

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: The sponsor or the CRO act as the importer of record.)

Facility facts		Offerings
Opened	2008	- 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 at ambient, refrigerated, frozen, and ultrafrozen (with dry ice) environments, with support for light-sensitive materials - Comparator sourcing - Clinical ancillary management - Distribution services that include temperature management and monitoring for local, regional, and international shipments - Clinical supply returns, storage, and destruction services
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	

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, frozen (–20°C), and ultrafrozen (–80°C with dry ice) packaging capabilities
	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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