SOVEREIGN PHARMA

Delivering High Quality Injectables Worldwide

SOVEREIGN

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Site Map


Utility Block-1
Open Space
Building-1
Scrap Yard
Utility Block-2
Building for Future Use
Building-3
Building-2
Diesel Generator room
Building for Future Use
Security Office
Admin office & Canteen Block
Raw Water Storage Tank
Building for Future Use
QA building

1 The Dadachanji Group

A Legacy of Innovation

30+ Years of Experience in the Pharmaceutical Industry

Founded by Mr. Kairus Dadachanji and headquartered in Mumbai, India, the Dadachanji Group of Companies is a diversified group with business interests that include Pharmaceuticals and Biotechnology, Primary and Secondary Packaging, Medical Devices, Machine Building, Automation, and Robotics.

Growing the Legacy of Innovation since 1990

2003 — **Sovereign Pharma** was established

2004 — Received CDSCO approval

2006 — Certified for WHO Geneva regulatory

2007 — Line 2 started in Building 1 for Lyophilized products, PFS and Cartridges

Line 3 started for ampoules

2010 — Received IEDRA award for healthcare excellence

2012 — Certified for SAHPRA, SA regulatory

2014 — Building 2 established for Line 4

2015 — Received the MHRA, UK approval

Received the EFDA, Ethiopia approval

2017 — Certified for MCAZ, Zimbabwe

Certified for Ministry of Health and Prevention, UAE

SAP, LIMS, DMS and QMS implemented

2018 — Certified for DIGEMID, Peru

2019 — Certified for PIC's Ukraine

2020 — Certified for FBI SID and GP, Russia

Certified for Ministry of Health ANVISA, Brazil

Certified for Turkish Medicines and Medical Device Agency, Turkey

WM and PPDS implemented

2023 — Certified by FDA Ghana, Jordan,BoMRA

2024 — Sovereign is approved for EUGMP (supplies for aseptic & terminally sterilised products)

2025 — Certified for Ministry of Public Health, Thailand

Certified for Ministry of Health, Iraq

2 About Sovereign Pharma

Cultivating a Culture of Quality

As a **WHO-GMP certified manufacturing facility** for terminally sterilized and aseptically filled injectables in Ampoules, Vials (Liquid and Lyophilized), Pre-filled Syringes, and Sterile Pre-crimped Cartridges, Sovereign Pharma cultivates the culture of quality across production.

WHO-GMP

To cope with the needs of the ever-evolving pharmaceutical industry, we at Sovereign Pharma, are continuously upgrading by improving our facilities and systems. We have successfully implemented the latest in digital tools and processes at our manufacturing site to further strengthen our robust quality system.

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350M pieces produced per annum

1B+ injection doses manufactured and sold annually

WHO-GMP Geneva-certified manufacturing facility

3 Our Facility

A State-of-the-art Manufacturing Facility

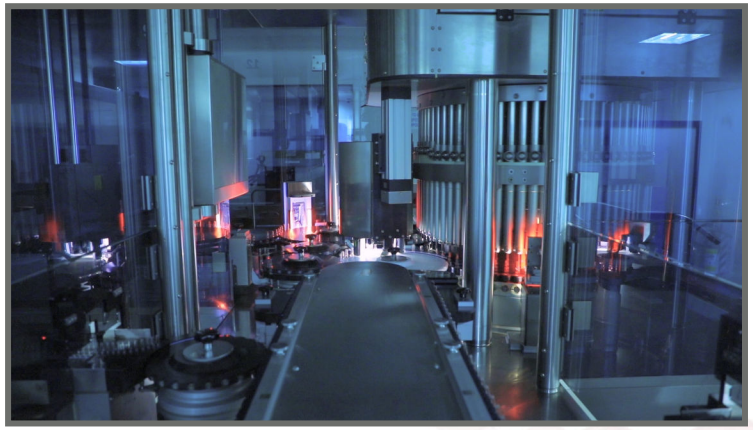
Our manufacturing suites are equipped with dedicated AHUs, pre- and post-autoclaves, integrated washing, depyrogenation, filling and sealing lines, camera inspection systems, labelling, and final packing machines.

