



جلف بايوتك
GULF BIOTECH

Your Wellness, Our Success

Situated in the Kingdom of Bahrain, Gulf Biotech is the first and only sterile fill and finish facility for Biopharmaceutical & Pharmaceutical products. With the deployment of best technology, we aim to research, develop & market medicines that improves patient's health.

Introduction

Gulf biotech has selected MENA region as primary market for it's parenteral products. Gulf Biotech is constructed on 16,000 sqm plot of land in Bahrain International Investment Park . Total built up area is around 20,000 sqm and designed to accomodate high-end manufacturing technology for the production of injectable product in vials, Cartridges, pre-filled syringes and ampules.



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Gulf Biotech

Gulf Biotech utilizes advance technology & highest quality standards to be most competitive, efficient and reliable company.



**Our Plant has
been designed
by Rieckerman
(Germany)**

Core Competencies

Gulf Biotech is designed to accomodate high end manufacturing technology for the production of Vials, Cartridges, Pre-filled Syringes and Ampules. We partner with highly reputed European equipment manufacturers including Bosch (Germany) & Marcheisini (Italy). Cleanrooms are constructed with modular pre-fabricated panels from Austar.

About Us

Gulf Biotech is capable of manufacturing a variety of generic sterile parenteral products.



Gulf Biotech offers a broad range of parenteral fill and finish “ Contract Manufacturing Services ” and can provide support throughout the entire sterile manufacturing process. Extensive production services for commercial drug products from formulation to primary packaging in Vials, Ampoules, PFS and cartridges are available at GBC Plant.

In addition, GBC offers comprehensive services of parenteral secondary & tertiary packaging including Automatic Inspection, Printing, Labeling, Blistering, Cartoning and Case packing with Serialization (Track & Trace system). Sufficient Warehousing capacities with controlled environmental conditions are available for storage of Raw Materials, finished Goods and Cold Storage.



Highly equipped with state-of-the-art production machines and QC Instruments

At Gulf Biotech, we have machines and equipments from world’s renowned partners like Bosch / Syntegon for production & clean utilities, Marcheisini for Integrated Secondary Packaging Line and Quality Control instruments from Shimadzu, Memmert, Sartorius, Thermo Scientific and Bioquell among others.



Our Mission

"We are committed to provide patients with better access to high-quality and affordable medicines in key therapeutic areas."

Our Vision

To build **Gulf Biotech** into a leading Biopharmaceutical & pharmaceutical company with global recognition. Our aim is to focus on developing a business that maintains high standards of ethics and responsibility towards our clients.

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Contract Manufacturing

Gulf biotech is open to discuss different pricing models with our valuable customers for Contract Manufacturing of Vials, Cartridges, Ampules and Prefilled Syringes



Cost Savings

With Contract Manufacturing our clients can save cost as they will not spend for facility design, construction, equipments, purchasing, installation & maintenance for production. They can save labour cost, salaries, government fee and other indirect cost.



Mutual Benefits

Our clients who get their products manufactured from us can focus on their other businesses which are their core areas. Gulf Biotech's benefit is to utilize our idle time which we cannot use because of any reason.



Skills & Knowledge

Companies can take advantage of experience, skills and knowledge of Gulf Biotech to produce their products with cGMP compliance.



Economies of Scale

Gulf Biotech has capability to deal with number of customers at the same time for contract manufacturing in order to keep running our machinery for maximum period of time so that we can offer competitive cost.

Pre Formulation

Gulf Biotech manufacturing facility has deployed state-of-the-art drug product formulation/compounding system in collaboration with Syntegon Technology (Robert Bosch Packaging Technology) to help meet the need for both process flexibility and exceeding the short delivery time.

Gulf Biotech process systems are fully integrated, automated, highly modular and flexible for the manufacturing of Sterile Liquid Formulations of various batch volumes.

The production is run under strictly controlled environmental conditions. The manufacturing vessels are placed under CLAF to ensure compliance with cleanroom requirements.



Solution Manufacturing System at Gulf Biotech is fully equipped with integrated interface for shared Clean-In-Place (CIP) and Sterilization-In-Place (SIP) systems.

CIP/SIP considerably reduces the risk of cross-contamination by highly efficient cleaning & Sterilization process.

Final Formulation

Gulf Biotech has a separate area for final formulation and holding the batch in vessels under a blanket of nitrogen. All holding vessels are dedicatedly connected to transfer vessel at filling line.



All the vessels are interconnected through a network of pipelines ensuring one way flow of the manufactured batches.

The network of pipelines is connected to CIP & SIP system to ensure efficient cleaning & sterilization in a short time period.

The manufacturing facility at Gulf Biotech is constructed by using pre-fabricated clean room panels from Austar.

This type of panels are easy to clean and ensures perfect solutions for maintenance of clean room areas.



Filling Machine

Bosch Vial Filling Machine with isolator (FLC) is designed to enclose the filling, stoppering, and capping operations while providing an aseptic environment for the process, achieving ISO-5 grade A Classification.

