Global Site Capabilities

Piramal
Pharma Solutions

DRUG SUBSTANCE SITES

Piramal Pharma Solutions provides development and manufacturing of Active Pharmaceutical Ingredients (APIs) and High Potency APIs through our fully inspected sites in North America, Europe, and Asia.

- DISCOVERY
- CLINICAL DEVELOPMENT
- COMMERCIAL SUPPLY

Piramal Pharma Solutions	Ahmedabad PDS, India	Riverview, USA	Aurora, Canada	Ennore, India	Digwal, India	Turbhe, India	Morpeth, UK
CAPABILITIES							
Chiral Resolution	●	● ●	● ●	● ●	● ●		
Continuous Flow Systems	●			●			
Cryogenic Capabilities (Organometallic)	●	● ●	● ●	● ●	● ●		
Cytotoxics, High Potency, Steroidal Chemistry		● ●	● ●				●
Deuteration		● ●	● ●	●			
Enzymatic Resolution	●	●	●	●	● ●		
High-Pressure Hydrogenation/ Carbonylation	●	● ●	● ●	● ●	● ●		
Lithiation and Hydride Chemistry	●	● ●	● ●	● ●	● ●		
Nucleosides, Nucleotides	●	● ●			● ●		
Payload-Linkers/Ligands for ADCs and PROTACs		●					
Peptides						● ●	
Peptidomimetics	●	● ●	● ●			● ●	
Prostaglandins			● ●				●
SFC Separations	●						

Ennore can support commercial projects with reference to KSMs/RSMs only

SITE DETAILS	Ahmedabad PDS, India	Riverview, USA	Aurora, Canada	Ennore, India	Digwal, India	Turbhe, India	Morpeth, UK
Key Features	• Medicinal chemistry support • *In-vitro* biology and ADME services • *In-vivo* PK (via local GLP/AAALAC accredited partner) • Route scouting • Custom synthesis (up to 2-3kg)	• Process research, early to late phase development, and scale-up • Non-GMP and cGMP clinical manufacturing • Process validation (PPQ) • Commercial API manufacturing • High potency and payload-linker manufacturing • High potency manufacturing capabilities: OEL of <1 µg/m³ at kilo-lab scale (as low as 10ng/m³) • 18 APIs launched	• Process research, route scouting, early to late phase development, and scale-up • Non-GMP and cGMP clinical manufacturing • Process validation (PPQ) • Analytical services • Commercial API manufacturing • High potency API handling (OEL >1µg/m³) • 15 APIs launched	• Chemical development • API Phase I and II clinical batches supply (GMP) • Small- and large-scale intermediates manufacturing • Complex reactions carried out at commercial scale	• Process development and optimization • Analytical services • Intermediates and KSMs • Late phase development • Large-scale commercial manufacturing • Dedicated areas for vitamin products	• Solid and solution phase peptide synthesis • Process research, early to late phase development, and scale-up • Multigram to kilogram GMP peptides for clinical trials • Deep portfolio of peptide API products (covers nearly 90% of all generic peptide APIs) • Scaled-up >12 peptide APIs for commercial supply	• Late phase development and large-scale commercial manufacturing • Development of oral contraceptive pills and hormone replacement therapies • Clinical trial supply services • Small-scale API plant manufacturing of discrete prostaglandins • High potency manufacturing (OEL of 0.04 µg/m³)
Capacity	• ~27,000 chemicals (16,000 building blocks) • >300 FTEs • 23 labs, ~300 fume hoods • Kilo lab: 0.5kg-5kg scale output	• Total GMP capacity: 25kL • Vessel volume range - Kilo lab: 300L - Pilot plant: 4,000L - Large-scale manufacturing: 25-4,000L - Hydrogenation: 200L up to 4 bar • API from gram scale to 250kg batches	• Total GMP capacity: 25kL • Vessel volume range - Kilo lab: 50-100L - Pilot plants: 200-4,000L - Hydrogenation: 200-800L up to 7-9 bar	• Total GMP capacity: 19kL • Vessel volume range - Kilo lab: 50-200L - Pilot plant: 50-2,000L - Large-scale manufacturing: 1.6-7kL - Hydrogenation: 250L-3kL up to 40 bar	• Total GMP capacity: 784kL • Vessel volume range - Kilo lab: 10L-63L - Pilot plant: 160L-1,600L - Large-scale manufacturing: 500L-15,000L - Hydrogenation: 250L-4kL up to 40 bar	• Total capacity: 4.5kL • Non-GMP: from milligram to multigram • GMP: 200L reaction vessels for solid phase synthesis • Tanks support up to 2,000L for synthetic modifications and downstream processing	• Total GMP capacity: 64kL • Large-scale manufacturing: 64kL • Dedicated small-scale API plant for prostaglandins
Regulatory	• Non-GMP discovery site	• USFDA • Health Canada • PMDA • Australia	• USFDA • Health Canada • PMDA	• Indian FDA • WHO-GMP	• USFDA • COFEPRIS • ANVISA • MHRA • CPI • Russian MoH • MCC • KFDA • PMDA • WHO-GMP • EDQM • AIFA	• USFDA • Health Canada • ECC-Net • EDQM • AIFA • Germany Hamburg • Germany Hannover • KFDA • WHO	• USFDA • MHRA • MFDA • EAEU • TMMDA
Development Phases	Discovery	Preclinical, phases I, II, III, & commercial	Preclinical, phases I, II, III, & commercial	APIs: Preclinical, phase I, phase IIa RSMs and KSMs: Late phase & commercial	Phases I, II, III, & commercial, life cycle management	Phases I, II, III, & commercial	Phases I, II, III, & commercial

