Piramal Pharma Solutions

Riverview, Michigan, USA

Drug Substance Development & Manufacturing

With more than 60 years experience in API manufacturing , Riverview is recognized as a world-class facility for drug substance manufacturing. The site has been fully inspected by numerous regulatory agencies, including USFDA, Health Canada, PMDA Japan, COFEPRIS Mexico, MFDS Korea, TGA Australia, and the Russian Ministry of Health. The Riverview site also has extensive experience in safely delivering high potency APIs (HPAPIs) and has advanced several HPAPIs from early development to commercial manufacture.

Site Capabilities

- Up to 4,000 L Glass-lined Reaction and Hastelloy Vessels with a Temperature Range of -10 °C to 200 °C
- Product Isolation Capabilities: Extraction, Filtration, and Distillation
- Drying/Finishing Capabilities: Rosenmund Agitated Filter Dryers with Glovebox Isolators
- Reactor Bays Equipped for Large Scale HPAPI Manufacturing (OEL ≥1 µg/m^3)
- Kilo Lab with Cryogenic Temperatures to -70 °C (up to 100 L scale)
- Hydrogenation Capability up to 60 psi and 200 L Scale
- High Potency Manufacturing Suites with Airlocks and Barrier Isolation Systems for Handling of Compounds with Occupational Exposure Limit (OEL) of <1 µg/m^3 at Kilo-lab Scale (as low as 10 ng/m^3)

Services Offered

- Process Research, Development, Optimization, and Scale-Up
- Manufacture of Non-Clinical Tox Batches
- cGMP Manufacturing for Clinical Trials
- Process Validation (PPQ)
- Commercial API Manufacturing
- Analytical Method Development and Qualification/Validation
- Impurity Identification, Characterization, and Synthesis
- Solid State Characterization (XRPD, DSC, TGA, Crystal 16, PVM, FBRM, and PSD)
- QbD Services Consistent with ICH Guidelines (QRA, FMEA, DoE, Parametric Studies)
- Development and Manufacture of High Potency APIs
- Reference Standard Qualification
- Forced Degradation and Stability Studies
- Preparation of Documentation for Regulatory Submissions (IND, NDA, DMF, CTD)

Site Strengths

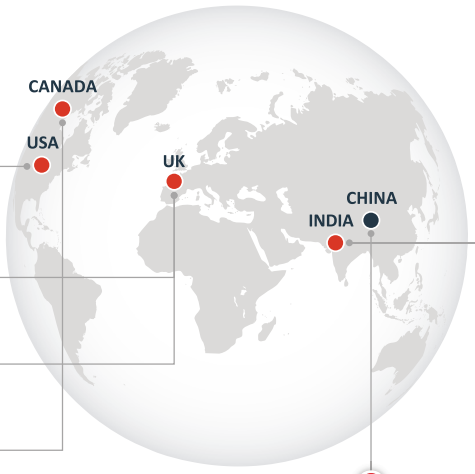
- 60+ Years Experience in API Manufacturing
- Experienced in All Therapeutic Areas
- Focused on Core Competencies – Small Molecule APIs
- API From Gram Scale to 250 kg Batches
- High Potency APIs
- Exceptional Record of FDA Manufacturing Approvals for Innovator APIs
- Significant Experience with Fast-Track Approvals, Breakthrough Status and Orphan Diseases
- Range of Clientele from Large Pharma & Biotechs to Virtual Start-Ups
- Customer Centric Project Management, Patient Centric Service

Project PRIME (Piramal Riverview Integrated Manufacturing Expansion)

A $38 million expansion was recently completed at the site dedicated to the production of APIs and HPAPIs. The featured technology in the new facility is 10,000 L of reactor capacity accompanied by an agitated filter dryer. The new reactor suite is capable of producing high potent APIs with Occupational Exposure Levels (OELs) of >1 µg/m^3. The facility adds 25,000 square feet including production, warehousing, and supporting utilities. The new facility is readily scalable to accommodate additional reactor suites.

OUR GLOBAL PRESENCE

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



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

*Yapan Bio: Associate Company of Piramal Pharma Ltd.

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