



DELIVERING
INTEGRATED SOLUTIONS
ACROSS THE DRUG LIFE CYCLE

Piramal Pharma Solutions is the contract development and manufacturing (CDMO) arm of Piramal Pharma Ltd. with a vast network of development & manufacturing facilities located in North America, Europe and India. We offer a comprehensive range of services across all phases of the drug life cycle, which includes Drug Discovery & Development, Manufacturing & Packaging of Clinical Trial Supplies, High Potency APIs, Antibody Drug Conjugates, and Delivering Commercial Volumes of APIs and Finished Dosage Forms.

DISCOVERY SERVICES

Chemistry & Biology Support for Hit to Lead/Lead Optimization:

- Chemistry Support for Drug Discovery Projects
- Custom Synthetic Chemistry Services;
 - Discrete Compounds (mg to gm)
 - Focused Libraries (20-100 compounds)
- In-vitro ADME/Biology, DMPK
- Expertise to Handle Wide Range of Chemistries
 - Including Heterocyclic, Organometallic, Peptide & Carbohydrate Chemistry
 - Chiral Separation using Supercritical Fluid Chromatography (SFC)



PROCESS R&D SERVICES

- Process Research and Route Scouting
- Process Development & Optimization
- Non-GMP & GMP Manufacturing
- CMC Support for API, from IND to NDA





HIGH POTENCY API (HPAPI) SERVICES

High Potency drug substance
development & commercial manufacturing

- Full range of scale and containment options for HPAPI manufacturing
- State-of-the-art HPAPI manufacturing suite with airlocks & barrier isolation systems
- Multiple global regulatory manufacturing approvals for innovator HPAPIs, several fast-track approvals

PEPTIDE API SERVICES

- Custom Synthesis of Peptide-Based NCEs for Early Stage Development & Preclinical
- Late Phase & Commercial Peptide API Manufacturing
- Comprehensive Portfolio of Commercial Peptide API Products, with Additional Products Under Development
- Site Inspected and Approved by Global Regulatory Authorities
- 40+ Years of Experience in Peptide APIs

CLINICAL TRIAL SUPPLY SERVICES

- Clinical Batch Manufacturing
 - Oral Solids
 - Sterile Liquids
 - Hormones & High Potent
- Clinical Batch Packaging
 - Primary and Secondary
 - Blinding, Labelling & Randomization
- Support Services
 - QP services
 - Returns and Destruction
 - Comparator Sourcing



PHARMACEUTICAL DEVELOPMENT SERVICES

- Pre-Formulation
- Phase I to III Clinical Development (NCEs)
- Sterile injectables
 - Liquids
 - Lyophilized
- Oral Solutions & Suspensions
- Oral Solid Formulations
 - MR, ER and Other release profiles
 - Bilayer & Press-Coated Tablets
- Special Capabilities
 - Pediatric Formulations
 - Oncology Molecules (Sterile & Solid Dosages)
 - Hormonal Formulations
 - Taste Masking Technology
- Complete Development of ANDAs/CTDs

STANDALONE ANALYTICAL SERVICES

GMP Analytical Services:

- Analytical Testing, Validation, Stability Study & Technology Transfer
- Evaluation of Nitrosamine, Genotoxic & Elemental Impurities
- Extractable and Leachable Study

Analytical Development Services:

- Impurity Isolation, Identification, Characterization and Structure Elucidation
- Determination of the Secondary Structure of Peptide by Circular Dichroism
- Solid-State Characterization

COMMERCIAL MANUFACTURING SERVICES

Manufacturing and Supply of:

- Key and Registered Starting Materials
- Advanced Intermediates and APIs
- Finished Dosage Forms - Oral Solids & Sterile Injectables

VACCINES, BIOLOGICS, & BIO-THERAPEUTICS*

- Process Development, Scale-up, & GMP Compliant Manufacturing
- Vaccines: Recombinant (Protein Antigens, Virus-Like Particles, Nano-Particles), Viral Vector-Based, RNA/DNA
- Biologics: Gene Therapies, Monoclonal Antibodies, Therapeutic Proteins, and Other Complex Biologics
- Proven Track Record of Success in Large Molecule Therapeutics

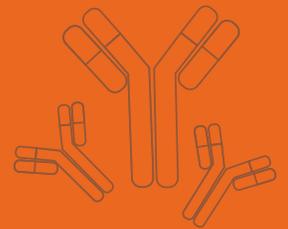
*Yapan Bio: A Piramal Pharma Ltd. Associate Company