DRUG PRODUCT SITES

We manufacture, supply, and distribute commercial formulations for oral solids, liquids, creams, and ointments. Our scalability is defined from pilot level to commercial level to serve customers at every stage of the drug life cycle from a manufacturing perspective.

- DISCOVERY
- CLINICAL DEVELOPMENT
- COMMERCIAL SUPPLY

Piramal Pharma Solutions	Ahmedabad PPDS, India (Precommercial)	Pithampur, India	Sellersville, USA	Morpeth, UK	Lexington, USA
ORAL SOLIDS					
Conventional Tablets	● ●	●	● ● ●	● ● ●	
Capsules	● ●	●	● ● ●	● ●	
Granules and Powders	● ●		● ● ●	●	
Press Coated Tablets (Morpeth - Tablet in Tablet, SLV – Spray Film Coating)			● ● ●	● ●	
Modified Release/Delayed Release Tablets	● ●	●	● ● ●	● ● ●	
Bilayered Tablets	● ●	●	●		
Effervescent Tablets	● ●	●			
Sublingual Tablets	● ●	●	● ● ●	● ● ●	
Liquid Filled Hard Gelatin Capsules	● ●				
Powder In Bottle	● ●			●	
Mini-Tablets	● ●	●	● ● ●	● ● ●	
Chewable Tablets	● ●	●	● ● ●	● ● ●	
Oral Disintegrating Tablets	● ●	●	● ● ●	● ● ●	
Multiple Unit Pellet System Tablets	● ●	●	● ● ●		
ORAL LIQUIDS					
Solutions and Suspensions	●		● ● ●		
INJECTABLES					
Liquid Filled Vials					● ● ●
Lyophilization in Vials					● ● ●
In-Situ Salt Formulations					● ● ●
Liposomes					● ●
High Potent Injections					● ●
Aseptic Fill/Finish					● ● ●
TOPICALS					
Creams and Ointments			● ● ●		
SPECIAL SERVICES					
Hormonal Products				● ● ●	● ● ●
Pediatric Formulations	● ●	●	● ● ●	● ●	
Potent Tablets/Capsules (down to 1 µg/m3)	● ●		● ● ●		
Controlled Substances Tablets and Capsules			● ● ●		

