

**Piramal - Now a
Trusted Partner for your
High Potency API Needs**



Piramal Pharma Solutions now offers High Potency API (HPAPI) services following its acquisition of Ash Stevens, a leader in HPAPI development and cGMP manufacture with over five decades of experience. Our FDA licensed cGMP facility located in Riverview, MI (USA) offers a full range of scale and containment

options for HPAPIs. Piramal's globally aligned resources enables sponsor companies to optimize a fully integrated range of high-quality services that can optimize your high potency drug development program for success.

PARTNER OF CHOICE AND A RECOGNISED GLOBAL LEADER IN HPAPIs

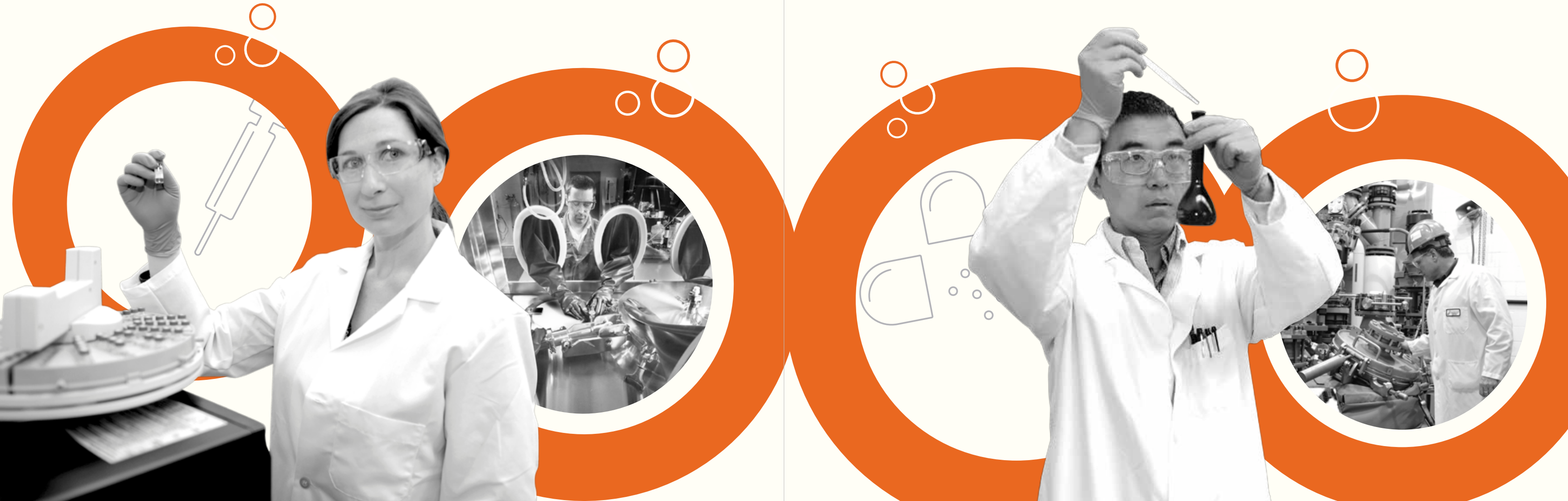
- 50+ years of Safe Operations Developing and Manufacturing APIs
- Advanced Several HPAPIs from Clinical Development through Commercial Launch
- Multiple Fast-Track Approvals
- 14 US FDA Manufacturing Approvals (NCEs)
- Successful Global Regulatory Inspection History (US FDA, UK MHRA/EU GMP, PMDA Japan, MFDS Korea, TGA Australia & Mexican Ministry of Health)
- Multiple Awards from SOCMA's ChemStewards® Program for Continuous Improvement in EHS&S Operations

LATE LIFECYCLE MANAGEMENT

- Process Research and Development, Scale-up and Validation
- cGMP Manufacture of Clinical Trial Material (CTM)
- Analytical Method Development and Validation
- Stability Studies
- Commercial cGMP Manufacturing for HPAPIs
- Regulatory Support and Documentation (INDs and NDAs)

DEVELOPMENT & MANUFACTURING CAPABILITIES

- Comprehensive API Development and Manufacturing Capabilities from Gram Scale to Hundreds of Kilos
- Up to 4,000 L Glass Lined Reaction Vessels with a Temperature Range of -70°C to +200°C
- Product Isolation Capabilities: Extraction, Filtration, Centrifugation, Distillation
- Drying/Finishing Facility: Rosenmund Filter Dryers, Forced Air & Vacuum Drying Ovens, Class 10,000 Clean Suites
- State-of-the-art High Potency API Manufacturing Suite with Airlocks and Barrier Isolation System
- Scaled Rosenmund Filter Dryer Capacity with Glovebox Technology to Facilitate Contained Isolations from Laboratory to Plant Scale
- Reactor Bays Equipped with Necessary Engineering and Process Controls to Safely Handle HPAPIs at Large Scale





OUR GLOBAL PRESENCE

1 LEXINGTON
STERILE DEVELOPMENT
& MANUFACTURING
USFDA

2 RIVERVIEW
HPAPI DEVELOPMENT
& MANUFACTURING
USFDA

3 AURORA
API DEVELOPMENT
& MANUFACTURING
USFDA, MHRA

4 MORPETH
API & FORMULATION
DEVELOPMENT
MANUFACTURING
USFDA, MHRA

5 GRANGEMOUTH
ADC DEVELOPMENT
& MANUFACTURING
USFDA, MHRA

6 AHMEDABAD
DRUG DISCOVERY
& FORMULATION
DEVELOPMENT
MPA Sweden

7 MUMBAI
API & FORMULATION
DEVELOPMENT

8 MAHAD*
VITAMINS & MINERALS
PREMIXES
USFDA, WHO-GMP

9 ENNORE
API DEVELOPMENT
& MANUFACTURING

10 DIGWAL
API DEVELOPMENT
& MANUFACTURING
USFDA, MHRA

11 PITHAMPUR
FORMULATION
MANUFACTURING
USFDA, MPA Sweden

12 SHANGHAI
SOURCING OFFICE

Note: * Dietary Ingredients



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