

**Health & Family Welfare Department
Drug Control Administration HP
Assistant Drug Controller Cum Drugs Licensing Authority
O/o CMO's Office Complex, Dharmshala
Kangra, Himachal Pradesh**

Certificate of Good Manufacturing Practices

This one page certificate confirm to the format recommended by the **World Health Organization (WHO)** [General Instruction & Explanatory Notes attached]

Certificate No. : HFW-NZ (Drugs) 2020- 224

On the basis of the inspection carried out on **30th & 31st January 2020**, we certify that the site indicated on this certificate complies with **Good Manufacturing Practices as per WHO TRS guidelines** for dosage form, categories and activities listed In **Table I:**

1. Name and Address of Site: **M/s Biozenta Lifescience Pvt. Ltd.**
Khasra No. 59, 60 & 61, Bela Bathri, Teh. Haroli
Distt. Una, Himachal Pradesh 174301 India
2. Manufacturing License No.: **NNZ/2019/144 Form 25**
BNZ/2019/145 Form 28
3. Table-I:

| Dosage Form[s] | Category[ies] | Activity[ies] |
|---|----------------------|---|
| Dry Injection | Cephalosporin | Production, Packaging & Quality Control |
| Tablets, Capsules, Liquid Injections & Lyophilized Injections | Cytotoxic | Production, Packaging & 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 **09.02.2023**. 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:

Assistant Drugs Controller,
Assistant Drug Controller-Cum
Drugs Licensing Authority
O/o CMO's Office Complex, Dharmshala
Kangra, Himachal Pradesh 176215, India

Name & Function of
Responsible Person:



Ashish Raina
Assistant Drug Controller-Cum
Drugs Licensing Authority

Telephone/email:

01892-224874, ashishraina25@gmail.com

Date: 10/02/2020

Signature:
Date

Ashish Raina
10/2/2020
Ashish Raina
Ass. Drug Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt Kangra et Dharmshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel No. 01892-224874

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.