4 Manufacturing suites

3 Ampoule lines

1 Vial line

Dedicated machine for ready-to-fill syringes and cartridges



Processing Area Classifications

Building	Processing Areas Block No. A (Building 1)			Processing Area Block No. E (Building 2)
	Line 1	Line 2	Line 3	Line 4
Filling & Sealing of Ampoules	Grade A/C (Isolator Technology)	NA	Grade A/B	Grade A/B
Vial, PFS filling & Stoppering / half stoppering	NA	Grade A/B	NA	NA
Vial Sealing		Grade A/C		
Filtration	Sterilized closed loop with background Grade C	Grade A/B	Grade A/B	Grade A/B
Solution Manufacturing	Grade C	Grade C	Grade C	Grade C
Container Washing & Depyrogenation	Grade C	Grade D	Grade D	Grade D
Raw Material Dispensing	Grade A/C			Grade A/C
Raw Material Sampling	Grade A/C			

A glimpse of our facility

Key Highlights

- Box-in-box type model with directional layout and segregated man-material movement
- Cool/cold storage area provision for intermediate and finished goods
- Dedicated areas for sampling and dispensing raw materials with segregated MAL and PAL
- 100% power backup with critical areas connected to UPS
- Highly equipped QC laboratory with three sterility rooms
- Segregated LAL and micro-testing rooms with dedicated PALs
- Stability chambers covering all major zones, temperatures, and humidity conditions
- Walk-in incubators for environmental monitoring and sterility testing/media fills

4 Our Manufacturing Capacities

Overview

BUILDING DESCRIPTION	MANUFACTURING FACILITY	CONTAINER TYPE	PROCESSING TECHNIQUE
BUILDING 1	Line 1	Ampoules	New line with Isolator (Aseptic & Terminal Sterilization)
	Line 2	Vials, PFS and Cartridges	Aseptic, Terminal and Lyophilization
	Line 3	Ampoules	Aseptic and Terminal Sterilization
BUILDING 2	Line 4	Ampoules	Aseptic and Terminal Sterilization
	Ground Floor	- Centralized Warehouse for both the buildings for RM, PM, SPM and FG - Sampling of RM, PM and SPM	

Manufacturing Capacity / Year

AREA	FACILITY	CAPACITY/DAY	CAPACITY/YEAR
LINE - 1 (300 WORKING DAYS)	Ampoules	0.25 million	75 million
LINE – 2 (150 WORKING DAYS)	Vial	0.1 million	15 million
	Vial [Lyophilized]	0.05 million	7.5 million (2mL)
		0.025 million	3.75 million (10 mL)
	Pre-filled Syringes / Cartridges	0.030 million	4.5 million
LINE – 3 (300 WORKING DAYS)	Ampoules	0.25 million	75 million
LINE – 4 (300 WORKING DAYS)	Ampoules	0.5 million	150 million

Area Equipment Summary

PROCESS	EQUIPMENT	QUANTITY			
		LINE 1	LINE 2	LINE 3	LINE 4
MANUFACTURING	Manufacturing vessels	01 (1000 L)	01 (1000 L)	01 (1000 L)	01 (1600 L)
WASHING	Washing machine	01	01	01	01
DEPYROGENATION	Depyrogenation tunnel	01	01	01	01
FILLING AND SEALING	Ampoule filling and sealing	01	-	01	01
	Vial filling and stoppering, sealing	-	01	-	-
	PFS filling and stoppering	-	01	-	-
	3-piece bottles filling and stoppering	-	01	-	-
LYOPHILIZATION	Lyophilizer	-	01	-	
INSPECTION	Automatic inspection machine	01	01	02	01
	HVLD (High Voltage Leak Detection)	-		-	01
PACKING	Vial labeling	-	01	-	-
	Ampoule labeling	02	-	02	02
	Blister packing	01	-	01	01

Utilities for Building 1 and 2

EQUIPMENT	BUILDING 1		BUILDING 2	
	CAPACITY	QUANTITY	CAPACITY	QUANTITY
PURIFIED WATER PLANT	3000 Liter/hr	01	3000 Liter/hr	01
WATER FOR INJECTION PLANT	1500 Liter/hr	01	1500 Liter/hr	01
PURE STEAM GENERATOR	750 Kg/hr	01	750 Kg/hr	01
	300 Kg/hr	01		
AIR COMPRESSOR	283 CFM	01	283 CFM	02
	273 CFM	01		
NITROGEN SYSTEM	10 NM^3 /hr	01	10 NM^3 /hr	01
	05 NM^3 /hr	01		
STEAM BOILERS	4 TPH	01	Common for both buildings	
	2.8 TPH	01		

