

Summary of capabilities

Ahmedabad, India

Special Economic Zone (SEZ)

Overview:

Located in one of India's special economic zones, we can bring products into the site for packaging, labeling, kitting, and for later re-export or definitive importation into India. (NOTE: Sponsor or CRO act as importer of record).

Facility facts		Offerings
Opened:	2008	<ul style="list-style-type: none"> • GMP temperature and RH-controlled storage at ambient (15°C to 25°C), refrigerated (2°C to 8°C), and frozen (-20°C and -80°C) temperatures, including commercial storage • Controlled drug and beta-lactam antibiotic storage • In-house design, translation, and production of single panel labels • Secondary kit assembly, including manual syringe assembly • Syringe, pen, and auto-injector assembly • Secondary packaging in ambient and refrigerated environment with support for light-sensitive packaging • Comparator sourcing • Clinical ancillary management • Distribution services that include temperature management and monitoring for local, regional, and international shipments • Clinical supply returns/storage/destruction service
Audited by:	20B, 20G, 21B, 25, and 28 from state licensing authority of India; storage and all services are GMP compliant	
Contact info:	Facility address: Pharmez, Sez, Plot No. 22 Matoda NH 8A Ahmedabad 382213 Gujarat, India Tel: +91 271 766 2200	

Ahmedabad clinical storage and packaging capabilities:

Capacity and services		
Storage	Controlled ambient (15°C to 25°C)	401,669 cu. ft. (11,374 cu. m.)
	Refrigerated (2°C to 8°C)	42,907 cu. ft. (1,215 cu. m.) and 72,465 cu. ft. (2,052 cu. m.)
	Frozen (-20°C-30°C)	3,072 cu. ft. (87 cu. m.)
	Ultra-frozen (-80°C)	6 x 17 cu. ft. units (6 x 482 L)
	Controlled drug (ambient) (15°C to 25°C)	424 cu. ft. (12 cu. m.)
	Controlled drug (refrigerated) (2°C to 8°C)	318 cu. ft. (9 cu. m.)
Returns	Ambient	77,515 cu. ft. (2,195 cu. m.)
Secondary packaging (11 production rooms)	Secondary kit assembly	Refrigerated and frozen (-20°C) packaging
	Light-sensitive packaging	Manual syringe assembly
	Carding/walleting	Production Assembly Scanning System (PASS)
Label services	Label design, single panel production	Labeling—print and apply, OCVR/OCV
	Cold chain labeling	Single panel, booklet, auxiliary, and expiry labeling
	Just-in-time labeling	Over labeling
Distribution	Pick and pack services	IP return and reconciliation
	Domestic distribution	Destruction

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