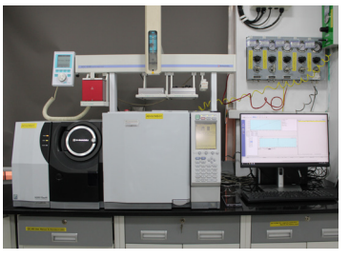
Ahmedabad PPDS, Gujarat, India
Analytical Development Services

Established in 2009, Ahmedabad PPDS is Piramal's Center of Excellence for Formulation Development. The site provides comprehensive analytical services in conjunction with developing and manufacturing drug products or as standalone offerings. Capabilities include various GMP analytical testing services such as solid-state characterization, impurity profiling, pharmaceutical analytical testing, extraction and leachability studies, and more.



GMP Analytical Services

- Pharmaceutical analytical testing, validation and stability
  - Assay, content uniformity, blend uniformity, and blend assay by HPLC
  - Identification test by HPLC/IR
  - Related substances/degradation products by HPLC/GC
  - Dissolution testing (USP-I/USP-II)
  - Chiral purity by HPLC
  - Residual solvents by GCHS
  - Preservative content by HPLC/UV
  - Cleaning validation by HPLC/ICPMS
  - Food study (apple sauce and yogurt) by HPLC
  - NG and G tube study
- Standalone stability support (stability chambers) as per ICH conditions
- Genotoxic impurity method validation and testing for drug substance and drug product by HRMS/LCMS/HPLC/GC
- Nitrosamine impurity method validation and testing for drug substance and drug product by HRMS/LCMS/GCMS
- XRPD method validation and testing for drug substance and drug product
- Elemental impurity method validation and testing for drug substance and drug product by ICPMS
- Extractable and leachable analysis by GCMS/LCMS/ICPMS/HPLC
  - Volatile impurities by GCMS
  - Liquid impurities by LCMS/HPLC
  - Elemental impurities by ICPMS
- Analytical technology transfer

Analytical Development Services

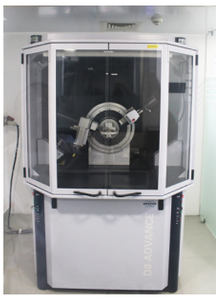
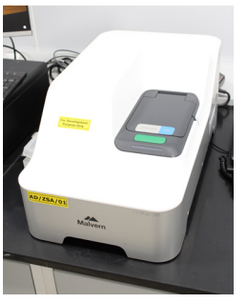
- Analytical method development for drug substance & drug product
- Impurity isolation, identification, characterization and structure elucidation by prep LC/LCMS/NMR
- Determination of the secondary structure of peptide by circular dichroism
- Method development for determination of ions by ion chromatography
- Solid-state characterization
  - Solid-state screenings - polymorphs, salts, co-crystals
  - Solid form studies - stability, solubility, form selection
- Polymorph identification
- Phase transition study
- Thermal behavior and transitions
- Particle morphology
- Experimental log P and pKa determination
- pH stability in physiological pH buffers and biorelevant buffers
- pH solubility in physiological pH buffers and biorelevant buffers

Salient Features of the Capability

- Expertise in fixed dose combinations (FDC)
- QbD approach to development
- "Project-based" and independent "stand alone" stability
- Computer controlled stability chambers
- ICH and customer specific approaches
- Backup generators and alarms (SMS)
- QA driven OOS, OOT, and CAPA investigations

Piramal Pharma Solutions

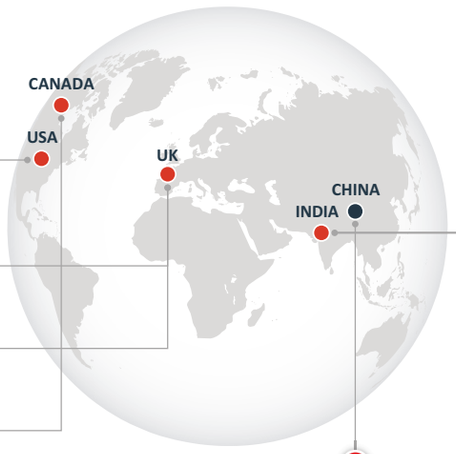





OUR GLOBAL PRESENCE

Riverview	HPAPI Development & Manufacturing USFDA, PMDA	1
Sellersville	Formulation Development & Manufacturing USFDA, EMA	2
Lexington	Sterile Development & Manufacturing USFDA, PMDA	3
Grangemouth	ADC Development & Manufacturing USFDA, MHRA	4
Morpeth	API & Formulation Development & Manufacturing USFDA, MHRA	5
Aurora	API Development & Manufacturing USFDA, PMDA	6



Shanghai
Sourcing Office

Digwal	API Development & Manufacturing USFDA, MHRA	7
Turbhe	Peptide API Development & Manufacturing USFDA	8
Ennore	API Development & Manufacturing WHO-GMP	9
Ahmedabad-PDS	Drug Discovery	10
Pithampur	Formulation Manufacturing USFDA, EU Finland, ANVISA	11
Ahmedabad-PPDS	Formulation Development USFDA, EU Finland	12
Mahad	Formulation Manufacturing (Indian Market), Vitamin & Nutritional Premixes USFDA, WHO-GMP	13
Rabale	API Development	14
Hyderabad*	Vaccines & Biologics Process Development & Manufacturing	15

*Yapan Bio: A Piramal Pharma Ltd. Associate Company

Get in touch with us
contact.us@piramal.com
piramalpharmasolutions.com

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