Food & Drugs Administration (Drugs Wing), Punjab,

Government Dispensary Complex, Mohali Stadium Road, Phase-9, Mohali,
District Sahibzada Ajit Singh Nagar-160062

To

M/s Kwality Pharmaceuticals Ltd. (Unit-1),
6th Mile Stone, Village Nag Kalan, Majitha Road, Amritsar,
District Amritsar-143601 (Punjab), India.

No. Drugs (2) Pb. 2025/8248
Dated : 13-11-25

Subject: **Regarding extension of validity of GMP Certificate (as per WHO norms).**

Reference your application dated 31-10-2025 regarding subject mentioned above,

Your application has been considered by the undersigned and keeping in view the office memorandum dated 08-05-2018 of Drugs Controller General India, FDA Bhawan, Kotla Road, New Delhi, the certificate of Good Manufacturing Practices (as per WHO norms) was issued to your company with the validity upto 25-12-2025 as the validity of drugs manufacturing licences No. 1800-OSP (Form 25) & 1804-B (Form 28) was 27-12-2025. Now after retention of your said drugs manufacturing licences upto 27-12-2030, the validity of Certificate of Good Manufacturing Practices (as per WHO norms) issued vide following details are hereby extended upto 28-08-2027 (upto three years from the date of issue).

Sr. No.	Name of Certificate	Certificate No.	Date of Issue	Now Extended upto
1.	GMP Certificate (as per WHO norms)	5991	29.08.2024	**28-08-2027**

This is for your information and necessary action.

13/11/2025
Assistant Commissioner (Drugs)
Food & Drugs Administration, Punjab

No. Drugs (2) Pb. 2025/ Dated

Copy forwarded to: -

(1) The Deputy Drugs Controller India, CDSCO (Baddi) Container Corporation of India Building, Village Sheetalpur, Tehsil Baddi, District Solan.

(2) The Drugs Control Officer, Amritsar-5 for information.

Assistant Commissioner (Drugs)
Food & Drugs Administration, Punjab

Food and Drugs Administration Punjab (Drugs Wing)

Government Dispensary Complex, Mohali Stadium Road, Phase-9, Mohali,
Distt. Sahibzada Ajit Singh Nagar

To

M/s Kwality Pharmaceuticals Ltd., (Unit-I),
6th Mile Stone, Vill. Nag Kalan, Majitha Road,
Amritsar, Distt. Amritsar, Punjab (India)

No.Drugs(1)Pb.2024/ 5988 Dated:- 29/08/2024

Subject :- Application for grant of GMP Certification as per WHO norms.

Reference your application dt. 12-08-2024, on the subject cited above.

Keeping in view the joint inspection report dtd 25 & 26-06-2024, received from Deputy Drugs Controller, India, CDSCO Baddi, vide no. . BDZO/PUN/COPP/KP/042/2159 dt 02-06-2024 and compliance verification report dtd 30-07-2024 of Drugs Control Officer Amritsar, the WHO GMP Certificate is hereby issued to your firm and sent here-with in original.

29/8/2024
Assistant Commissioner (Drugs)
Cum- Licensing Authority
O/o FDA, Punjab.

P.S

No.Drugs(1)Pb.2024/ Dated:-

Copy of the above is forwarded to

1) The Deputy Drugs Controller India, CDSCO (Baddi) Container Corporation of India Building, Village Sheetalpur, Tehsil Baddi, District Solan (HP) for information.
2) The Drugs Control Officer, Amritsar for Information.

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Assistant Commissioner (Drugs)
Cum- Licensing Authority
O/o FDA, Punjab.

Food and Drugs Administration Punjab (Drugs Wing)

Government Dispensary Complex, Mohali Stadium Road, Phase-9, Mohali,
Distt. Sahibzada Ajit Singh Nagar

Certificate of Good Manufacturing Practices

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

Certificate No. : 5991

Dated: 29-08-2024

On the basis of the joint inspection made by Drugs Inspectors of CDSCO (Sub Zone Baddi) and Drugs Inspectors of State on 25 & 26 June, 2024, it is certified that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name and address of site: M/s Kwality Pharmaceuticals Ltd., (Unit-I), 6th Mile Stone, Vill. Nag Kalan, Majitha Road, Amritsar, Distt. Amritsar, Punjab (India)

2. Manufacturer's license number: 1800-OSP (Form 25) & 1804-B (Form 28), issued on 15-02-2016 & retained upto 27-12-2025.

3. Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Tablets Section; along with coating section (except Hypodermic Tablets)	General	Production, Packing & Quality Control
Hard Gelatin Capsule Section;	General	Production, Packing & Quality Control
Oral Liquid Section	General	Production, Packing & Quality Control
Small Volume Parenteral Section;	General	Production, Packing & Quality Control
Sterile Powders For Injection Section:	General	Production, Packing & Quality Control
External Preparation Section	General	Production, Packing & Quality Control
Powder for Oral Use Section;	General	Production, Packing & Quality Control
Dry Powder for Oral suspension;	General	Production, Packing & Quality Control
Sterile Ophthalmic Solution Section	General	Production, Packing & Quality Control
Suppositories Section	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 till 25-12-2025. 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: Food and Drugs Administration Punjab (Drugs Wing)
Government Dispensary Complex, Mohali Stadium Road,
Phase-9, Mohali, Distt. Sahibzada Ajit Singh Nagar,
Punjab, (India)

Name and function of responsible person: Amit Duggal,
Asstt. Commissioner (Drugs)
Email: punjabdrugscontrolorg@gmail.com

Date: 29-08-2024

Signature: 29/8/2024

Stamp: Assistant Commissioner (Drugs)
Cum- Licensing Authority
O/o FDA, Punjab.

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 within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified. Record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
   List the dosage forms, starting materials, categories and activities
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 in 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

Address of certifying authority: Food and Drugs Administration Punjab (Drugs Wing)
Government Dispensary Complex, Mohali Stadium Road,
Phase-9, Mohali, Distt. Sahibzada Ajit Singh Nagar
Punjab, (India)

Name and function of responsible person: Amit Duggal,
Asstt Commissioner (Drugs)
Email: punjabdrugscontrolorg@gmail.com

Signature: 29/8/2024

Stamp: Assistant Commissioner (Drugs)
Cum- Licensing Authority
O/o FDA, Punjab.

P.S