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] 184/09

On the basis of the inspection carried out on 04th & 05th August 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 Onyx Biotec Pvt. Ltd.

Village Bir Pallasi, Near Saini Majra,

Ropar Road, Tehsil Nalagarh, Distt. Solan [H.P.] INDIA

2. Manufacturer's License No:

MB/09/813

Valid up to 29.03.2025

3. Table-I:

Dosage Form[s]	Category[ies]			Activity[ies]			
Sterile Water for Injections	Small (FFS)	Volume	Parenterals	Production, Control	Packing	&	Quality
,			,	a .			

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 23-09-2024. 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 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

01795-244288

Date: 24.09/20

Signature:

Stamp:

(NAVNEET MARWAHA)
State Drugs Controller

Controlling cum Licensing Authority
Baddi Distt. Solan (H. P.)-173205

01795-244283,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

Category [ies]	Activity [ies]		
	Activity [les]		
Cytotoxic	Pagiragina		
	Packaging		
	Production, Packing, Quality Control		
	Repackaging and Labeling Aseptic preparation, Packaging, Labeling		
	Category [ies] Cytotoxic Hormone Penicillin Cephalosporin		

Example 2

Pharmaceutical Product[s]1	· Category [ies]	Activity [ies]
Starting Material [s]		
Paracetamol	Analgesic	Synthesis, Purification, packing,
Use, whenever available	Intomatical N	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.