JIUZHOU Pharmaceutical | Raybow Pharmaceutical

Molecule to Market: Your Trusted Partner

Analytical Services Menu Items

Raybow USA's Analytical Services are tailored to meet the unique demands of each project, ensuring that your goals are not just met, but exceeded.

Our highly qualified chemists communicate closely with you every step of the way, ensuring the efficient application of resources and expertise.

	Product Stage		
Service	**Development / Pre-GMP**	**Phase 1 Qualified / Partial Validation**	**Phase 2 Full Validation**
Method Development	Fit-for-purpose methods for process monitoring or release	Optimized methods with basic qualification (accuracy, precision)	Method development + full ICH-compliant validation package
Method Transfer	Informal transfer between labs	Comparative runs with limited documentation	Formal transfer protocol, execution, and reporting.
Release Testing (API)	Identity, purity, assay, water, residual solvents (non-GMP)	GMP release with qualified methods; limited validation	GMP release with validated methods; full CoA package
In-Process Testing	HPLC, GC, KF, titrations as needed (non-GMP)	GMP in-process methods qualified	Validated IPC methods supporting commercial readiness
Stability Studies	Short-term stability (stress testing, feasibility)	GMP stability study setup, Phase 1 trending	Full ICH Q1 stability program with reporting
Impurity Profiling	Screening for process impurities and degradants	Qualified impurity methods; limited quantitation	Full impurity profiling with validated methods per ICH Q3
Reference Standard Qualification	Non-GMP reference material (fit-for-purpose)	GMP qualification of standards (purity, ID)	Fully validated reference standards with CoA package
Raw Material Testing	Basic testing (identity, purity)	GMP release testing (identity, assay, water, solvents)	Full vendor qualification + release testing per pharmacopeia
Vendor Qualification	Informal testing of raw materials	GMP vendor qualification testing package	Full vendor qualification with audit support and documentation
Residual Solvents / Elemental Impurities	Development screening	GMP qualified method with partial validation	Full validation per ICH Q3C/Q3D guidelines
Cleaning Verification	Method feasibility studies	Qualified cleaning verification methods	Fully validated cleaning methods for regulatory use
Chiral / Polymorph Characterization	Fit-for-purpose chiral separation or XRPD/DSC	Qualified methods, supportive of Phase 1 batches	Fully validated chiral/polymorph methods for submission
Documentation / Reporting	Internal reports (non-GMP format)	GMP reports with qualification/validation summaries	IND/IMPD-ready reports with full validation package

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Analytical Services Package Examples

Ask about creating Custom Packages to suit your needs.

Sample Development Package

Fit-for-Purpose

Intended for: Early process development, non-GMP material, feasibility batches

Includes:

- custom method development (fit-for-purpose, non-validated)
- Basic in-process testing support (HPLC, GC, KF, etc.)
- Preliminary impurity screening
- Non-GMP release testing (assay, purity, residual solvents, water)
- Internal (non-GMP) analytical report

Sample Phase 1 Package

Qualified Methods

Intended for: GMP production of toxicology and first-in-human batches

Includes:

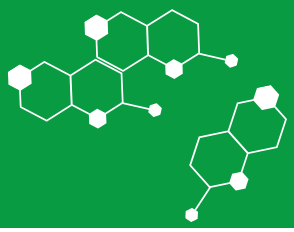
- 1–2 method qualifications (accuracy, precision, linearity)
- GMP release testing of API (identity, assay, purity, residual solvents, water)
- Qualified impurity profiling
- Reference standard qualification
- Stability study setup under 2 conditions
- GMP analytical report + Certificate of Analysis (CoA)

Add-ons :

- Additional method qualification
- Extra stability conditions
- Vendor qualification testing

Sample Phase 2 Package

Validated Methods



Intended for: Early Phase 2 clinical material, IND/IMPD support

Includes:

- 2–3 full method validations (ICH Q2 compliance)
- GMP release testing of API with validated methods
- Full impurity profiling and validated reference standard
- Stability study setup under 3 conditions
- Cleaning verification method development & validation
- IND/IMPD submission-ready validation report package + CoA

Add-ons:

- Additional full method validation
- Elemental impurities validation per ICH Q3D
- Chiral or polymorph characterization

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