**GOVERNMENT OF KERALA**

**DRUGS CONTROL DEPARTMENT**

ML1. 4576/2021/DC
Dated: 30/10/2021

Office of the Drugs Controller
Thiruvananthapuram-695035

## CERTIFICATE OF GOOD MANUFACTURING PRACTICES (TRS 908)

This Certificate conforms to the format recommended by the **World Health Organisation**
(General instructions and explanatory notes are attached)

On the basis of the inspection carried out, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage form categories and activities listed in Table 1.

1. Name and Address of Site: **M/S. NITTA GEALTIN INDIA LIMITED**
**MAIN PLANT X/762L & LABORATORY X/762C**
**KINFRA EXPORT PROMOTION INDUSTRIAL PARK LTD**
**INFO PARK P.O, KAKKANAD, COCHIN - 682042**

2. Manufacturer's License Number: **08/25/99 dated 14/10/1999**

3. TABLE 1

| Pharmaceuticals Products | Categories | Activities |
|---|---|---|
| **Dosage Form(s)** | | |
| BULK DRUGS | GELATIN IP/BP/USP/EP<br>GELATIN(Non Gelling Grade) USP | Production, Packing and Quality Control |

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

This certificate remains valid up to **29/10/2024**. It becomes invalid if the activities and for categories certified herewith are changed and if the site is no longer considered to be in compliance with **GMP**.

Address of the Certifying Authority : DRUGS CONTROLLER (I/C)
OFFICE OF THE DRUGS CONTROLLER
THIRUVANANTHAPURAM
KERALA – 695 035

Name and function of the responsible person Sri. P.M.JAYAN
Drugs Controller (i/c) & Licensing Authority
Kerala State

Phone / Fax No. : +91 471 2473256

E Mail ID : dckerala@gmail.com

Signature

Stamp

DRUGS CONTROLLER AND LICENSING AUTHORITY KERALA

Date: 30/10/2021

## EXPLANATORY NOTES

1. This certificate, which is in the format recommended by **WHO** certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable with the regulating authorities issuing the certificate.
3. Where the regulatory authority issues a license for the site this number should be specified. Record not applicable in case where there is no legal frame work for the issuing authority.
4. Table 1

   Pharmaceutical products are any substances intended for human use or veterinary product administered to food particularly animals, presented in finished dosage form or a starting material for use in such a dosage form.

   Starting materials – Any substance of a defined use in the production of a pharmaceutical product, but excluding packing material ie, subject to control by pharmaceutical legislation in both exporting state and the importing state.

   Use whenever available, International Nonproprietary Name (INN) or otherwise national nonproprietary names.
5. The certificate remains valid until the specified date. The certificate become 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 in the manufacturing and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceutical Compendium of guidelines and related materials Good manufacturing practices and inspection, volume 2 1999 World Health Organization, Geneva and subsequent updates.