

Summary of capabilities

Ahmedabad, India

Special Economic Zone (SEZ)

Overview:

Located in one of India's special economic zones (SEZ), 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 | 6 x 17 cu. ft. units at -80°C |
| | Controlled drug (ambient) | 424 cu. ft. (12 cu. m.) |
| | Controlled drug (refrigerated) | 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 |



Summary of capabilities

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