SITE DETAILS	Ahmedabad PPDS, India (Precommercial)	Pithampur, India	Sellersville, USA	Morpeth, UK	Lexington, USA
Key Features	• Preformulation development and material characterization • Formulation development of oral solid dose: NCEs, complex generics and generics • Manufacturing and packaging (bottles, sachets and blisters) of scale-up and clinical batches • Ability to handle highly potent molecules (OEL down to 1µg/m³) • Analytical method development and validation, analytical testing, and stability services • Nitrosamine and heavy metals testing	• Commercial manufacturing services for tablets and capsules • Oral solids (granulation, compression, coating) • Capsule filling • Clinical trial manufacturing • Manufacturing of drug product and matching placebos for clinical trials	• Preformulation and material characterization • Product development and clinical trial material manufacturing for IR tablets/capsules, MR tablets, multiparticulates and minitablets • Commercial manufacturing and packaging (bottles and blisters) of oral solid dose, liquids, ointments, and creams • Handling of HPAPIs and potent compounds down to 1 µg/m³ • DEA/controlled substance handling (Class II-V) • Serialization and aggregation of packaged OSD products	• Commercial manufacturing and packaging (bottles and blisters) of oral solid dosage forms • Pharmaceutical product development: IR tablets and capsules, MR tablets, multiparticulates • Clinical trial supply services • Dedicated/segregated hormonal manufacturing area: capable of handling HPAPI and products with OELs as low as 1 µg/m³	• Development and manufacturing of sterile liquid and lyophilized parenterals and injectables • Fully integrated ADC and sterile fill/finish needs • Clinical to commercial scale • Isolator technology for controlled environments, ensuring stability and protection of operators • Handling of HPAPIs: cytotoxics, steroids, and acutely toxic compounds, down to 0.03 µg/m³
Capacity	• Manufacturing scale: 50g-50kg • Bulk, bottle, blister, and sachet packaging	• OSD capacity: 4.5 billion tablets • Immediate and modified release formulations • Bottle, bulk, and blister packaging • Batch sizes range from 4-600kg	• Tablets - 2.5 billion/year • Capsules - 1.4 billion/year • Liquids - 350 batches • Creams - 150 batches • Ointments - 100 batches • Precommercial: 200g-100kg • Scale-up/commercial: 10-850kg	• Oral solids manufacturing capacity of up to 3 billion tablets annually • Hormonal manufacturing and packaging of up to 1.3 billion tablets/capsules annually • Precommercial: 200g-100kg • Scale-up/commercial: 10-500kg	• Three fully contained (isolators) automated filling lines, fill speeds up to 40 vials per minute • Sterile solutions: 100,000 vials of 10 mL or equivalent for 2-100 mL vials • Non-sterile liquids or suspensions: 500L • Terminal sterilization: 5,000 vials of 10mL or equivalent surface area • Vial capabilities for liquid products: 2-100mL • Vial capabilities for lyophilized products: 2-50mL • Liposomal batch size capabilities: <50->500L
Regulatory	• USFDA • FIMEA • MPA	• USFDA • FIMEA • WHO • ANVISA • TGA • Peru MoH • EMA	• USFDA • DEA • EMA	• USFDA • MHRA • KFDA • MCC • PMDA • COFEPRIS • ANVISA	• USFDA • PMDA • SFDA • TFDA
Development Phases	Phases I, II, & III	Phases II, III, & commercial	Phases I, II, III, & commercial	Phases I, II, III, & commercial	Phases I, II, III, & commercial

ADC, VACCINE & BIOLOGICS SITES

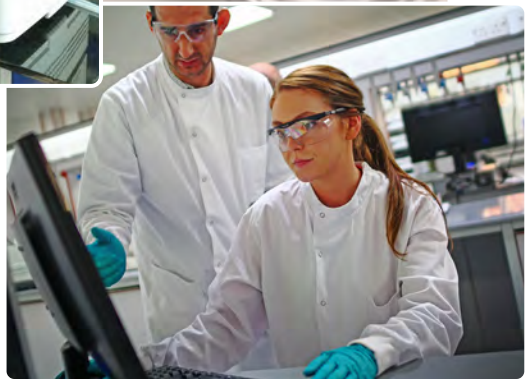
Piramal Pharma Solutions offers development, clinical manufacturing, and commercial manufacturing for a variety of large molecules. Our mAb, bioconjugation and sterile fill/finish services combine with our API capabilities to provide a fully integrated ADC service offering.

