



# KMPS

**K. M. Pharma Solution Pvt. Ltd.**



## Experience Backed Research Solutions



**CRDO &  
CDMO**



**Custom  
Synthesis**



**Certified  
Reference  
Standards**



**Nitrosamines  
Standards**



**Stable  
isotopes and  
Metabolites**



**Analytical  
Services**

## An Integrated CRDO & GMP CDMO

K. M. Pharma Solution Pvt Ltd is a chemistry-based, innovation-driven organization specialising in the synthesis of nitrosamine impurities, pharmacopeial and non-pharmacopeial impurity standards, reference standards, drug metabolites, glucuronides, process degradants, excipient-related impurities, unknown impurity isolation and characterisation, and stable isotope products.

We are a State - FDA audited and accepted facility, certified to ISO 17034, ISO/IEC 17025 and ISO 9001. We supply all pharmacopeial reference standards (USP, EP, BP, IP, JP) alongside pesticide, phytochemical, food and environmental standards – with more than 6,000 in-house impurities ready to ship.

### SNAP SHOT

**2012**

Founded

**100+**

Employees

**01**

R&amp;D Centre

**01**

WHO-GMP site

**10,000+**

Certified reference standards

**15+**

Commercial APIs

**100+**

Indian customers

**25+**

International Customers



### Standards you can Qualify Against

Every standard ships with a full analytical data package – COA, HPLC, MS, 1H NMR and IR – supporting pharmacopeial compliance and regulatory impurity qualification dossiers.

#### Nitrosamine, Pharmacopeial & Non-Pharmacopeial Standards

- Custom synthesis of nitrosamine impurity reference standards – NDMA, NDEA, NMBA and drug-specific nitrosamines
- Pharmacopeial reference standards (USP / EP / BP / IP grade) – synthesis & characterization
- Non-pharmacopeial / in-house working standards for R&D and routine QC
- Certified reference materials with full analytical data package
- Custom synthesis to customer-specific structures and specifications

#### Drug Metabolites & Glucuronides

- Synthesis of Phase-I and Phase-II drug metabolites.
- Glucuronide and sulfate conjugate synthesis
- Stable isotope-labeled metabolite standards, as required
- Metabolite identification support for bioanalytical and DMPK studies
- Custom quantities from milligram to gram scale

#### Unknown Impurity Identification

- Isolation, enrichment and structural elucidation of unknown impurities
- Structure confirmation by LC-MS/MS, NMR (1H, 13C, 2D), IR & UV
- Synthesis and supply of the identified impurity as a reference standard
- Degradation product identification and characterization
- Support for regulatory impurity qualification dossiers



## Method Development, Validation & Testing

Comprehensive analytical solutions across the pharmaceutical development lifecycle delivered by an experienced analytical R&D and regulatory affairs team, with CTD Module 3 documentation support and ALCOA+ data integrity.

### Method Development, Validation & Testing

- Assay, Related Substances, Dissolution & Residual Solvents (HPLC / UPLC / GC / GCHS)
- Validation per ICH Q2(R2) – specificity, linearity, accuracy, precision, robustness
- Stability-indicating methods & forced degradation studies
- Method transfer, verification & compendial verification (USP/EP/IP/BP)
- Cleaning validation method development & validation
- Routine & stability testing of API, intermediates, excipients & finished products

### Impurity Identification & Characterization

- Isolation & identification of unknown impurities and degradation products
- Structure elucidation using LC-MS/MS, NMR (1H, 13C, 2D), IR & UV
- Genotoxic impurity (GTI) assessment and control strategy support
- Impurity synthesis and reference standard characterization
- Impurity fate & purge studies for process-related impurities

### Extractables & Leachables (E&L)

- Container Closure System (CCS) qualification studies
- Controlled extraction studies under simulated / exaggerated conditions
- Leachables studies to support drug product shelf-life
- Component-level screening – rubber closures, elastomers, plastics, coatings
- AET-based evaluation & reporting per USP <1663>/<1664> and PQRI guidance

### Instrumentation

- HPLC / UPLC
- GC / GC-MS
- LC-MS/MS
- GC-MS/MS
- HRMS
- ICP-MS / ICP-OES
- NMR
- PXRD
- PSD
- DSC
- TGA

## Built for Emerging Regulatory Requirements

### Nitrosamine Impurities

- Risk assessment per ICH M7(R2) and current guidance (USFDA, EMA, CDSCO)
- Method development & validation by LCMS/ MS, GC-MS/MS & HRMS
- Trace-level quantification down to ppb / ppt levels
- NDMA, NDEA, NMBA and other nitrosamine analogues
- Root-cause investigation and mitigation strategy support

