F. No.7-5/2018/Misc/048
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi - 110002
Dated:- 3/3/2020

To
All Drugs Controllers of States/UTs

Circular

Subject: Disposal of the applications of WHO-GMP (Certificate of Pharmaceutical Products) – Reg.

In order to streamline the process of issuance of WHO-GMP (CoPP) through a uniform procedure of review and joint inspection, a detailed deliberation was made in the 47th DCC held on 30-31 July, 2014 and a guidance of joint inspection was minuted under Agenda 12 . In accordance with guidance laid down in the 47th DCC and to reduce the number of inspections for the same manufacturing sites for various reasons by officers of CDSCO zonal, sub-zonal and State Licensing Authorities (SLAs), it has been decided to adopt following procedures for the inspectorate in India with primary focus towards quality compliance to product and manufacturing process:

For issuance of CoPP for the purpose of grant/revalidation/ or issuance of additional product :

A. - The applicant shall submit the application along with supporting document & details given in checklist (**Annexure A)** & Product Summary Sheet (**Annexure B)**, as per the guidance in the 47th DCC minutes

Checklist (Annexure-A):

a. Application from Manufacture
b. Site master file (as specified under WHO TRS 961, Annexure 14)
c. Copy of Manufacturing license.
d. List of Approved products.
e. List of products applied for issuance of CoPPs.
f. List of SOPs and STPs
g. Stability data (3 batches) Accelerated/Real Time
h. List of equipmen and Instruments
i. List of Technical Staff, their Qualification, Experience and approval status& Organogram.

j. Manufacturing Layout Plan.

k. Process Validation for 3 batches of each Product.

l. Schematic diagram of water system specifying circulation loop and MOC (Material of Construction), if not provided with Site Master File

m. Schematic diagram of HVAC system specifying terminal filter configuration (Specify Class A,B,C,D etc.), if not provided with Site Master File

Product Summary Sheet (Annexure B):-

Sl.No	Name of the product	Number of batches produced in last two years (with scale R&D/Pilot/ Commercial)	Stability studies (maximum period completed) in months		Status of Process Validation (Completed/ Not completed)	Status of Analytical Method Validation (Complete d/Not completed)	If the product is approved by DCGI (Y/N/Not required)
			Accelerated (temp/Humidiy)	Real time (temp/Humidity)			

B. Disposal of application:- From the date receipt of complete application submitted to CDSCO Zonal or Sub-zonal offices and State Licensing Authorities (SLAs)

i. Recommendation for issuance/further compliance /rejection of CoPP by the CDSCO Zonal or Sub-zonal office shall be forwarded to the concerned SLAs as per the following timeline:

   a. When no joint inspection is required – 21 working days

   b. When joint inspection is required – 28 working days

ii. Based on the recommendations of joint inspection team, CDSCO & SLA, COPP shall be issued within 5 days.

C. First time Applicant for WHO-GMP (CoPP):

Joint inspection shall be planned by officers of Zonal or Sub-zonal and State Licensing Authorities (SLAs) after review of documents submitted under Annexure A and Annexure B. CoPP shall be issued when the firm had made necessary compliance to the deficiencies observed during such inspection, (if any) as per procedures laid down in 47th DCC minutes .

iii. Application for additional product to the WHO-GMP (CoPP):

For those firms which have been previously jointly inspected within two years by officers of CDSCO zonal or sub-zonal and State Licensing Authorities (SLAs) and found to comply with requirements of applicable WHO TRS guidelines, WHO-CoPP shall be issued on providing the complete data of products as mentioned in Annexure B.

Inspection shall be carried out as per the guidelines laid down in 47th DCC minutes, relevant inspection SOPs and self appraisal checklist for compliance with respect to all current WHO TRS guidelines of GMP and report shall be prepared as per guidance for GMP inspection report in the format of Appendix 1 with categorisation of deficiencies as per Appendix 11 of Annex 4 of WHO TRS 996.

This circular/document is to be treated as dynamic for updation as per suggestions and new developments.

Yours faithfully,

V.G.S

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy for information and necessary action to :-

1. All Zonal, Sub-Zonal offices of CDSCO to co-ordinate with respective states/UTs for compliance
2. Stakeholders

CC:

Joint Secretary (R), MoHFW, Govt. of India, Nirman Bhawan, New Delhi