

Generic Peptide APIs

Peptides for Toxicology & Clinical Trials

As part of our market-leading expertise in drug substances, Piramal Pharma Solutions offers multigram to kilogram GMP peptides for clinical trials and a deep portfolio of generic peptide APIs. Our GMP manufacturing capabilities include 4,500 liters of reactor volume, while our non-GMP R&D facility features more than twenty scientists with vast experience in peptide chemistry. It's another example of how we are continually expanding the ways in which we help reduce the burden of disease on patients.

R&D Capabilities

- Non-GMP facility in Thane, Mumbai, India
- Reaction facility from milligram to multigram
- 5 independent synthetic lines
- 2 downstream process lines with axial compression columns for chromatography
- 2 dedicated freeze dryers for development
- Reverse osmosis facility
- Team of 24 scientists led by 2 PhDs with vast experience in peptide chemistry



Manufacturing Capabilities

- GMP facility in Turbhe, Navi Mumbai, India
- 4,500 liters total reactor volume
- 200 liters reaction vessels for solid phase synthesis
- Up to 2000 liters tanks for synthetic modifications and downstream processing
- 14 individual production lines capable of operating simultaneously
- 11 downstream processing lines (HPLC Purification, Reverse Osmosis, Filtration)
- Successfully scaled-up over 12 peptide APIs for commercial supplies
- A site expansion that will triple capacity of the manufacturing plant is underway



Our peptide facilities have been successfully inspected by numerous regulatory agencies including the World Health Organization, US FDA, European Directorate for the Quality of Medicines & HealthCare, Italian Medicines Agency, ECC-Germany, and the Korean Ministry of Food and Drug Safety. The site averages more than 10 customer audits every year.

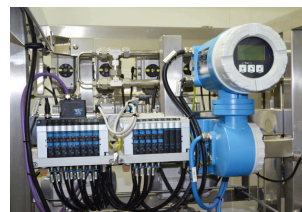


Product List:

We also offer a product portfolio covering almost 90% of all generic peptide APIs (commercialized and under development).

Commercial Products	Products Under Development
Buserelin acetate	Abaloparatide acetate
Calcitonin Salmon acetate	Atosiban acetate
Carbetocin acetate	Corticotropin acetate
Cetrorelix acetate	Glatiramer acetate
Desmopressin acetate	Glucagon acetate
Gonadorelin acetate	Lanreotide acetate
Gonadorelin diacetate*	Linaclotide acetate
Goserelin acetate	Liraglutide acetate
Leuprolide acetate	Plecanatide acetate
Octreotide acetate	Semaglutide acetate
Oxytocin acetate	Teduglutide acetate
Terlipressin acetate	Triptorelin acetate
Tetracosactide acetate	
Vasopressin acetate	

*Veterinary Drug



OUR GLOBAL PRESENCE

1 RIVERVIEW, USA

HPAPI Development & Manufacturing
USFDA, PMDA

2 SELLERSVILLE, USA

Formulation Development & Manufacturing
USFDA, EMA

3 LEXINGTON, USA

Sterile Development & Manufacturing
USFDA, PMDA

4 GRANGEMOUTH, UK

ADC Development & Manufacturing
USFDA, MHRA

5 MORPETH, UK

API & Formulation Development & Manufacturing
USFDA, MHRA

6 AURORA, CANADA

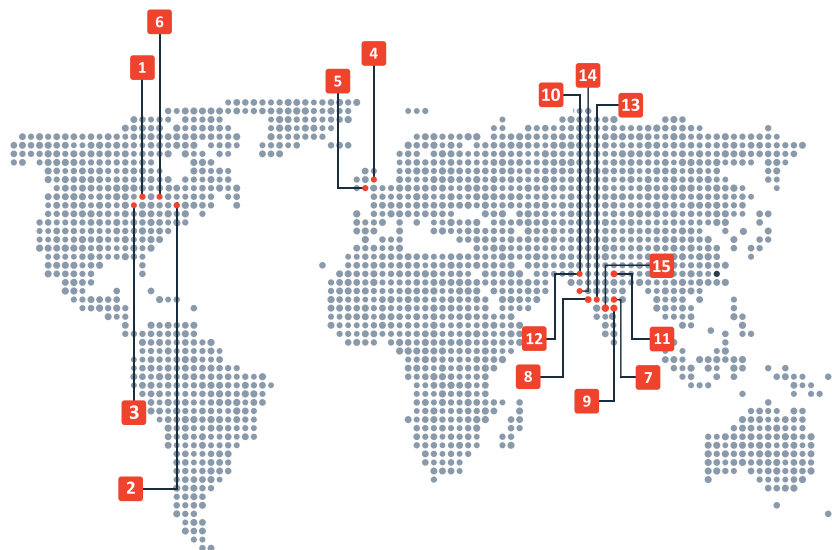
API Development & Manufacturing
USFDA, PMDA

7 DIGWAL, INDIA

API Development & Manufacturing
USFDA, MHRA

8 TURBHE, INDIA

Peptide API Development & Manufacturing
USFDA



SHANGHAI, CHINA

• Sourcing Office

9 ENNORE, INDIA

API Development & Manufacturing
WHO-GMP

10 AHMEDABAD - PDS, INDIA

Drug Discovery

11 PITHAMPUR, INDIA

Formulation Manufacturing
USFDA, EU Finland, ANVISA

12 AHMEDABAD - PPDS, INDIA

Formulation Development
EU Finland

13 MAHAD, INDIA*

Vitamins & Minerals Premixes
USFDA, WHO-GMP

14 RABALE, INDIA

API Development

15 HYDERABAD, INDIA**

Vaccines & Biologics Process Development & Manufacturing

Note: *Dietary Ingredients
**Through PPS Minority Investment in Yapan Bio

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