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] 208/09

On the basis of the inspection carried out on **25th & 26th April, 2022**, 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 Hetero Labs Ltd. Unit-II, Vill. Kalyanpur, Chakkan Road, Baddi, Distt. Solan [H.P.] India**

2. Manufacturer's License No: **MNB/ 09/780 & MB/09/781 Valid upto 21.03.2025**

3. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Tablets	**General**	**Production, Packing & Quality Control**
Capsules	**General**	**Production, Packing & Quality Control**
Dry Syrup	**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 remains valid until **21/03/2025.** 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**,
Licensing-cum-Controlling Authority
Nagar Panchyat Bhawan, Sai Road
Baddi, Distt. Solan [H.P.] 173 205

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

Telephone/Fax No: 01795-244288

Date: 19 /05/2022

Licensing Authority cum Drug Controller * Himachal Pradesh *

Signature: 19.5.22
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 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.

ANNEXURE-I

list of products applied for Revalidation of COPP in favour of M/s Hetero Labs Limited. (Unit-II), Village- Kalyanpur, Chakkan Road, Tehsil –Baddi, Dist. Solan Himachal Pradesh-173205

S.No.	Product Name	Composition	Shelf Life	Section	Pack style
47.	Deflazacort Tablets 6 mg	Each Uncoated tablet contains: Deflazacort ..... 6 mg Excipients .....q.s.	36 Months	Tablets	Strip (1X10's)
48.	Tamsulosin Hydrochloride Prolonged Release Capsules IP 0.4 mg	Each Hard Gelatin Capsule contains: Tamsulosin Hydrochloride IP..... 0.4 mg (As prolonged Release Pellets) Excipients .....q.s. Approved colours are used in capsule shell	24 Months	Capsules	Blister (1X30's)
49.	Dapoxetine Tablets 30 mg	Each Film coated tablet contains : Dapoxetine Hydrochloride Eq. to Dapoxetine ..... 30 mg Excipients .....q.s.	24 Months	Tablets	Strip (1X 6's)
50.	Sofosbuvir 400 mg & Velpatasvir 100 mg Tablets	Each film coated tablet contains: Sofosbuvir.....400mg Velpatasvir.....100mg Excipients.....q.s	24 Months	Tablets	HDPE Container (1X28's)
51.	Linezolid Tablets IP 600 mg	Each film coated tablet contains: Linezolid IP .....600 mg Excipients.....q.	24 Months	Tablets	Strip (1X4's)
52.	Levofloxacin (250 mg) & Ornidazole (500 mg) Tablets	Each film coated tablet contains: Levofloxacin hemihydrate IP Eq. to Levofloxacin ..... 250 mg Ornidazole IP ..... 500 mg Excipients .....q.s.	24 Months	Tablets	Blister (1X10's)

Total 52 products for Revalidation of COPP in General Category.

26/4/22