

**Health & Family Welfare Department
Himachal Pradesh, Baddi, Distt. Solan**

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] 93/91

On the basis of the inspection carried out on 23rd & 24th Jan. 2019, 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 Morepen Laboratories Ltd.
Village-Masulkhana, Parwanoo,
Distt. Solan [H.P.] India**

2. Manufacturer's License No: **MNB/93-05 & MB/93-06**

3. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Montelukast Sodium USP/EP/BP/IP	Antiasthmatics	Synthesis, Purifications, Packing, Labeling
Desloratadine USP/EP	Antihistaminic	Synthesis, Purifications, Packing, Labeling
Loratadine USP/EP	Antihistaminic	Synthesis, Purifications, Packing, Labeling

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

This certificate remains valid until **30/04/2022**. 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
Baddi, Distt. Solan, H.P. 173205
01795-244288, sdc4hp@gmail.com**

Name & Function of Responsible person: **Navneet Marwaha
State Drugs Controller
Controlling cum Licensing Authority**

Telephone/Fax No: 01795-244288
Date: 01/05/2019



Signature: **(NAVNEET MARWAHA)**
Stamp: **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 A
4. Applicable" in cases where there is no legal framework for the issuing of a license.
5. 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

6. 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.
7. 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.

