

Ahmedabad, India – (Special Economic Zone - SEZ)

Facility facts:

Opened: 2008

Audited: MHRA 2009, QP 2012, EU GMP 2015; storage and all services are GMP compliant

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Capabilities:

- GMP temperature and RH-controlled storage at ambient (15°C to 25°C), refrigerated (2°C to 8°C), frozen (-20°C and -60°C), and commercial storage, etc.
- Controlled drug and beta lactam antibiotic storage
- In-house label design, translation, and production
- Secondary kit assembly
- Syringe, pen, and auto-injector assembly
- Primary and secondary packaging at ambient, refrigerated, and frozen temperatures, with support for light-sensitive packaging
- Comparator sourcing
- Clinical ancillary management
- Pick and pack, and distribution services that include temperature management, and monitoring for local, regional, and international shipments
- Clinical supply returns / storage / destruction service

Overview:

- Strategically located in one of India's Special Economic Zones (SEZ), our ability to act as Importer of Record (IOR) for import into the Free Trade Zone and our ability to procure a regulatory manufacturing permit for 3rd parties make clinical trial supply conduct simpler and safer for sponsors worldwide.

Ahmedabad clinical storage and packaging capabilities

Capacity and services		
Storage	Controlled ambient (15°C to 25°C)	401,669 cu. ft. (11,374 m ³)
	Refrigerated (2°C to 8°C)	42,907 cu. ft. (1,215 m ³)
	Frozen (-20°C / -30°C)	3,072 cu. ft. (87 m ³) -20°C 3 x 17 cu. ft. at -30°C
	Ultra frozen	2 x 17 cu. ft. units at -60°C
	Controlled drug (ambient)	424 cu. ft. (12 m ³)
	Controlled drug (refrigerated)	318 cu. ft. (9 m ³)
Clinical manufacturing	Over-encapsulation	Blinding of primary and secondary materials
	Capsule filling	

Ahmedabad clinical storage and packaging capabilities

Capacity and services		
Primary packaging (6 production rooms)	Fully automated and semi-automated bottling line	Mono-product and two product blister line (thermo and cold forming) for oral solid dosage form
	Carding	Blister strip walleting
	Light sensitive and low-humidity packaging	
Secondary packaging (9 production rooms)	Secondary kits assembly	Refrigerated packaging
	Light-sensitive packaging	Syringe / pen / autoinjector assembly, including limited cold assembly
	Production Assembly Packaging Module (PASS) System ensures effective randomization	
Label services	label design	Labelling - print and apply, OCVR / OCV
	Cold chain labelling	Single panel and booklet
	Precision syringe labeling	Expiry panel and booklet
	Fixed and variable text	Ancillary labelling
	Warehouse labelling	Over labelling
Distribution	Pick and pack services	
	Domestic distribution	
	IP return & reconciliation	
	Destruction	

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