ANTIBODY DRUG CONJUGATES

- Proof of Concept Studies
- Process Development, Optimization & Characterization
- Clinical & Commercial Manufacturing of Conjugates
 - US-FDA Approval for Commercial Manufacturing
 - 900 + Clinical Batches Manufactured
- Manufacture of linker and cytotoxic payload with OEL $\geq 20\text{ng}/\text{m}^3$
- Analytical & Bio-analytical Method
- Development & Validation
- Stand-alone Analytical Services like
 - Cell-Based Assays
 - Stability Study Design & Execution



GENERIC APIs

- | | | |
|---|-----------------------------|---|
| • Amiodarone Hydrochloride | • Dexlansoprazole | • Mirabegron |
| • Anagrelide | • Diltiazem Hydrochloride | • Misoprostol |
| • Aprepitant | • Donepezil Hydrochloride | • Monusulfiram |
| • Azilsartan Kamedoxomil | • Dronedarone Hydrochloride | • Pramipexole Dihydrochloride Monohydrate |
| • Baclofen | • Droxidopa | • Rivaroxaban |
| • Bisoprolol Fumarate | • Empagliflozin | • Spironolactone |
| • Cinacalcet Hydrochloride | • Fosaprepitant Dimeglumine | • Tetrabenazene |
| • Clobazam | • Ketoconazole | • Trazodone Hydrochloride |
| • dl-Cloprostenol* | • Lercanidipine | • Varenicline Tartrate |
| • Dabigatran Etxilate Mesylate | • Levoketoconazole | • Verapamil Hydrochloride |
| • Dapagliflozin Propanediol Monohydrate | • Lurasidone Hydrochloride | • Vortioxetine Hydrobromide |
| • Deferasirox | • Mebeverine Hydrochloride | |

APIs (Under Development)

- Apremilast
- Bilastine
- Brivaracetam
- Desvenlafaxine Succinate Monohydrate
- Dexmedetomidine
- Edoxaban

OUR CAPABILITIES-API SITES

Piramal Pharma Solutions is a contract development and manufacturing organization, offering services across the entire drug-cycle, from development to commercial manufacturing of APIs and Formulations, from our vast network of facilities located in North America, Europe and Asia.

| Piramal Pharma Solutions | DISCOVERY | CLINICAL DEVELOPMENT | | | | | COMMERCIAL SUPPLY | | | | | |
|-----------------------------|------------------|----------------------|----------------|---------------|---------------|---------------|-------------------|----------------|----------------|---------------|---------------|-------------|
| | Ahmedabad, India | Riverview, USA | Aurora, Canada | Ennore, India | Digwal, India | Turbhe, India | Riverview, USA | Aurora, Canada | Ennore*, India | Digwal, India | Turbhe, India | Morpeth, UK |
| CAPABILITIES | | | | | | | | | | | | |
| Chiral Resolution | | | | | ● | | | | | ● | | |
| Continuous Flow Systems | | | | ● | | | | | | | | |
| Cryogenic Capabilities | ● | ● | ● | | ● | | | ● | ● | ● | | |
| Cytotoxics | ● | ● | | | | | ● | | | | | |
| Deuteration | | | ● | | | | | ● | | | | |
| Enzymatic Resolution | | | | | ● | | | | | ● | | |
| High Potency | | ● | ● | | | | ● | ● | | | | |
| Peptides | | | | | | ● | | | | | ● | |
| High-Pressure Hydrogenation | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | |
| Lithium Chemistry | ● | ● | ● | ● | ● | | | ● | ● | ● | | |
| Nucleosides, Nucleotides | ● | ● | | | ● | | ● | | | ● | | |
| Peptidomimetics | ● | ● | ● | | | ● | ● | ● | | | ● | |
| Prostaglandins | | | ● | | | | | ● | | | | ● |
| SFC Separations | ● | | | | | | | | | | | |
| Steroidal Chemistry | | ● | | | | | ● | | | | | ● |
| REACTION TYPES | | | | | | | | | | | | |
| Alkylation | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | ● |
| Amide Bond | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | |
| Amination | ● | ● | ● | ● | | | ● | ● | ● | | | ● |
| Boc Protection/deprotection | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | |
| Boron Chemistry | ● | ● | ● | ● | | | | ● | ● | | | |
| Buchwald Coupling | ● | ● | ● | ● | | | | ● | ● | | | |
| Debenzylation | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | |
| Electrophilic Addition | ● | ● | ● | ● | ● | | | ● | ● | ● | | ● |
| Epoxidation | ● | ● | ● | ● | | | | ● | ● | | | |
| Esterification | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | ● |
| Fluorination | ● | | | ● | | | | | ● | | | |
| Friedel-Crafts | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | |
| Grignard Chemistry | ● | ● | ● | ● | ● | | | ● | ● | ● | | ● |
| Halogenation | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | ● |
| Heterocycle Synthesis | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | ● |
| Hydrolysis | | | | | ● | | | | | ● | | |
| Metathesis | ● | | ● | ● | | | | ● | ● | | | |
| Mitsunobu | ● | ● | ● | ● | | | ● | ● | ● | | | |
| Nitration | ● | | ● | ● | | | | ● | ● | ● | | |
| Oxidation | ● | ● | ● | ● | | ● | | ● | ● | | ● | |
| Reductions | | | | | ● | ● | | | | | ● | |
| Reductive Amination | ● | ● | ● | ● | ● | | ● | ● | ● | | | |
| Silylation | ● | ● | ● | ● | ● | | ● | ● | ● | ● | | ● |
| SnAr | ● | ● | ● | ● | ● | | | ● | ● | ● | | |
| Sonogashira | ● | ● | ● | ● | | | ● | ● | ● | | | |
| Suzuki | ● | ● | ● | ● | | | ● | ● | ● | | | |
| Ozonolysis | ● | | | ● | | | | | ● | | | |

