Piramal Pharma Solutions

Lexington, Kentucky, USA
Formulation Development & Manufacturing of Sterile Injectables

Established in 2007, Piramal's Lexington site provides sterile compounding, fill/finish and lyophilization capabilities for sterile injectable drug products. The site is fully self-sufficient, with in-house analytical, microbiological, formulation development, and manufacturing services that support customer needs from preclinical to clinical and commercial. Lexington boasts a rich history of expertise across the complexity scale, from simple formulations such as liquid and lyophilization solutions to complex drugs like ADCs and nanoparticle suspensions.

Site Capabilities – Development Services

- Formulation Development
  - Liquid products (solutions and suspensions)
  - Lyophilized products (aqueous and non-aqueous)
- Analytical Methods Development
  - Variety of analytical techniques and instrumentation to support cGMP manufacturing of clinical and commercial products
- Microbiological Methods Development
  - Full-service microbiology lab on site with wide range of services
- Lyophilization Development
  - Shelf loading configurations to account for different radiant heat transfer
  - Ability to leverage in-process sampling and pressure rise to determine sublimation rates and residual moisture levels
  - Historical record of sublimation rates to transition step durations within given cycles
  - Lyophilization cycle development based on fundamental thermal properties of each individual solution

Site Capabilities – Manufacturing

- 22,000 square foot manufacturing facility
- 100% isolator based fill/finish technology
- Sterile and non-sterile compounding
- Vial capabilities from 2ml to 100ml for liquid products
- Vial capabilities from 2ml to 50ml for lyophilized products
- Full cold chain, gas overlay, and light protection capabilities

Site Capabilities – Potent Compounds

- Able to handle highly potent drugs: cytotoxics, steroids, acutely toxic compounds
- Standard Operating Procedure (SOP) detailing a process for the assessment of the potency of each compound being handled
- Occupational Exposure Limit (OEL) is determined for each compound by a certified third-party toxicologist
- Mobile isolator technology provides a physical barrier that protects staff from toxic substances and encloses products in a Grade A Environment
- Similar fixed isolators used in the development labs to mimic manufacturing operations and enable formulation and analytical development on toxic substances

Site Capabilities – Liposomal Formulations

- Experienced in complex multi-step/multi-day formulations
- In-process testing to ensure proper particle size, concentration, absence of endotoxin
- Small (<50L) to large (>500L) batch size capabilities
- Capability to run extended campaign-style batches on commercial grade Steriline Filling Line
- Multiple clinical and late phase projects completed
- Technology expertise: large scale extrusion, microfluidization, tangential flow filtration (TFF), rotary evaporation, complex filtration

Regulatory Approvals

FDA · PMDA · Taiwan FDA · SFDA Saudi Food & Drug Authority

Piramal Pharma Solutions

ADCelerate

Rapid, Integrated ADC to IND

ADCelerate is Piramal Pharma Solutions' rapid approach to delivering Phase-I appropriate ADC drug substance and drug product, so that you can accelerate the delivery of your product to patients in the clinic.

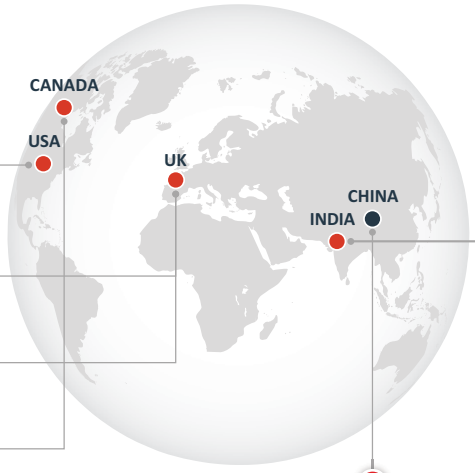
Fully Integrated ADC Services

- **mAb** → Yapan Bio, Hyderabad, India*
- **Payload/Linker** → Riverview, USA; Aurora, Canada
- **Conjugation** → Grangemouth, UK
- **Fill Finish** → Lexington, USA

*Yapan Bio: A Piramal Pharma Ltd. Associate Company

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	

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