SOP No. 004-QA-GMP/CERT

Title: Issuance of GMP Certificate

Effective Date: 15.12.2018

Version: 00.05

Next Review date: 14.12.2021 (if not required before)

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Document History:

Version	Effective date	Significant Changes	Previous Version
00.01	01.06.2010	Initial version	
00.02	01.04.2012	Consequential amendments due to establishment of Drug Regulatory Agency of Pakistan.	00.01
00.03	01.06.2013	Establishment of Drug Regulatory Authority of Pakistan Act No. XXI of 2012	00.02
00.04	08.11.2017	The words, "Director (Quality Assurance and Laboratory Testing)" replaced with Additional Director (E&M) / Officer In-charge and Deputy Drugs Controller (QA) replaced with "Area Federal Inspector of Drugs" as per decision of 8th Meeting of DRAP held on 7th October, 2013. Inclusion of panel details.	00.03
00.04	08.11.2017	Right of appeal provided to the applicant at serial 4.9.	00.03
00.04	08.11.2017	Timelines for re-inspection at serial 4.10.	00.03
00.05	12.11.2018	The word "180 days" replaced with "Three Years" at serial 4.3, 4.4 and 4.5.2.	
00.05	12.11.2018	The word "one Year" replaced with "Three Years" at serial 5.1 and Annex-I	

1. Purpose:

1.1. Purpose of this SOP is to describe the procedure for issuing the cGMP Certificate to licensed Pharmaceutical Manufacturing Units.

1.2. This SOP shall be followed for issuance of cGMP certificate to the applicants intending to present it to relevant authorities of Pakistan or abroad, for the purpose of medicine supplies/exports.

1.3. This SOP is for the whole of pharmaceutical units and not separate for the section wise.

2. Scope:

2.1. This SOP applies to all the Pharmaceutical Units licensed under the Drugs Act, 1976 and rules framed there under.

2.2. This SOP allows certification to Pharmaceutical Unit applying for the grant of cGMP certificate for export purpose.

3. Responsibilities:

3.1. *Additional Director (E&M) / Officer In-charge* shall be the authority to permit issuance of cGMP Certificate for export purpose.

3.2. *Federal Inspector of Drugs* shall be responsible for processing of the cGMP Certificate (export purpose) after observing all the codal formalities as per procedure given at serial No. 4 of this SOP.

3.3. A panel comprising of following members shall be responsible for conducting the inspection of the firm with reference to the cGMP compliance as per cGMP audit pro-forma under Schedule B-II of the Drugs Act, 1976, and shall submit the report within 7 working days from the date of receipt of application:-

i. Additional Director (E & M) / Officer In-charge.
ii. Area Federal Inspector of Drugs
iii. Area Assistant Director (I & E)

3.4. Assurance of maintaining cGMP compliance and quality of the finished products, under the prescribed rules throughout the certified period, shall be responsibility of the firm.

4. Procedure:

4.1. The application for grant of cGMP Certificate (complete in all aspect) shall be submitted to office of the *Additional Director (E & M) / Officer In-charge*, who shall forward/mark to *Federal Inspector of Drugs* for processing on the same day. The application for the issuance of cGMP Certificate should be disposed off within 07 working days.

4.2. *Federal Inspector of Drugs* shall scrutinize the cGMP inspection reports of the concerned Pharmaceutical Unit as per record available in the office.

4.3. The cGMP compliance of the Pharmaceutical Unit shall be evaluated on the basis of panel inspection report for the grant of cGMP Certificate. Such inspection report should not be older than three years of the receipt of the application.

4.4. If cGMP panel inspection of the firm is not conducted within last three years of receipt of application, the panel shall conduct the inspection of the firm to verify cGMP compliance and submit the report on approved cGMP audit pro-forma under Schedule B-II of the Drugs Act, 1976, within 05 working days.

4.5. The applicant shall provide the following documents for obtaining the cGMP certificate for export purpose:

4.5.1 Request letter addressed to *Additional Director (E & M) / Officer In-charge,* along with the following documents.

4.5.2 Latest panel GMP inspection report as per cGMP audit performa under Schedule B-II conducted within last three years.

4.5.3 Copy of valid Drug Manufacturing License (DML)

4.5.4 Fee amounting to Rs.5000/- as per SRO.1117/(I)/2012 under the head / item of Miscellaneous Applications (S. No. VIII)

4.5.5 Evidence of export for export purpose cGMP Certificate.

4.5.5 (a) A certificate from *Area Assistant Director (I & E)* to the effect of exports during last one year, or

4.5.5 (b) A certificate/document in original from the importing country to the effect of the process/negotiations/registration for exports.

