

Pithampur, India

Commercial Manufacturing of Oral Solid Dose Formulations

The Pithampur site provides clinical, pilot, and commercial-scale manufacturing of oral solid dosage (OSD) forms and packaging services to the Americas, Europe, and Australia. Established in 1992, the site currently has OSD capacity of 4.5 billion units. Major regulatory accreditations include USFDA, EU GMP, Brazil Anvisa, TGA Australia, and FIMEA Finland.



Featured Services

- Commercial manufacturing & packaging
- Pilot & pivotal bio batches
- Manufacturing of clinical, exhibit, and validation batches
- Full analytical services, including a large microbiology laboratory

Dosage Form Capabilities

- Immediate & modified release oral solids (tablets)
- Aqueous & solvent granulation & film coating
- Hard gelatin capsule filling
- Batch sizes range from 4kg to 600kg
- Form fill seal/blow fill seal technology for ophthalmics
- Bottle, bulk, & blister packaging with autocartonating for bottle and blister

Production Competencies

- Direct compression granulation
- Aqueous & nonaqueous high & low shear wet granulation
- Aqueous & nonaqueous top spray granulation
- Roller compaction
- Aqueous & nonaqueous Wurster
- Single & bilayer compression
- Tamping-based capsule filling
- Isolation insertion technology with blow fill seal for ophthalmics



Quality Competencies

- Segregated wet, instrument, & microbiology laboratories
- Automated QMS (Trackwise)
- Stability studies for all markets as per ICH requirements
- 99.5% of all testing is done in-house

Warehousing Competencies

- cGMP warehouse with various temperature-controlled capabilities
- Inventory management with bar code system for container level traceability
- Dedicated sampling booth for APIs & excipients
- Five cGMP dispensing booths
- Dispensed material staging area with separate access-controlled entry
- Controlled substances handling (Schedule IV)

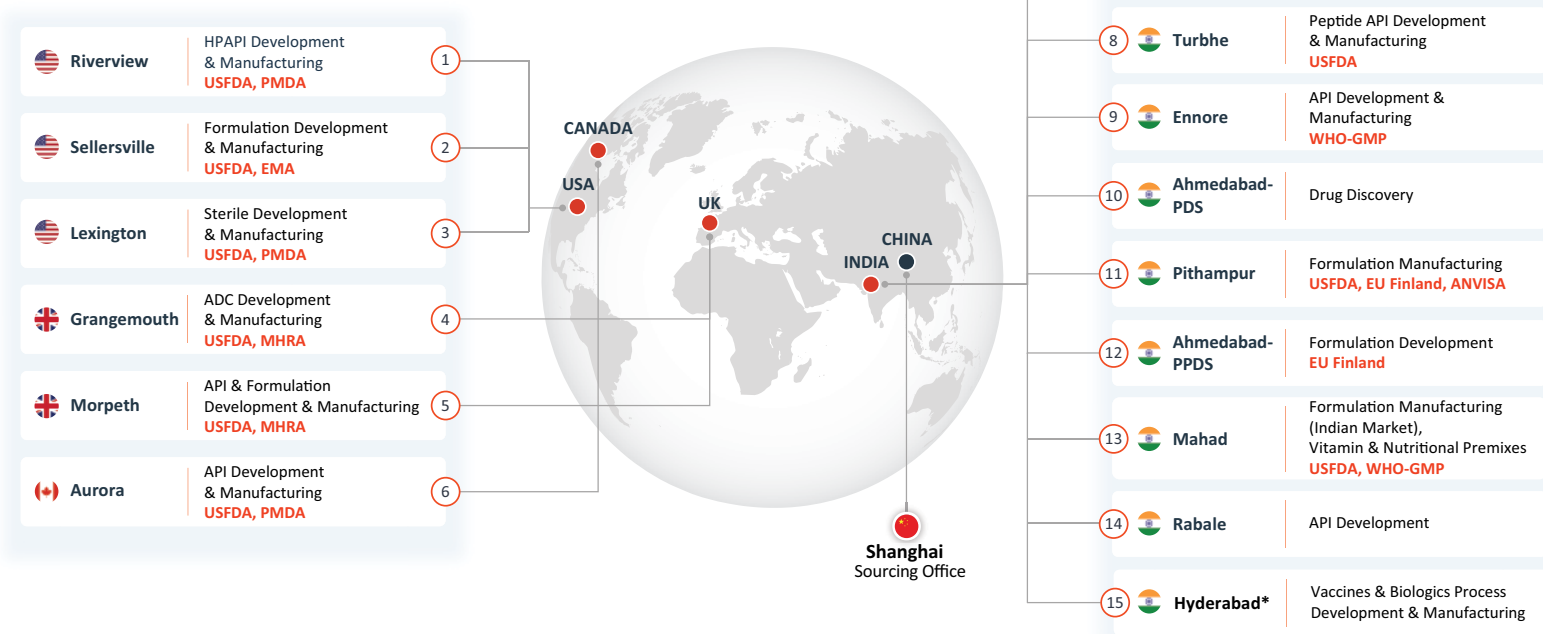


Pithampur Site Features & Benefits

- Geopolitically stable location with excellent global connectivity
 - Consistently high record of delivering on time and in full
- Excellent track record in both Tech Transfer (handling from Phase III CT to exhibit/registration for ANDA, NDA & 505b2 followed by commercial) and Site Transfer (transferring commercial products from client sites)
 - Extremely nimble and adaptable to changes
 - A trusted partner on IP protection
- Highly integrated with our formulations R&D site in Ahmedabad: more than 35 projects have been successfully transferred to Pithampur
- Site capable of handling the entire supply chain, from negotiation & procurement with vendors to managing inventory
 - Can be an end-to-end solution or cost optimization solution via backward integration with our large API site in Hyderabad
- Cost effective for large volume late life cycle products to extend commercial lifespan



OUR GLOBAL PRESENCE



*Yapan Bio: A Piramal Pharma Ltd. Associate Company



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