HEILEN BIOPHARM PRIVATE LIMITED -INIDA

1. Calamine Powder (IP/BP/USP/IH*/Cosmetic grade)

We are one of the very few manufacturers in India to provide the following documents for all our products:

1. CTD/DMF (Open part) for Regulatory markets
2. GMP & GLP certificates
3. COA
4. MOA
5. MSDS
6. ISO:9001 NABCB certificate
7. Halal declaration
8. Kosher declaration
9. Country of origin
10. TSE/BSE Certificate
11. Dioxin free statement

ABOUT US

We are enforced with strong business ethics and unbound commitment to our clients which has enabled us to achieve such heights. As we build our strategies to promote growth for the years to come, our ideas of value creation, teamwork & constant progress will continue to be the driving force of our initiatives.

Apart from our manufacturing unit where we manufacture Calamine powder (IP/BP/USP/Cosmetic grade) and Triticum Vulgare Aq. Extract, we also do contract manufacturing of Calamine lotion, Calamine prickly heat powder, Calamine cream.

MEMBERSHIP

Member of Pharmexil (Pharmaceuticals Export Promotion Council)

QUALITY AND COMPLIANCE

Quality is one of the major areas of our focus. Our sourcing and exporting expertise helps provide us full documentation support for our clients who wish to export their finished product into regulatory markets.

INFRASTRUCTURE AND FACILITIES

Situated in Vadodara our dedicated state of the art manufacturing unit for Phyto-active API helps us to meet the needs of our clients. The unit is **GMP** and **ISO : 9001 – 2015** certified assuring our clients of consistent quality products. Through our dedication, hard work and keen eye to quality we have a successful **GLP** certified dedicated and well equipped Analytical and Microbiological laboratory and R&D centre.

CORPORATE OFFICE:	**MANUFACTURING PLANT:**
#1201, Matrix, Near Divy-bhaskar press, SG Highway, Prahladnagar, Ahmedabad-380015 Tel: +91-079-2970 3351 Mobile no : +91-7359672496 E-mail: skumar@heilenbiopharm.com	FF-931, GIDC Makarpura, Erda road, Vadodara-390010 CIN: U72300GJ2015PTC083933

GMP

Food & Drugs Control Administration
BLOCK NO. 8, 1ST FLOOR, DR. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA PIN : 382010

Certificate No. : S-GMP1706157

G.M.P. CERTIFICATE

This is to certify that M/s. HEILEN BIOPHARM PVT. LTD., FF 931, G.I.D.C. MAKARPURA, ERDA ROAD,VADODARA – 390 010, is holding valid drug manufacturing license in Form No. 25 bearing No. G/25/2204 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules there under. Under the said license the firm is permitted to manufacture & sell drugs covered under the following categories.

Dosage Form (s)	Category (ies)
Bulk Drugs (APIs)	General

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE-M of Drugs & Cosmetics Act 1940 & Rules There under.
The manufacturing plant is subjected to inspection at suitable intervals by competent authority.
This certificate is valid from Dt : 12/06/2017 to 11/06/2019.

(Dr. H. G. KOSHIA)
Commissioner
Food & Drugs Control Administration
Gandhinagar, Gujarat State

Email : comfdca@gujarat.gov.in
Phone : 91-79-23253417, Fax : 91-79-232-53400

ISO : 9001 – 2015

AGSI CERTIFICATION PRIVATE LIMITED

Certificate of Registration

This is to certify that the Quality Management System of:

HEILEN BIOPHARM PVT. LTD.

FF-931, G.I.D.C., MAKARPURA, ERDA ROAD, VADODARA – 390010, GUJARAT, INDIA.

has been assessed and approved to the requirements of standard :

ISO 9001 : 2015

The Quality Management System applies to:

MANUFACTURE & SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (API)

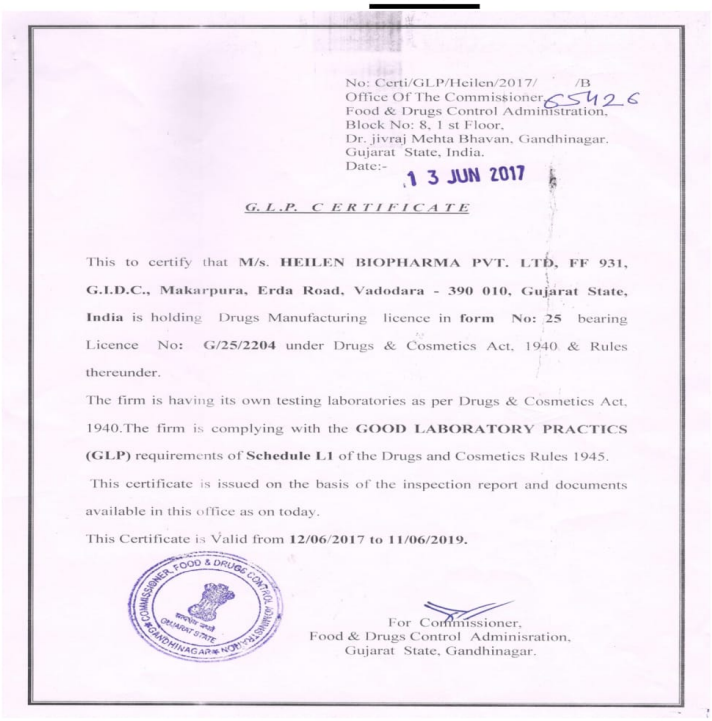
Certificate no.: 2949
Valid from: 26-06-2017
Valid upto: 25-06-2020 *
Client File no.: AGSI/Q/2699

For AGSI Certification Pvt. Ltd.
(Mehul Desai)
Director
26-06-2017

Registered office: 208, Kartik Complex, Opposite Laxmi Industrial Estate, New Link Road, Andheri (West), Mumbai - 400 053, India.
Email: agsicert@gmail.com, Web site: www.agsicertification.in

The document remains the property of AGSI-CPL. This approval is subject to the organization maintaining its system to the requirements of the standard as monitored by AGSI-CPL.
*Subject to yearly re-approval by AGSI-CPL on surveillance assessments. Due date for re-approval: 26-06-2018

GLP



No: Certi/GLP/Heilen/2017/ 6542 /B
Office Of The Commissioner,
Food & Drugs Control Administration,
Block No: 8, 1 st Floor,
Dr. jivraj Mehta Bhavan, Gandhinagar.
Gujarat State, India.
Date:- 13 JUN 2017

G.L.P. CERTIFICATE

This to certify that **M/s. HEILEN BIOPHARMA PVT. LTD, FF 931, G.I.D.C., Makarpura, Erda Road, Vadodara - 390 010, Gujarat State, India** is holding Drugs Manufacturing licence in **form No: 25** bearing Licence No: **G/25/2204** under Drugs & Cosmetics Act, 1940 & Rules thereunder.

The firm is having its own testing laboratories as per Drugs & Cosmetics Act, 1940.The firm is complying with the **GOOD LABORATORY PRACTICS (GLP)** requirements of **Schedule L1** of the Drugs and Cosmetics Rules 1945.

This certificate is issued on the basis of the inspection report and documents available in this office as on today.

This Certificate is Valid from **12/06/2017 to 11/06/2019.**

For Commissioner,
Food & Drugs Control Administration,
Gujarat State, Gandhinagar.