Utilities for Building 1 and 2

EQUIPMENT	BUILDING 1		BUILDING 2	
	CAPACITY	QUANTITY	CAPACITY	QUANTITY
CHILLERS	120 TR	02	120 TR	02
	127 TR	01		
COOLING TOWERS	190 TR	02	446 TR	01
	90 TR	02		
	225 TR	01		
ELECTRICITY GENERATING SETS	1250 KVA	02	Common for both buildings running in synchronization	
	750 KVA	01		

Our Workforce

DEPARTMENTS	STAFF & TECHNICIANS	WORKERS	TOTAL
PRODUCTION	338	182	520
QUALITY ASSURANCE	66	4	70
QUALITY CONTROL	83	8	91
ENGINEERING	66	18	84
PPIC & STORES	27	24	51
ACCOUNTS	7	0	7
PURCHASE	3	1	4
EHS	2	0	2
IT	6	0	6
HR & ADMIN	20	43	63
BUSINESS DEVELOPMENT	1	0	1
MANAGEMENT	3	0	3
SECURITY	10	0	10
TOTAL	**632**	**280**	**912**

5 Our Products

Core Products

Sovereign Pharma has over a decade and a half of experience in manufacturing and supplying diluents - Sterile Water for Injection and Sodium Chloride Injection, to all major vaccine manufacturers.

The diluents are supplied across the world through our customers, in addition to various organizations such as WHO, UNICEF, PAHO, and The Bill Gates Foundation, among others.

We have several formats of diluents available in glass ampoules.

Core Products

Sterile Water for Injection (SWFI) IP

- 0.5 ml, 1.0 ml, 2.5 ml, 5.0 ml SWFI

Sterile Water for Injection (SWFI) BP

- 0.5 ml, 1.0 ml, 2.5 ml, 5.0 ml, 10.0 ml SWFI

Sterile Water for Injection (SWFI) IP

- 0.5 ml Pre-filled Syringe (Loan License)

Sodium Chloride Injection IP

- 0.5 ml, 1.0 ml (0.3% Sod. Chloride)
- 0.5 ml (0.4% Sod. Chloride)
- 1.0 ml, 2.5 ml, 5.0 ml (0.9% Sod. Chloride)

Sodium Chloride Injection BP

- 0.5 ml (0.3% Sod. Chloride)
- 0.5 ml (0.4% Sod. Chloride)
- 1.0 ml (0.9% Sod. Chloride)

Sodium Chloride Injection B.P (Vial)

- 6.5 ml (0.9% Sod. Chloride)

Contract Manufacturing Products

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As a CMO, besides our diluents, we manufacture several other general category injectable products for our clients who range from major global multinationals to large Indian companies. Some of the products manufactured are:

- ✓ Aciclovir Intravenous Infusion
- ✓ Anidulafungin for Injection
- ✓ Abaloparatide Injection
- ✓ Bivaliriduin for Injection
- ✓ Caspofungin Acetate for Injection
- ✓ Cetrorelix Acetate for Injection
- ✓ Colistimethate Sodium for Inhalation
- ✓ Carbetocin Injection
- ✓ Clevidipine Injection
- ✓ Citicoline Injection
- ✓ Calcium Sandoz Injection
- ✓ Clindamycin Injection
- ✓ Daptomycin for Injection
- ✓ Diclofenac Sodium for Injection
- ✓ Diluent r-BCG for Immunotherapy (aqueous)
- ✓ Enoxaparin Sodium for Injection
- ✓ Esomeprazole Sodium for Injection
- ✓ Furosemide Injection
- ✓ Ferric Carboxymaltose Injection
- ✓ Hydroxy Propyl Methyl Cellulose Ophthalmic Solution
- ✓ Hyoscine Butyl Bromide Injection
- ✓ Injection for Vitamin B Complex
- ✓ Lidocaine Injection
- ✓ Methylergometrine Injection
- ✓ Micafungin Sodium for Injection
- ✓ Minocycline for Injection
- ✓ Mecobalamin Injection
- ✓ Ondansetron Injection
- ✓ Omeprazole Sodium Injection.
- ✓ Oxytocin Injection
- ✓ Pantoprazole for Injection
- ✓ Phenytoin Sodium Injection
- ✓ Piroxicam Injection
- ✓ Remdesivir Injection
- ✓ Rabeprazole Sodium for Injection
- ✓ Sodium Chloride Injection
- ✓ Sterilized Water for Injection
- ✓ Sugammadex Injection
- ✓ Semaglutide Injection
- ✓ Tiecoplanin Injection
- ✓ Tigecycline for Injection
- ✓ Trental Solution for Infusion (Pentoxifylline Solution for Infusion)
- ✓ Water for Injection

