Shreepati Pharmaceuticals Pvt. Ltd.

Your business partner & integrated solution provider for API & Intermediates

Shreepati's fact sheet

- Incorporated in 1996 and headquartered in Indore – India
- Over 25 years of experience in Chemical & Knowledge-based industry.
- Have the certification of the renowned quality model, ISO-9001 : 2015 & GMP certificate issued by MP FDA.
- Global positions in key products, exported to over 15 countries

Plant Details

- Manufacturing site spreads over 7000 sq. meters.
- Processes relating to manufacturing viz. Synthesis, Isolation, Packaging, In-process control and Test by the quality control laboratory are carried out in this plant.
- The plant has a different building for raw materials store, utilities building and effluent treatment plant.
- Has suitable size and is constructed to facilitate easy cleaning, maintenance, and proper operations.
- The building has been built with adequate space and facilities to prevent processing mix-up and cross contamination.
- Attention has been given to keep proper distances for operational safety and provide appropriate ventilation.
- The plant is well equipped with all the necessary machineries required for smooth production such as reactors, pumps and centrifuges etc.

Reaction Capabilities

- Acetylation
- Chlorination
- Chloro Sulphonation
- Condensation
- Grignard
- High Vacuum Distillation
- Hydrochlorination
- Hydrolysis
- Friedel Craft
- Nitration
- Oxidation

List of Equipments

Name	Capacity	No. of equipments
Glass Lined Reactor	3000 ltrs	4
Glass Lined Reactor	2000 ltrs	2
Glass Lined Reactor	500 ltrs	2
Glass Flask	200 ltrs	1
SS High Vacuum Vessel	100 ltrs	1
SS Reactors	3000 ltrs	6
SS Reactors	2500 ltrs	3
SS Reactors	2000 ltrs	3
SS Reactors	1000 ltrs	2
SS Reactors	700 ltrs	1
HDPE Reactor Sintex	5000 ltrs	1
HDPE Reactor Sintex	4000 ltrs	1
HDPE Reactor Sintex	2000 ltrs	1

List of Equipments... contd.

Name	Capacity	No. of equipments
SS Centrifuge	48”	4
SS Centrifuge	36’’	4
SS Centrifuge	24’’	1
SS Tray Dryer	48 Trays	10
Multimill	60 kg/hr	5
SS Blender	1000 Ltr	1
SS Pressure Filter	50 Kg	3
SS Pressure Filter	25 Kg	1
SS Pressure Filter	15 Kg	3
SS Nutch Filter	600 Ltr	2
SS Nutch Filter	400 Ltr	1
SS Nutch Filter	200 Ltr	1
SS Shifter	30 kg/hr	3

Product List – API

Name	CAS No.	Therapeutic Use	Installed Capacity
Bisacodyl	603-50-9	Stimulant laxative	2 M.T./month
Chlorzoxazone USP	95-25-0	Muscle Relaxant	5 M.T./month
Dicyclomine HCL	67-92-5	Anti-Spasmodic	3 M.T/month
Sodium Pico Suphate	10040-45-6	Stimulant laxative	1 M.T./month

Product List – Intermediate

Name	Capacity	End Use
4-(2-aminoethyl)benzene sulfonamide	4 M.T./month	Glipizide , Glibenclamide
4-(3-Methyl-Phenyl)-Amino-3-Pyridine-Sulfonamide	3 M.T/month	Torasemide
3- (4 Chloro Phenyl) Glutaric Acid	2 M.T/ month	Baclofen

Certifications

FIRST QUALITY CERTIFICATION

FQC
FIRST QUALITY CERTIFICATION

CERTIFICATE

This certificate is granted to the organization,

SHREEPATI PHARMACEUTICALS PVT. LTD.

