

Certificate of Good Manufacturing Practices

This one page certificate conforms to the format recommended by the **World Health Organization** [General Instructions and Explanatory Notes attached].

Certificate No. HFW-H [Drugs] 227/96

On the basis of the inspection carried out on 13th & 14th April 2021 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:

1. Names and Address of Site: **M/s Fermenta Biotech Limited,
Village Takoli, PO Nagwain,
Distt. Mandi (H.P.) INDIA.**
2. Manufacturer's License No: **MNB/2000/32 on Form 25
MB/2004/NZ/5 on Form 28**

3. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Active Pharmaceuticals Ingredients: 1. Cholecalciferol (IP, USP, Ph. Eur.) 2. Phenyramidol Hydrochloride 3. Silicon Powder 4. Cholecalciferol Solution/ Cholecalciferol Concentrate (Oily Form) in Soyabean Oil (Ph. Eur./USP) 5. Cholecalciferol Solution/ Cholecalciferol Concentrate (Oily Form) in corn oil (Ph. Eur./USP) 6. Cholecalciferol Solution/ Cholecalciferol Concentrate (Oily Form) in MCT Oil (Ph. Eur./USP)	General	Production, Packing & Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate is valid until **25.03.2024**. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of Certifying Authority:

State Drugs Controller,
Controlling cum Licensing Authority,
2nd floor, Himuda Commercial Complex, Phase-I,
Housing Board, Baddi, Distt. Solan [H.P.] 173 205, INDIA.

Name & Function of Responsible person:

Navneet Marwaha
State Drugs Controller
Controlling cum Licensing Authority
01795-244288, sdc4hp@gmail.com

Telephone/Fax No:

Date: **4.08.2021**



Signature:
Stamp:

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

Explanatory Notes:

- 1 This certificate, which is in the format recommended by WHO certifies the status of the site, listed in point I of the certificate.
- 2 The certificate number should be traceable within the regulatory authority issuing the certificate.
- 3 Where the Regulatory Authority issues a license for the Site, this number should be specified. Record 'Not Applicable' in cases where there is no legal framework for the issuing of a license.
- 4 Table I

List the Dosage Forms, starting materials, categories and activities. Examples are given below:

Example 1

Pharmaceutical Product[s]1	Category [ies]	Activity [ies]
Dosage Form [s]:		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packing, Quality Control
	Penicillin	Repackaging and Labeling
Injectables	Cephalosporin	Aseptic preparation, Packaging, Labeling

Example 2

Pharmaceutical Product[s]1	Category [ies]	Activity [ies]
Starting Material [s]		
Paracetamol	Analgesic	Synthesis, Purification, packing, Labeling

Use, whenever available, International Non proprietary Names [Inns] or otherwise national Non proprietary Names

- 5 The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
- 6 The requirements for good practices, the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good Manufacturing Practices and Inspection. Volume 2, 1999 World Health Organization. Geneva and subsequent updates.