- DISCOVERY
- CLINICAL DEVELOPMENT
- COMMERCIAL SUPPLY

Piramal Pharma Solutions	Hyderabad, India*	Lexington, USA	Grangemouth, UK
VACCINES			
Virus Like Particles (VLP)	● ●		
Protein Antigens	● ●		
Protein Nano-particles	● ●		
Viral Vector Based Vaccines	● ●		
RNA Vaccines	● ●		
DNA Vaccines	● ●		
BIOLOGICS/BIO-THERAPEUTICS/GENE THERAPY			
Monoclonal Antibodies	● ●		
Therapeutic Proteins	● ●		
Oncolytic Viruses	● ●		
Viral Vectors	● ●		
Non-viral Vectors	● ●		
ANTIBODY-DRUG CONJUGATION SERVICES			
Antibody-Drug Conjugates			● ● ●
Antibody-Oligonucleotide Conjugates			● ● ●
Antibody-Chelator Conjugates			● ● ●
Enzyme-Mediated Conjugation			● ● ●
Bioconjugate Formulation Development			● ● ●
Proof of Concept			● ● ●
Bioconjugation			● ● ●
Scale-up and Commercial Bioconjugate DS Batches			● ● ●
ADC Fill/Finish		● ●	
EXPRESSION SYSTEMS			
Mammalian Cell Culture	● ●		
Insect Cell Culture	● ●		
Microbial Fermentation	● ●		
CMC			
Cell Banking	● ●		
Virus Banking	● ●		
Upstream Process Development and Optimization	● ●		
Downstream Process Development and Optimization	● ●		
Analytical Method Development	● ●		
Analytical Method Qualification	● ●		
Analytical Method Validation	● ●		
Process Characterization (DoE)	● ●		
FORMULATION			
Aseptic Formulation	● ●	● ● ●	
Lyophilization (Vials)	●	● ● ●	
Liquid Fill (Vials)	● ●	● ● ●	
Stabillity Studies	● ●	● ● ●	● ● ●

SITE DETAILS	Hyderabad, India*	Lexington, USA	Grangemouth, UK
Key Features	• Process development, scale-up, and GMP compliant manufacturing of vaccines and biologics/biotherapies • High containment product classes (up to BSL–2+) • Recombinant vaccines, viral vector-based vaccines, gene therapies, monoclonal antibodies, therapeutic proteins, and other complex biologics	• Development and manufacturing of sterile liquid and lyophilized parenterals and injectables • Fully integrated ADC and sterile fill/finish needs • Clinical to commercial scale • Isolator technology for controlled environments, ensuring stability and protection of operators • Handling of HPAPIs: cytotoxics, steroids, and acutely toxic compounds, down to 0.03 µg/m³	• ADC proof of concept studies, process development, optimization, and scale-up • Preclinical and toxicology batch preparation • GMP manufacture of clinical and commercial supplies • Integrated ADC development programs: mAb > payload-linker > conjugation > fill/finish • Capable of handling compounds with OEL <0.01 µg/m³
Capacity	• Four process development suites (up to 50L bioreactor scale) • Four dedicated GMP suites for clinical manufacturing (up to 1,000L bioreactor scale) • Liquid fill in vials: automatic precision filling line with single-use/disposable flow path; 2-10mL vials; 1,000-2,000 vials/hour • Lyophilized products 1,000-2,000 vials per batch	• Three fully contained (isolators) automated filling lines, fill speeds up to 40 vials per minute • Sterile solutions: 100,000 vials of 10mL or equivalent for 2-100mL vials • Non-sterile liquids or suspensions: 500L • Terminal sterilization: 5,000 vials of 10mL or equivalent surface area • Vial capabilities for liquid products: 2-100mL • Vial capabilities for lyophilized products: 2-50mL • Liposomal batch size capabilities: <50->500L	• Five dedicated GMP production suites for clinical and commercial manufacturing • Multi-product manufacturing facility characterized by specialized or single-use product-contact manufacturing components • Bioconjugate drug substance batches up to ~10kg scale • Hundreds of unique ADCs developed • Full on-site release, stability and bioassay testing capabilities • 700+ GMP batches manufactured • 2 commercial ADC products currently manufactured • 2 BLAs and >42 INDs successfully supported • >600 lab-scale, toxicology, and preclinical batches produced
Regulatory	• GMP compliant	• USFDA • PMDA • SFDA • TFDA	• USFDA • PMDA • KFDA • MHRA • ANVISA • Türkiye MoH
Development Phases	Phases I, II	Phases I, II, III, & commercial	Phases I, II, III, & commercial

*Yapan Bio: A Piramal Pharma Ltd. Associate Company



ADCelerate™
Rapid, Integrated ADC to IND

Fully Integrated ADC Services

mAb → Payload-Linker → Conjugation → Fill Finish

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	USFDA, 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: A Piramal Pharma Ltd. Associate Company

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