Food & Drug Administration, Punjab, Near Civil Hospital, Kharar, District Sahibzada Ajit Singh Nagar (

To,

M/s Kwality Pharmaceuticals Ltd., Village Nag Kalan, Majitha Road, Amritsar (Punjab)

No.Drugs(01)/Pb.2021/2081
Dated: 2014/2021

Subject: Application for grant of GMP certificate and certificate of Pharmaceuticals products (COPP)

Reference your application date 15.03.2021 and Letter No. NZ/BD-SZO/PUN/COPP/KP/001/4490-4492 dated 15.03.2021 of deputy controller India, CDSCO (Baddi) Container Corporation of India building, Village Sheetalpur, Tehsil Baddi, District Solan regarding subject cited above.

As per your application and as per recommendation of deputy drugs controller India, CDSCO (Baddi), village Sheetalpur, Tehsil Baddi, District Solan (HP) under reference, Please find enclosed herewith, the GMP certificate and certificates of Pharmaceuticals products (COPP) for 402 products duly signed by the undersigned.

Encl: GMP certificates & 402 COPPS

Assistant Commissioner (Drugs)-cum-Licensing Authority, FDA Punjab, Near Civil Hospital Kharar-140301, District Sahibzada Ajit Singh Nagar.

No.Drugs(01)/Pb.2021 Copy of above is forwarded to: Dated:

- (i) The Deputy Drug Controller India, CDSCO (Baddi), Village Sheetalpur, Tehsil Baddi, District Solan (HP) (Copies of COPP certificate are attached).
- (ii) The Drug Inspector, Amritsar for Information

Assistant Commissioner (Drugs)-cum-Licensing Authority, FDA Punjab, Near Civil Hospital Kharar-140301, District Sahibzada Ajit Singh Nagar.

Food & Drug Administration, Punjab, Near Civil Hospital, Kharar, District Sahibzada Ajit Singh Nagar

Certificate of Good Manufacturing Practices

(This one page certificate confirms to the format recommended by the World Health Organisation as per WHO Technical Report Series, No. 908, 2003).

Certificate No.: 6085/2021

Dated: 20/4/2021

On the basis of the Joint Inspection made by Drugs Inspectors of CDSCO (Sub Zone Baddi) and Drugs Inspectors of State on 18th & 19th March 2021, it is certified that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories & activities listed in Table 1.

1. Name and address of site:

M/s Kwality Pharmaceuticals Limited, Situated at 6th mile stone, Village Nag Kalan, Majitha Road, Amritsar-143601 Punjab (India).

2. Manufacturer's Ligense number

4800-OSP (Form 25) & 1804-B (Form 28)

Issued on 15-02-2016 & valid up to 27-12-2025.

3. Table 1:

| Dosage Form (s) क्रिक्ट सत्यमेय जयते | Category (ies) | Activity (ies) |
|--|------------------------|----------------|
| Dosage Form (s) कि सत्यमेय जवते Tablets | Beta Lactam & Non Beta | Formulations |
| TIGI III II SE | Lactam | |
| Hard Gelatin Capsules | Beta Lactam & Non Beta | Formulations |
| | Lactam | |
| Oral Liquids Preparations | | Formulations |
| Small Volume Parenteral | Non Beta Lactam | Formulations |
| Sterile Powders for injection | Beta Lactam & Non Beta | Formulations |
| | Lactam | |
| External Preparation (Cream, | - | Formulations |
| Ointment, Liquid External and | | |
| Lotions) | | |
| Dry powder for oral suspension | Beta Lactam & Non Beta | Formulations |
| | Lactam | |
| Powder for oral use | Non Beta Lactam | Formulations |
| Sterile Ophthalmic Solution | Non Beta Lactam | Formulations |
| Suppositories | | Formulations |

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 till 11-03-2024, 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.

Administration

Licensia: Anthority, FDA Punjab, Near Civil Hospital Kharar-140301,

Address of certifying authority:

Assistant Commissioner (Prugs) zada Ajit Singh Nagar.

Food & Drugs Administration, Punjab, Near Civil Hospital, Kharar, District

Sahibzada, Ajit Singh Nagar (Punjab), India Email:<u>punjabdrugscontrolorg@gmail.com</u>

Name and function of responsible person:

Sh. Dinesh Kumar

Date:

Assistant Commissioner (Drugs) Email:punjabdrugscontrolorg@gmail.com