Solvents

Quantification and identification of residual solvents in drug substances and products, ensuring compliance with ICH Q3C guidelines for patient safety

Specialized Capabilities:

High potency and cytotoxic compounds require specialized expertise for safe and secure handling.

At SK pharmteco, we have extensive experience and a dedicated sample handling facility to ensure rigorous safety and compliance.

- Capability to handle Band 5 & Band 5 SC compounds
- OEL < 0.1 µg/m³

Additional Capabilities:

- Compendial Testing (USP / EP / BP / JP)
- Calorimetry
- Chiral Separations
- Dissolution
- Impurity Identification
- Mass Spectrometry
- Microbiology
- Optical Rotation
- Osmolality
- Particle Size Analysis
- Particulate Matter
- Spectroscopy
- Thermogravimetric Analysis

Our Global Presence

5 CGMP Small Molecule Manufacturing Facilities

With facilities around the world, we ensure uninterrupted manufacturing and delivery of your critical products, safeguarding against potential disruptions. Our network supports a wide range of production scales, enabling you to seamlessly adjust to changing demand, from clinical to commercial production.

Equipped with State of the Art Instrumentation

HPLC/UHPLC Agilent/Thermo/Waters	FTIR and Raman Perkin Elmer/Thermo	XRPD Malvern Panalytical/Bruker	Dissolution Agilent	Stability Chambers Caron and Others
LC Detectors DAD,VWD, RID, CAD, FLD, MS & MS/MS	Particle Size Analysis (laser light scattering) Malvern/Sympatec	NMR Bruker	Liquid Particle Counter Beckman Coulter	Photostability (with temp/RH control) Caron
LC-MS and LC-MS/MS Single Quad, Triple Quad, High-Res (QTOF)	Particle Size Analysis (jet and shaker sieves) Hosokawa	Optical Microscopy Leica/Olympus	Osmometer Advanced Instruments	TOC Analyzer Shimadzu/Suez
GC/HSGC and GC-MS Agilent/Thermo	ICP-MS Thermo/Agilent	SEM Jeol	Polarimeter Rudolph	UV/Vis Agilent/Mettler Toledo/Perkin Elmer
GC Detectors FID, TCD, ECD, & MS	ICP-OES Thermo/Perkin Elmer	Surface Area Micrometrics	Moisture Analyzer Mettler Toledo	pH and Conductivity Mettler Toledo
Ion Chromatography Thermo/Dionex	Karl Fischer (coulometric and volumetric) Mettler Toledo/Metrohm	Differential Scanning Calorimeter Mettler Toledo/TA	DVS Surface Measurement Systems	Densitometer Mettler Toledo
ThermoFisher Chromeleon Chromatography Data System	Auto Titrators Mettler Toledo/Metrohm	Thermogravimetric Analyzer Mettler Toledo/TA	Powder Rheometer Freeman	Refractometer Mettler Toledo

About SK pharmteco:

At SK pharmteco our mission is to build strong relationships that create happiness for our customers through the shared goal of producing and delivering life-changing therapies that improve patient outcomes and save lives. With our network of seven global, cutting-edge, facilities our capabilities cover the entire product lifecycle, from initial development to commercial manufacturing. We work with customers in a flexible 'One Team' approach, prioritizing collaboration, transparency, and trust to make every interaction easy and seamless.

SK pharmteco offers CDMO services for small molecule APIs and cell and gene therapies as well as analytical testing services; contact our experts to learn more!

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