(NEW)



OUR CAPABILITIES-FORMULATION SITES

Piramal Pharma Solutions is a contract development and manufacturing organization, offering services across the entire drug-cycle, from development to commercial manufacturing of APIs and Formulations, from our vast network of facilities located in North America, Europe and Asia.

| Piramal Pharma Solutions | PREFORMULATION | | | CLINICAL DEVELOPMENT | | | | | COMMERCIAL SUPPLY | | | | |
|--|--------------------|-------------|-------------|----------------------|----------------|-------------|-------------|-----------|-------------------|----------------|-------------|-------------|-----------|
| | AHD PPDS, India | SLV, USA | LEX, USA | AHD PPDS, India | Morpeth, UK | SLV, USA | LEX, USA | GM, UK | PTP, India | Morpeth, UK | SLV, USA | LEX, USA | GM, UK |
| ORAL SOLIDS | | | | | | | | | | | | | |
| Conventional Tablets | ● | ● | | ● | ● | ● | | | ● | ● | ● | | |
| Capsules | ● | ● | | ● | ● | ● | | | ● | ● | ● | | |
| Granules & 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-Tablet | ● | | | ● | | | | | ● | | | | |
| Chewable Tablets | ● | ● | | ● | ● | ● | | | ● | ● | ● | | |
| ODT | ● | | | ● | ● | | | | ● | ● | | | |
| MUPS | ● | | | ● | | | | | | | | | |
| ORAL LIQUIDS (SOLUTIONS AND SUSPENSIONS) | ● | ● | | | | ● | | | | | ● | | |
| INJECTABLES | | | | | | | | | | | | | |
| Liquid Filled Vials | | | ● | | | | ● | | | | | ● | |
| Lyophilization in Vials | | | ● | | | | ● | | | | | ● | |
| In-Situ Salt Formulations | | | ● | | | | ● | | | | | ● | |
| Liposomes | | | | | | | ● | | | | | ● | |
| High Potent Injections | | | ● | | | | ● | | | | | | |
| Aseptic Fill/Finish | | | ● | | | | ● | | | | | ● | |
| CREAMS & OINTMENTS | | ● | | | | ● | | | | | ● | | |
| ANTIBODY DRUG CONJUGATION SERVICES | | | | | | | | | | | | | |
| Proof Of Concept | | | | | | | | ● | | | | | ● |
| Bioconjugation | | | | | | | | ● | | | | | ● |
| Scale up & Commercial Batches | | | | | | | | ● | | | | | ● |
| ADC Fill/Finish | | | | | | | ● | | | | | ● | |
| SPECIAL SERVICES | | | | | | | | | | | | | |
| Hormonal Products | | | | | ● | | | | | ● | | | |
| Paediatric Formulations | ● | | | ● | ● | | | | ● | ● | | | |
| Potent Tablets/Capsules | ● | ● | | ● | | ● | | | | | ● | | |
| Controlled Substances Tablets & Capsules | | ● | | | | ● | | | | | ● | | |



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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