

Fermentation Derived High-Potent APIs

SAFC Pharma™ – Jerusalem

SAFC Pharma™ has invested in a new HPAPI contract manufacturing fermentation facility in Jerusalem, Israel. The 50,000 sq. ft. state-of-the-art Biosafety Level 2 facility has been designed to meet both EU and FDA compliance standards for large-scale cGMP production of fermentation-derived biologic products and small organic molecules. Highly experienced scientific teams can provide a complete range of services, including process evaluation and development, optimization and scale up, technology transfer, manufacturing, analytical testing and regulatory filing.

This new facility underlines SAFC's commitment to support customers at every stage of the drug development pipeline for new emerging technologies.



Manufacturing Features

The Jerusalem site can provide a complete range of state-of-the-art fermentation, downstream processing and purification capabilities including:

- Customized master and working cell banks of natural or recombinant microorganisms, including Risk Group 2 (RG2) pathogens
- Sourced bacterium, streptomycetes, filamentous fungi or yeast for fermentation
- Wide range of fermentation capacity (19 L, 100 L, 1,000 L, and 4,000 L fermentors)
- Downstream processing and final purification using contained equipment
- Clean In Place (CIP) and Sterilization or Steam In Place (SIP)
- Jacketed and/or explosion proof equipment
- Continuous disc stack and high speed centrifuges
- Processing vessels up to 4,000 L
- Liquid-liquid extraction column (200 L)
- Evaporation train (550 L)
- Cross flow ultra/diafiltration
- Fast Protein Liquid Chromatography (FPLC)
- Medium Pressure Liquid Chromatography (MPLC)
- Freeze dryer (Lyophilization)

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Containment and Safety

The facility is designed to follow the most stringent criteria for biohazard fermentation and HPAPI manufacturing to prevent cross contamination, ensure personnel safety and protect the environment. The HVAC system provides 100% HEPA filtered single pass air in airlocked segregated, purpose built manufacturing areas.



- Class 100,000 (ISO 8) fermentation and harvesting suites equipped with biohazard cabinets
- Class 100,000 (ISO 8) recovery suites including an explosion proof environment
- Class 10,000 (ISO 7) purification clean rooms equipped with Class 100 (ISO 5) safety cabinets
- Routine environmental monitoring
- Pre-disposal treatment of all biological and chemical waste material



Analytical Services

Analytical support compliant with Pharmacopoeia (EP/USP) methods and ICH guidelines managed via a validated Informatics System for QC analytical data (SAP-QM) and includes:

- Development and validation of analytical methods
- Raw materials, in-process and final product release testing

- Stability testing
- Cleaning efficiency testing
- Selected Tests: HPLC, TLC, GC, UV-VIS, FT-IR, NMR, TOC, ICP, Moisture (KF), LAL, Polarimetry, ELISA, PAGE, enzymatic activity, microbiological testing

Quality Management and Regulatory Affairs

All activities are subject to review and audits with Quality Assurance (QA) approval in compliance with ICH guidelines. Regulatory affairs communicate through appropriate agencies including the FDA and the EMEA to ensure full compliance with emerging regulatory requirements.

- Document review and approval (e.g. MMF, SOPs, batch records, product release)
- Validated Electronic Document Center (e-DOC)
- Qualification of equipment and systems (including 21CFR Part 11)
- Validation of processes
- Investigation of non-conformances
- Change control procedures in place
- Corrective And Preventive Action (CAPA)
- Personnel training and qualification programs
- Drug Master File (CTD-DMF) experience



SAFC Pharma's Jerusalem fermentation operations support fermentation-derived high potent APIs, from preclinical to commercialization.