FORMULATION SERVICES

Piramal Pharma Solutions

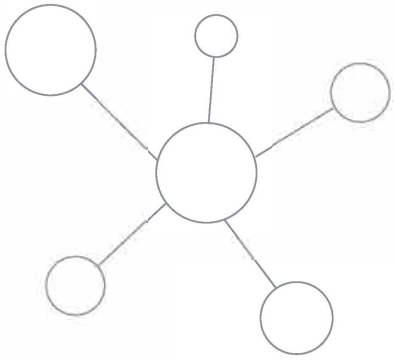
Committed to Quality

Delivering Excellence

Piramal Pharma Solutions is a leading Contract Development and Manufacturing Organization (CDMO) with a global network of facilities in North America, Europe, and India. We offer a comprehensive range of services across all phases of the drug life cycle, including drug discovery and development; manufacturing and packaging of clinical trial supplies; and commercial manufacturing of APIs and finished dosage forms (FDFs). Our deep expertise in developing and manufacturing innovative formulations ensures we can deliver cutting-edge products to meet our client's unique needs, ultimately helping bring life-changing treatments to patients.

PRE-FORMULATION STUDIES AND FORMULATION/PROCESS DEVELOPMENT

- Material characterization
- Physical-chemical attributes
- Excipient compatibility
- Formulation development for testing
- Process development
- Analytical methods development & validation
- Analytical testing
- Stability storage and testing
- CMC support services



CLINICAL TRIAL SUPPORT SERVICES

- Clinical trial manufacturing, packaging, and GMP supply services
- Post-study drug and patient kit returns, reconciliation, and destruction management
- TrakPak®- clinical kit supplies tracking tool
- Regulatory and QP services

COMMERCIAL MANUFACTURING AND PACKAGING

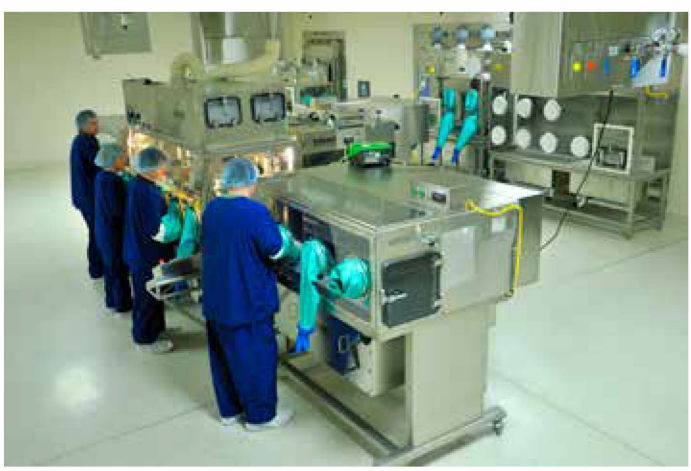
- Oral solids - various dosage forms handled
  - Tablets (film-coated, press-coated, bi-layered, IR, ER, MR)
  - Hard gelatin capsules (powders, granules, and pellets)
  - Controlled release solids
- Sterile injectables
  - Vials - liquid (solutions and suspensions) and lyophilized (aqueous and non-aqueous)
  - Nanoparticles and liposomes
  - Stable emulsions
- Liquids, creams, and ointments
- Cytotoxic and potent compounds
- Bottle, bulk, and blister packaging

PHARMACEUTICAL DEVELOPMENT SERVICES

- Phase I-III clinical development (NCEs)
  - Oral solids
  - Sterile injectables
  - Liquid-filled capsules
  - Creams and ointments
  - Powder-in-bottle to drug-in-capsule
- Formulation development in various dosage forms
  - Oral solids (e.g. sublingual tablets, modified and delayed release, etc.)
  - Liquid-filled capsules
  - Sterile formulations (e.g. sterile liquids - injectable and ophthalmic, in-situ salt formulations)
  - Creams and ointments
- Specialized formulations
  - Pediatric formulations (mini-tablets, powders for oral suspension, chewable tablets)
  - Hormonal formulations
  - Controlled drug substances
  - Oncology drug products

LATE LIFE CYCLE MANAGEMENT

- Improve the margins of late life cycle products
- Patent extensions by new dosage form development
- Improving operational efficiencies
- Improve supply chain modalities
- API source change/additions
- Regulatory support



SPECIALIZED SERVICES

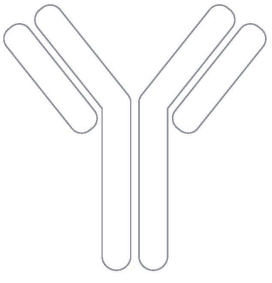
- HPAPIs (e.g. oncologics)
- Controlled substances
- Pediatric formulations
- Hormonal formulations

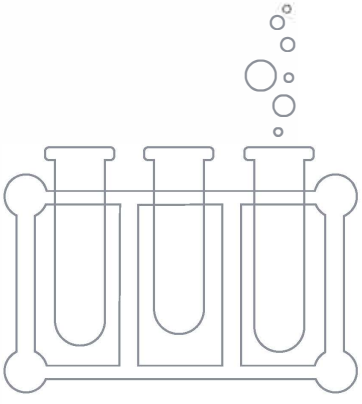
ANTIBODY-DRUG CONJUGATIONS (ADCs)

- Proof-of-concept studies
- Bio-conjugation development
- Clinical/commercial manufacturing
- Fill/finish
- Analytical development services

REGULATORY SERVICES

- IND, NDA, ANDA filing in USA, Europe, and Asia Pacific
- DMF, ASMF, and CEP/COS filing
- eCTD submissions for US and EU





OUR FORMULATION SITES

Lexington
Kentucky, USA

Liquid & Lyophilized Sterile Fill/Finish
ADC Fill/Finish

Sellersville
Pennsylvania, USA

Solid Oral Dosage Forms
Liquids, Creams, & Ointments

Morpeth
Northumberland, UK

Integrated API & Drug Product Site,
Solid Oral Dosage Forms

Ahmedabad
Gujarat, India

Solid Oral Dosage Forms and
Clinical Scale GMP Manufacturing

Pithampur
Madhya Pradesh, India

Commercial Manufacturing &
Packaging of Tablets & Capsules

Mahad
Maharashtra, India

Solid/Liquid Drug Products
Nutritional Premixes & Vitamins

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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