### Characterization Studies

- Physicochemical characterization particle size distribution, solubility, pKa, LogP
- Solid-state characterization by XRPD, DSC, TGA & hotstage microscopy
- Spectral characterization – UV, IR, NMR & mass spectrometry
- Polymorphism screening and crystal form characterization

### Elemental Impurities · ICH Q3D

- Risk assessment per ICH Q3D (Class 1, 2A, 2B & 3 elements)
- Method development & validation for elemental impurity analysis
- Analysis by ICP-MS / ICP-OES
- Testing of raw materials, excipients, API & finished products
- Support for PDE-based specification setting



### INDUSTRIES WE SERVE

Generic  
Pharmaceuticals

Innovator / NCE  
Development

Biotech &  
Biosimilars

Nutraceuticals &  
Herbals

Veterinary  
Products

## CMO / CDMO for Peptides, APIs & Intermediates

From client-specific synthetic routes to pilot-scale supply, with analytical and regulatory documentation built in at every step.

- Contract manufacturing of peptides - solid-phase and solution-phase synthesis
- API and intermediate manufacturing - gram to kilolab scale
- Custom synthesis to client-specific routes, with process development support
- Analytical and regulatory support - CoA, specifications, stability data
- Scale-up support from laboratory to pilot scale
- WHO-GMP manufacturing site, State-FDA audited and accepted



### WHY K.M. PHARMA SOLUTION P.V.T. L.T.D.

#### One-stop chemistry partner

Standards, analytical services and manufacturing under a single quality system.

#### Fast, Flexible turnaround

6,000+ in-house impurities ready to ship; responsive custom synthesis.

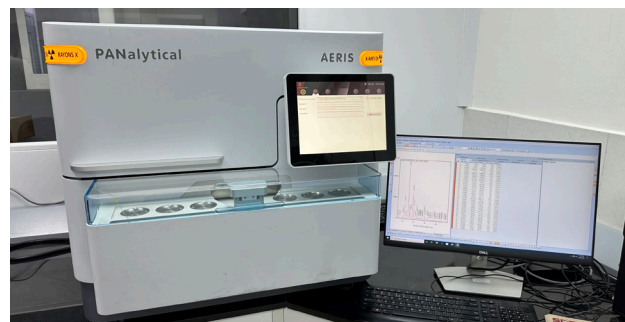
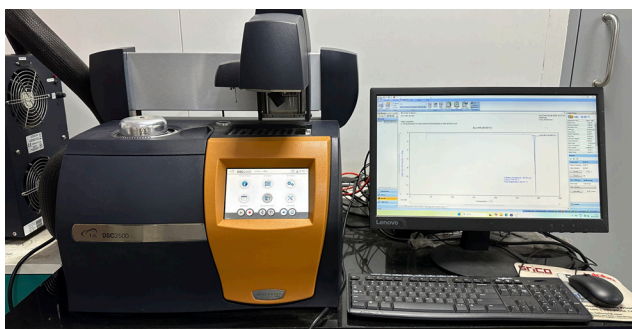
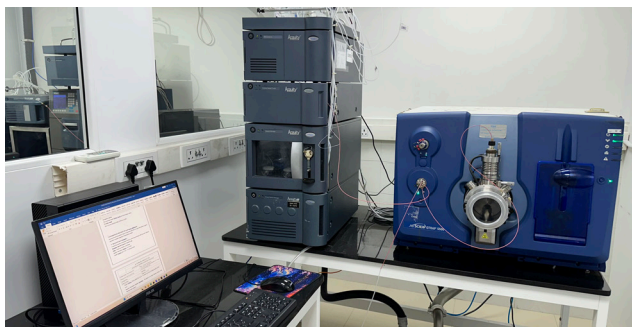
#### Advanced infrastructure

HPLC/UPLC, GC/GC-MS, LC-MS/MS, ICP-MS, NMR, PXRD, PSD, DSC, TGA.

#### Regulatory-ready data

CTD Module 3 support and data integrity assured to ALCOA+.

### Inside Our Laboratories



### ACCREDITATIONS & CERTIFICATIONS



### Trusted by Leading Pharmaceutical Companies



LET'S WORK TOGETHER

#### DISCUSS YOUR PROJECT WITH OUR SCIENTIFIC TEAM

Standards, analytical services and contract  
manufacturing under one quality system.

write to us

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