



Analytical Services

At GVK BIO, we provide a full range of analytical services from Discovery to Commercial Phase III. The Analytical Service portfolio includes method development and validation, stability studies, analytical testing and release, structure elucidation, GMP separation and CMC Support.

Discovery & Medicinal Chemistry

- Analytical Method Development of compounds by chiral and achiral methods
 - Quick development of fast assays to evaluate chemical and chiral purity
 - Isolation & Purification : SFC or prep-HPLC for chiral & achiral compounds based on compatibility
- High-throughput Purification Services
 - Mass and UV mediated LC purification
 - Standard LC-UV-ELSD-MS platform for QC of isolated compound
 - Capability to purify and characterize 20,000 compounds annually
- Natural Product Purification
 - Analytical reference standard isolation and characterization
 - Lab-scale natural product purification capability
 - Isolation process development
- Physio-chemical Characterization
 - Solubility
 - LogP /log D determination
 - Pka determination by potentiometric and UV spectroscopic techniques
- Isolation and Structure Elucidation
 - Isolation of related substances by various methods including HPLC, SFC, etc.
 - Elucidate structure by the combination of various analytical techniques, including NMR, LC-TOF MS, elemental analysis, FTIR, etc
 - In NMR, 1D spectra of ¹H, ¹³C, ¹⁹F, ³¹P, ¹¹B, ¹⁵N...
 - 2D COSY, TOCSY, HSQC, HMBC, NOESY, VT Experiments and HOESY
 - Q-NMR Method to determine potency factor

NCE Development & API

- Analytical Method Development
 - Potency
 - Impurities : forced degradation studies for identification and LCMS/MS as a tool for identification and purification
 - Residual solvents
 - Physical and chemical tests
 - Cleaning assessment
 - Chiral purity
 - Particle Size
 - Identification tests (FTIR, NMR, LCMS)
 - Counter-ion*
 - X-ray Powder diffraction*
 - Metals*

Validation of Analytical Procedures

- Assay of actives
- Related substances or impurities
- Cleaning validation
- Chiral purity / Enantiomeric Excess
- Residual solvents by HS-GC
- Non specific assay methods (UV & potentiometer)
- Impurities at trace levels (LC-MS/MS and GCMS)
- Particle size
- Estimation of residual metals*
- Microbiology

CMC Support to Commercial Manufacturing

- Analytical method Development Report with:
 - Preliminary degradation data
 - Physical & chemical characteristics
- Standard Test Procedures for:
 - Raw material, Intermediates and Finished product
 - In-process controls
 - Cleaning methods
- Characterization data for impurities and reference standards
- Analytical method qualification / validation report for final product & Key Starting materials (KSM's)
- Report for "Cut-Off" / "Carry over studies" data with scientific rationale
- Impurity profiling for Key starting materials and final product.
- Report on Holding study (Wet & packaged)
- Report on indicative stability studies
- Analytical Testing and Release
 - Primary Reference Standard Qualification and Characterization (Purity, Assay, ROI, KF, Residual Solvents, etc)
 - COA Issuance
 - Establishment of Qualified Reference Standard – R&D / Separation
 - Packaging/Storage
 - Stability studies (ICH conditions)
 - Analytical Method transfer
- Physical state characterization & polymorph screening*

Instrumentation

Purification Equipment:

SFC

Flash Chromatography

MPLC, Prep LC

Identification:

LCMS, LCMS/MS

NMR, CHNS Analyzer, FTIR

Impurities & Assay:

HPLC and UPLC with PDA, UV

ELSD and RI detectors

LCMS/MS with UPLC

PDA and ELSD

Residual Solvents:

GC with headspace and GCMS

Counter-ion:

Potentiometry and Ion Chromatography*

Stability Studies:

Stability Chambers – ICH conditions

Microbiology Testing Laboratory

Particle Size Analyzer

Differential Scanning Calorimetry (DSC)

Impurities of toxic concern:

LCMS/MS, GCMS

Analytical services from Discovery to Commercial Phase III