Survey No.184/1,Village-Silotia,Sector-1,Pithampur,Distt-Dhar ,
Madhya Pradesh

MANUFACTURING & SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS AS PER PHARMACOPOEIA STANDARDS

EA 13

according to the scope,

ISO 9001:2015

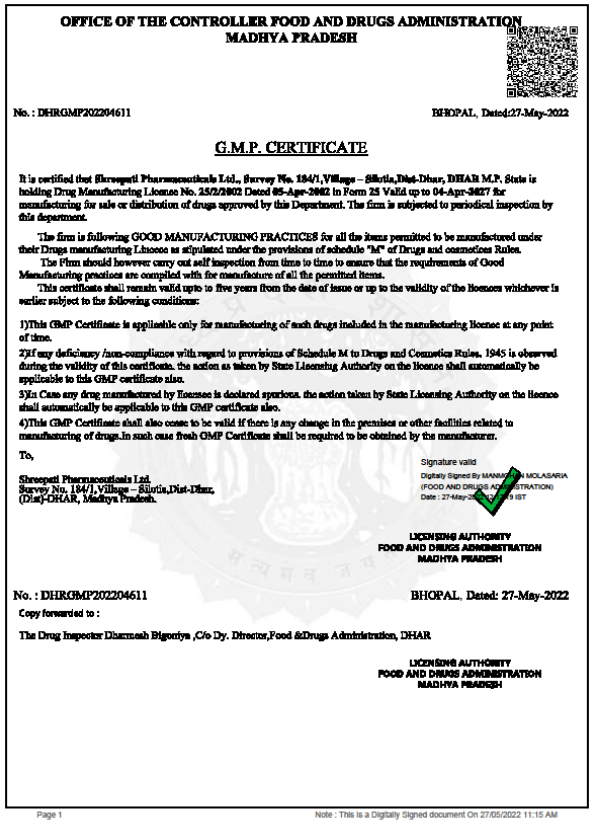
to certify that Quality Management System in accordance with standard's clauses is established and being implemented.

First Date of Issue	**: 17.03.2016**
Date of Issue	**: 16.03.2023**
Certificate Period	**: 3 Years**
Reissue Due Date	**: 16.03.2024**
Certificate No	**: 01.IN.0050.0036.D**

First Quality Certification
System Certificate Approved
India

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-19276-01-00

FQC First Quality Certification Private Limited



OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. : DHRGMP202204611 — BHOPAL, Dated:27-May-2022

G.M.P. CERTIFICATE

It is certified that Shreepati Pharmaceuticals Ltd., Survey No. 184/1,Village – Silotia,Dist-Dhar, DHAR M.P. State is holding Drug Manufacturing License No. 25/2/2002 Dated 05-Apr-2002 in Form 25 Valid up to 04-Apr-3027 for manufacturing for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this department.

The firm is following GOOD MANUFACTURING PRACTICES for all the items permitted to be manufactured under their Drugs manufacturing Licence as stipulated under the provisions of schedule "M" of Drugs and cosmetics Rules.

The Firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing practices are complied with for manufacture of all the permitted items.

This certificate shall remain valid upto to five years from the date of issue or up to the validity of the Licence whichever is earlier subject to the following conditions:

1)This GMP Certificate is applicable only for manufacturing of such drugs included in the manufacturing licence at any point of time.

2)If any deficiency /non-compliance with regard to provisions of Schedule M to Drugs and Cosmetics Rules, 1945 is observed during the validity of this certificate, the action as taken by State Licensing Authority on the licence shall automatically be applicable to this GMP certificate also.

3)In Case any drug manufactured by licensee is declared spurious, the action taken by State Licensing Authority on the licence shall automatically be applicable to this GMP certificate also.

4)This GMP Certificate shall also cease to be valid if there is any change in the premises or other facilities related to manufacturing of drugs.In such case fresh GMP Certificate shall be required to be obtained by the manufacturer.

To,

Shreepati Pharmaceuticals Ltd.
Survey No. 184/1,Village – Silotia,Dist-Dhar,
(Dist)-DHAR, Madhya Pradesh.

Signature valid
Digitally Signed By MANMOHAN MOLASARIA
(FOOD AND DRUGS ADMINISTRATION)
Date : 27-May-2022 [illegible] IST

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. : DHRGMP202204611 — BHOPAL, Dated: 27-May-2022

Copy forwarded to :

The Drug Inspector Dharmesh Bigoriya ,C/o Dy. Director,Food &Drugs Administration, DHAR

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

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Plant Overview

Quality Control Policy

- The **Quality Control Laboratory** situated in the plant has the necessary testing facilities and are well equipped.

- **Analytical Laboratory :**
  - Raw material testing
  - In-process and finished product testing
  - Stability storage and testing
  - Cleaning validation and testing

Quality Control...contd.

R&D Capabilities

- Strict Compliance IPR / Non-infringing roots.
- Infrastructure includes facility for scale-up & validation.
- Handling complex chemistries.
- Process optimization.

E.H.S System

- We are fully committed in achieving EHS excellence and conduct our activities in the most responsible manner.
- EHS performance is periodically reviewed at our facility to monitor the progress and EHS improvement plans.
- Effluent treatment plant takes care of the residue and various effluents generated during the manufacturing process and adhere to statutory requirements of the Pollution Control Board.
- The company also has policy for creating safety awareness at all levels.
- We also have a facility for solid waste management.

Our Core Strength

- Insightful and Experienced Senior scientific staff bringing an average of 15 years of experience to various products.
- Knowledgeable and capable
- Responsive
- Professional

Our Promise

We'll work in partnership with you
to deliver outstanding quality products,
efficiently and reliably through a
highly responsive and flexible service
at a very competitive cost in a
shorter than industry-standard
time period

Thank You