The filling line is integrated with vials washing machine and depyrogenation tunnel, enabling the filling process to be fully conducted under aseptic conditions.



Isolator

The isolator allows for the entry of Pre-sterilized stoppers and flip-off seals through a Rapid Transfer Port (RTP). Liquid formulation is transferred from transfer vessel to the filling machine after passing through the filtration skid.

Glass vials are transferred to the Isolator after washing and depyrogenation through the sterilization tunnel.



Vials Coding

The Vials are automatically moved by the filling machine through the filling, stoppering, capping stations and exit through a "mouse hole" at the end of the Isolator.

A conveyor carries the filled vials from the isolator to the adjoining room for coding of each individual vial. A 2D barcode is stamped on each vial carrying information about the complete identity of the individual vials.





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Continuous capping at high speeds ensures safe and reliable packing process. Compliance is increased with 100% weighing and inline inspection system for empty vial inspection, stopper position, crimp quality and printing check and control.





Automatic Inspection Machine

Inspect vials for particulates and cosmetic defects and fully integrated high voltage leak detection.



Gulf Biotech Vial Inspection Machine is engineered for safe operation, ease of use and compliance with cGMP standards.

The machine integrates high resolution CMOS Cameras with high speed interfaces for particulates in liquid and cosmetic container defects on a single inspection table and offers the possibility to combine it with High Voltage Leak Detection (HVLD).



Secondary Packaging

Gulf Biotech have procured best packaging equipment from the market to ensure that the highest quality standards are met.

Packaging Line Marchesini (Italy)

At Gulf Biotech, our packaging experts make sure that manufactured products are packed in safest way without losing product's chemical and physical properties. Our fully automated packaging preserves the product through out supply chain starting from packing to patient.

We have a wide range of packaging formats for sterile products. Experience and expertise define our packaging capabilities with the best available high speed machinery. Our Production facilities for vials, cartridges, ampules and prefilled syringes are equipped with fully dedicated and segregated capabilities for secondary packaging.



Gulf Biotech Packaging Facility has capability to pack sterile products including Vials, Ampules and Prefilled Syringes in 14 different formats. We also have options to pack products in combinations e.g. prefilled syringes plus lyophilized vials along with 2 needles.



Warehouse & Cold Storage

Gulf Biotech has spacious Warehouse to cater the storage needs for Raw materials, packing materials and finished goods.

Separate Storage areas are allocated for Raw/ Packing Materials, a quarantine area and for finished goods.

A separate warehouse is provided for storage of semi-finished goods awaiting QC release before packing.

There are 3 Cold Storage rooms at different floors maintained at 2-8° C for transient and long-term storage of Raw materials, semi-finished goods and finished goods.

Cold Storage





UTILITIES

Pure Media System (PMS)

PW & WFI Generation Unit

Skid Mounted Pharmatec Purified Water Generation Unit (PWGU) is a compact and pre qualified system designed for the continuous production of Purified Water (PW).

The PW is used for the generation of pure steam and Water for Injection (WFI). The PW & WFI are generated as per the regulations of the American and European Pharmacopia (USP and Ph EUR) and the ISPE Guidelines.

Pure Steam Generation Unit

The Pharmatech Pure Steam Generator (PSG) is a compact and prequalified system designed for the continuous production of sterile, pyrogen-free pure steam "PS" according to the regulations of the American and European Pharmacopia (USP and Ph EUR) and the ISPE Guideline for pharmaceutical pure steam.





Quality Control

At Gulf Biotech, we have a spacious QC Lab with hi-tech testing instruments from renowned brands like Shimadzu, Memmert, Light-house, Sartorius & Bio-Quellamong others.

More instruments can be added based upon the need and types of testing requirements.



Microbiology Section

Fully equipped microbiological testing lab at Gulf Biotech ensures complete & reliable finished products testing before release for marketing.





Stability Studies

Stability studies section is provided with constant climatic chambers from Memmert (Germany)





Research & Development

A dedicated Research & Development Lab is available for product development activities equipped with all necessary machines for small scale batches manufacturing.

Sterile Liquid Injectables and Lyophilized Formulations are developed in Gulf Biotech R&D unit. Our experts at R&D unit primarily focus on stability of the molecule as parenteral formulation and many other interrelated parameters which are required to develop sterile formulations.

After successful product development, the processes are validated and transferred to concerned department for Commercial scale production.



Our R&D team is fully involved in formulation development, cleaning methods developments and post-development technology transfer activities.



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Bahrain, a well established Business hub in the Gulf, providing the most free, open, liberal & transparent environment for businesses and communities. Bahrain has provided us the best opportunity to continue our operations in the most cost effective way.





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We as Gulf Biotech experience the most open & favorable business conditions in Bahrain. By virtue of it's strategic location, Bahrain has the advantage of being an ideal gateway to the Multi-Billion Dollars Gulf Market.



Our world is built on biology and once we begin to understand it, it then becomes a technology

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