4.5.6 List of registered products (registration number should be mentioned).

4.5.7 Copy of NOC of Central Research Fund (CRF).

4.5.8 If cGMP Certificate expired, cancelled/withdrawn or in case of first application for cGMP certificate, two previous inspection reports within a year as per Drug Act, 1976 and rules framed there under shall be required.

4.5.9 An undertaking on stamp paper (Rs.20/-) which should be attested by Notary Public / Oath Commissioner, that there are no case / litigation pending in any Court / Board or Authority which relates to quality control or quality assurance of therapeutic goods and also there is no sample declared spurious / substandard / adulterated at any laboratory, e.g., CDL, NIH, DTL, NCL etc. during a period of last 180 days.

4.5.10 The export purpose certificate shall be issued only for one country. Where the applicant intending to export to more country (ies) the applicant should deposit Rs.5000/- for each certificate.

4.6. After evaluating the cGMP report of the firm, the *Federal Inspector of Drugs* shall put up the case to *Additional Director (E & M) / Officer In-charge* with recommendation either for approval or rejection, as the case may be. *Additional Director (E & M) / Officer In-charge shall decide the matter within 02 working days.*

4.7. In case the pharmaceutical unit complies with the cGMP requirements, the *Additional Director (E & M) / Officer In-charge* shall issue the cGMP certificate on approved format (Annex-I) for export purpose.

4.8. In case the application is not approved by the *Additional Director (E&M) / Officer In-charge,* the *Federal Inspector of Drugs* shall inform the applicant within 05 working days accordingly along with reasons to this effect.

4.9. Applicant may appeal to the *Drug Licensing Board / Licensing Authority* in case if they do not agree with the inspection report and require intervention of the *Drug Licensing Board / Licensing Authority.* For valid presentation by the Applicant, the *Drug Licensing Board / Licensing Authority* may require re-inspection and constitute inspection panel including its members.

4.10. For re-inspection panels, same timelines by the Division of Quality Assurance & Laboratory Testing shall be followed as specified in 4.6 & 4.8 above. New timeline starts from date of new inspection.

5. Validity of Certificate:

5.1. cGMP Certificate issued as per this SOP shall remain valid for a period of three years for export purpose from the date of inspection unless withdrawn / cancelled earlier.

6. Withdrawal / Cancellation of Certificate

6.1. cGMP Certificate shall stand invalid if either the activities or categories certified therein are changed or not conforming to the Drugs Act, 1976 and the rules framed there under or where any restraining orders have been issued by the Court or any such directions by the respective Boards of the DRAP.

7. References:

7.1. The Drugs Act, 1976 (XXXI of 1976).

7.2. WHO Technical Report Series, No. 908, 2003

Annex-I

GOVERNMENT OF PAKISTAN
Drug Regulatory Authority of Pakistan
Islamabad
*****

CERTIFICATE OF CURRENT GOOD MANUFACTURING PRACTICES (Abroad)

Certificate No._____

Exporting Country:	***Islamic Republic of Pakistan***
Importing Country:	_____

It is to certify that _____holding DML No. _____ is authorized to produce medicine of following categories and is found complying with cGMP in terms of process control maintenance of equipment and area documentation etc. as per provisions of Drugs Act, 1976 and the rules framed there under:

Formulation	Pharmacological Categories	Activity(ies)
For example Tablets	Non antibiotics Antibiotics	Mixing, Drying, Granulation, compression

Certification is based on evaluation conducted on _____.

- This certificate is valid for three years from the date of inspection.
- Responsibility to maintain quality of Good Manufacturing Standard throughout the period of validity of this certificate shall lie on the manufacturer itself as per Drugs Act, 1976 and the rules framed there under:
- This certificate also permits the firm to apply for registration of their products, manufactured as per valid Drug Manufacturing License issued by Drug Regulatory Authority of Pakistan, in the importing country.
- The validity shall automatically cease in case of reporting of non-compliance of current Good Manufacturing Practices (cGMP) under the Drugs Act, 1976 and rules framed there under.
- This certificate is in line with the format as recommended by WHO (TRS No. 908, 2003).
- This certificate is issued on the request of M/s_____on the demand of importing country _____

Stamp : _____

Signature : _____

Date : _____

Disclaimer: *This certificate is issued for export purpose only. Not to be used for any promotional activities within Pakistan. This certificate remains the property of the Drug Regulatory Authority of Pakistan and must be returned on demand.*

223. Reference para 219-222/N. following amendments have been made in the SOP for issuance of GMP certificate, as per decision of 61st meeting of Authority.

Version	Effective date	Significant Changes
00.05	12.11.2018	The word "180 days" replaced with "Three Years" at serial 4.3, 4.4 and 4.5.2.
00.05	12.11.2018	The word "one Year" replaced with "Three Years" at serial 5.1 and Annex-I

224. Accordingly, fair typed SOP is placed on the file for signature, please.

18/12/2018.

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Deputy Director (QA)

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