Esteemed customers

6 Quality Management and Control

Quality Management Systems

- Site Master File, Validation Master Plan, Quality System Manual
- Management Review
- Qualification & Validation
- Quality Risk Management
- Product Quality Review
- Change Control (Permanent & Temporary)
- Deviation Management
- Corrective & Preventive Action
- Product Complaint
- Product Recall
- Training Management
- Stability Program
- Internal Audit
- Vendor Management
- OOS (Out of Specification)
- OOT (Out of Trend)

Quality Control

Our QC functions comprise of the following:

Chemical lab

Microbiological lab

Instruments lab

Packaging Material lab

Our QC lab is equipped with all required analytical instruments and supported by Caliber LIMS Software (LIMS 3.3.0E standard version) for electronic data management.

Major Quality Control Instruments

NAME OF INSTRUMENT	MAKE	SUPPORTING SOFTWARE
HPLC	Shimadzu (02), Dionex (05)	Chromeleon
GC	Shimadzu (01)	Chromeleon
Ion Exchange Chromatography	Metrohm (01)	Magic Net
UV Visible Spectrophotometer	Shimadzu (01), Thermo (01)	Lab Solution & Insight
FTIR	Shimadzu (01)	Lab Solution
TOC	Shimadzu (01)	TOC - L
Karl Fischer Auto Titrator	Metrohm (01)	Tiamo
Coulometer	Metrohm (01)	Tiamo
Liquid Particle Counter	HIAC RAYCO (01)	PharmaSpec
Airborne Portable Particle Counter	PMS (03), HACH (02)	NA
Microbial Air Sampler	Merck (03), PBI (03)	NA

Computerized System Applications

SYSTEMS	SCOPE	
QAMS (Caliber – Version 3.0.0)	▪ Change Management ▪ Deviation Management ▪ CAPA Management ▪ Product Complaint	
DMS (Caliber – Version 2.2.0)	▪ Validation Master Plan ▪ Site Master File ▪ Quality System Manual ▪ SOP's	
LIMS (Caliber – Version 3.3.0E)	▪ All Quality Control Operational Modules ▪ LDMS, EDAP, and CDS, i.e., for Equipment/Instrument Interfacing (Under Implementation) ▪ Environment Monitoring Module (Under Implementation)	
SAP (S4/ HANA) Implementation Partner - Deloitte	▪ Finance and Controlling Module ▪ Human Resource Module ▪ Material Management Module ▪ Warehouse Management and PPDS Module	▪ Quality Management Module ▪ Production Planning Module ▪ Plant Maintenance ▪ Sales and Distribution Module

7 Our Accreditations

Accreditations

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CDSCO, India

WHO Geneva Prequalified

Medicines & Healthcare Products Regulatory Agency, U.K.

EMA

Brazilian Health Regulatory Agency

MOH UKRAINE

Russian Institute of Drugs & Good Practices

Medicines Control Authority of Zimbabwe

Tanzania Medicines & Medical Devices Authority (TMDA)

Turkish Medicines and Medical Device Agency

EAEU- Armenia, Belarus, Kazakhstan, Kyrgyzstan & Russia

Botswana Medicines Regulatory Authority (BoMRA)

United Arab Emirates, Ministry of Health & Prevention

Food & Drugs Authority, Ghana

Food & Drug Administration, Philippines

Jordan Food & Drug Administration

Food, Medicine & Healthcare Administration & Control Authority of Ethiopia

Ministry of Public Health (Thailand)

Republic of Yemen

Ministry of Health of the Republic of Uzbekistan

COFEPRIS, Mexico

National Administration of Drugs, Food and Medical Technology, Argentina

8 Upgradation Plan

Facility Upgradation Plan

We planned the upgradation of the facility, to meet the Revised EU Annex 1 requirements of the Aseptically processed products and enhance our production capabilities as a part of continuous improvement. The proposed Modification will be carried out in Phase wise manner as below:

Phase	Planned Activity	Start Date	End Date
Phase 1	Shifting of Packing lines from Building 1 Ground Floor to First Floor.	October End 2024	Completed
	Visual Inspection & Quarantine area modification on Building 1 Ground Floor		
Phase 2	Modification & Upgradation of Production Line 1	November 2024	September 2025
	Setting up new facility for PFS and cartridge (Line 5)	January 2025	April 2026
Phase 3	Modification & Upgradation of Production Line 2 & Line 3	Sep/Oct 2026	June 2027

Equipment Upgradation Plan

Upgradation / Changes	Line 1	Line 2	Line 3
New **Solution Manufacturing & Filtration tank** of 1000 liters with In-place CIP/SIP with printout, audit trail facility, and IPC with 21 CFR part 11 Compliant.	✓	✓	✓
New **washing machine & Depyrogenation tunnel** with the additional feature of Cool Zone Sterilization and IPC with 21 CFR part 11 Compliant.	✓	✓	✓
New **filling and sealing machine** has **a closed containment Isolator system** with SCADA and 21 CFR part 11 Compliant.	✓	✓	✓
New **filling and stoppering machine** has **a closed containment Isolator system** with SCADA and 21 CFR part 11 Compliant.	X	✓	X
New **Equipment Autoclave** having Air detector test facility & IPC with 21 CFR part 11 Compliant.	✓	✓	✓
New **Terminal Autoclave** with IPC & 21 CFR part 11 Compliant.	✓	✓	✓
New Fully automatic **GMP Equipment washer** with IPC and 21 CFR part 11 Compliant.	✓	✓	✓
New **PUPSIT arrangement** with online filter integrity.	✓	✓	✓
New **Lyophilizer** with auto loading/unloading provision.	X	✓	X
New **Rubber stopper/Cap Processor** with Docking system which will aseptically transfer the sterilized rubber stopper & seal cap to its designated area inside the isolator	X	✓	X
Standby Rapid **decontamination isolator** for transfer of surface decontaminated accessories directly into the isolator	✓	✓	✓
New Environment Monitoring System (EMS) with SCADA & 21 CFR Part 11 Compliant to continuously monitoring of the Temperature, % Relative Humidity & Differential pressure of the area	✓	✓	✓
New **Automatic Inspection for ampoule and vial** with online 100% leak detection machine with IPC & 21 CFR Part 11 Compliant.	✓	✓	✓

NEW BUILDING INTRODUCTION

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Upgradation / Changes	Line 5
New **Solution Manufacturing & Filtration Vessel** of 10, 40, 125 Liter with In-place CIP/SIP with printout, audit trail facility, and IPC with 21 CFR part 11 Compliant.	✓
New PFS /Cartridges filling and **stoppering machine** has **a closed containment Isolator system** with SCADA and 21 CFR part 11 Compliant.	✓
New **Rubber stopper bung processor**	✓
New **Equipment Autoclave** having Air detector test facility & IPC with 21 CFR part 11 Compliant.	✓
New Fully automatic **GMP Equipment washer** with IPC and 21 CFR part 11 Compliant.	✓
Standby Rapid **decontamination isolator** for transfer of surface decontaminated accessories directly into the isolator	✓
New fully automatic filter integrity tester with 21 CFR part 11 compliant	✓
New Glove integrity tester with 21 CFR part 11 compliant	✓
New **PUPSIT arrangement** with online filter integrity.	✓
New Environment Monitoring System (EMS) with SCADA & 21 CFR Part 11 Compliant to continuously monitoring of the Temperature, % Relative Humidity & Differential pressure of the area	✓
New **Hot water system for HVAC facility**	✓
New nitrogen plant	✓
New Purified water generation and distribution system (after pre-ultra filtration) shall be installed	✓
New Water for injection Generation and Distribution plant shall be installed	✓

DADACHANJI GROUP

KAISHA Packaging | KAISHA Lifesciences | KAISHA Packwell

KAIRISH Innotech | KAIRISH Shared Services | DADACHANJI AVIATION

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Manufacturing Site:
Survey No. 46/1-4, Kadaiya Village,
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