

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
SUB ZONE HYDERABAD AP

**IMPLEMENTATION OF
WHO CERTIFICATION SCHEME
(CERTIFICATION OF
PHARMACEUTICAL PRODUCT)**

BY

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**IMPLEMENTATION OF WHO CERTIFICATION SCHEME
BY CDSCO**

- DCG(I) Letter No. X-11053/1/2009-D Dt. 01.09.2009.
- Modalities for grant of WHO GMP Certificate of Pharmaceutical Product by CDSCO, DGHS, Ministry of H & FW, Govt. of India wef 01-10-2009 – notified in the www.cdsc.nic.in website.
- Decided to issue WHO GMP (COPP) by DCGI wef 01-10-2009.
- Application for grant of WHO GMP (COPP) shall be made to respective Zonal / Sub Zonal Offices of CDSCO in the prescribed format.

GENERAL REQUIREMENTS FOR SUBMISSION OF APPLICATION FOR ISSUE OF CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) AS PER WHO CERTIFICATION SCHEME TO CDSCO

- Applications shall be addressed to ADCI, CDSCO Sub Zone, Cargo Satellite Building, 2nd Floor, RGI Air Port, Shamshabad, Hyderabad with covering letter, Product Summary Sheet, SMF, etc. as given in the web site.
- Copy of covering letter/application and product summary sheet only shall be sent to DCGI Office, WHO Cell, FDA Bhawan, New Delhi.
- Application should clearly indicate for fresh certification (Grant) or reissue of products applied, accordingly it will be scrutinized for the products applied.
- Applications will be reviewed by CDSCO officers and completed applications in all respects would be accepted for inspection on first come first serve basis.

GENERAL REQUIREMENTS FOR SUBMISSION OF APPLICATION FOR ISSUE OF CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) AS PER WHO CERTIFICATION SCHEME TO CDSCO

- Products related information should be given in Product Summary Sheet as given in the Format
(S.No. 2 of the Gen. Requirements) --- **Product Summary Sheet: S.No. , Name of the Product, Number of batches manufactured in last 2 years with scale (R&D/Pilot/Commercial); Process Validation; Analytical Method Validation; Cleaning Validation; Annual Product Review; Permitted by DCGI**
(S. No. 7 of the Gen. Requirements) --- List of Primary & Secondary Impurity and Reference Standards / Cultures available with the firm (relevant to the products applied for COPP)

GENERAL REQUIREMENTS FOR SUBMISSION OF APPLICATION FOR ISSUE OF CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) AS PER WHO CERTIFICATION SCHEME TO CDSCO

- Site Master File related documents as per WHO GMP requirement (TRS 823)
 - Should contain about 25 A4 size pages with relevant annexures given in TRS 823 page Nos. 89 to 91 (Appendix 2 C)(S.No. 2 of General requirements)
 - List of Major/master documents like VMP, Quality Manuals, Specifications, List of Master Formula Records maintained by firm and list of SOP's. (S.No. 3)
 - Manufacturing Lay out (Men & Material Flow, Pressure Flow Drawings (S. No. 4 of General requirements)
 - HVAC Schematics and details of areas (wherein clearly specify the filtration level & Classification of core areas and rooms as required in Sec. 3.3 of SMF) & Water System Diagrams along with components (S. No. 5 of General requirements)
 - List of Personnel (with designation, qualification & experience),
List of Equipments, Instruments along with make, model & capacity (S. No. 6 of General requirements)

Procedure for accepting the application for issue of COPP wef 01-10-2009 by CDSCO HYDERABAD

- Applications forwarded by SLA before 01-10-2009 will be considered provided they should resubmit the application in the revised format with forwarding letter, notarized product summary sheet and other documents which were not submitted earlier as per requirement on first come first serve basis.
- All applications received will be scrutinized by CDSCO Officials after receipt and query letter will be sent to applicant, if any or other wise will be considered for inspection.
- Inspection will be carried out by CDSCO Officers as per WHO GMP guidelines of TRS 823/908 for non sterile products, TRS 822/902 for Sterile Products and other relevant guidelines in TRS 937, TRS 929, TRS 863 etc. as applicable from time to time.

Procedure for accepting the application for issue of COPP wef 01-10-2009 by CDSCO HYDERABAD

- Self appraisal checklist shall be sent to the applicant before the inspection after 30th Nov. 2009.
- Checklist is based on Sch. M and not included certain WHO GMP requirements but included in technical guidance note to industry
- Self appraisal checklist should be filled and submitted to CDSCO officer before inspection.
- Inspection team verify the checklist at the time of inspection

Procedure for accepting the application for issue of COPP wef 01-10-2009 by CDSCO HYDERABAD

- Inspection report will be based on Sch M and WHO GMP guidelines based on technical guidance note.
- Inspection report will be summarized by CDSCO officer based on critical aspects of the firm in the representative format.
- Inspection and reporting for APIs is based on lines of WHO GMP requirements in the running report format as no specific checklist is decided.

Procedure for accepting the application for issue of COPP wef 01-10-2009 by CDSCO HYDERABAD

- Inspectors brief the inspection findings at the exit meeting.
- The report should clearly define deficiencies as per WHO GMP guidelines.
- Respective Zonal/ Sub-Zonal certifying authority prepare “Review Report” based on review of observations of check list and written inspection report as per WHO GMP guidelines

Procedure for accepting the application for issue of COPP wef 01-10-2009 by CDSCO HYDERABAD

- If firm is complying with requirements COPP may be issued in Standard Format.
- If firm is not complying with requirements, a list of deficiencies may be communicated to the applicant, application may not be considered.
- Firm **may reapply**, if required after proper compliance after **5 months** from **date of rejection**.
- If the same firm applies after 5 months, scrutiny of such application should be asked for earlier compliance with documentary evidences in addition to the usual general requirements for submission of application for issue of COPP

Fees Structure

- Inspection of Mfg. Units for issue / grant of COPP is not covered under the provisions of D& C Act and Rules.
- No Fees is collected as of now from the applicants.
- Initially it is a voluntary activity by NRA and build up confidence for facilitation of COPP issue.
- Fees Structure shall be decided in the second phase with necessary approvals from various authorities, if required.

FORMAT FOR ISSUE OF COPPs

- COPPs / Certificates issued SLA before 01-10-2009 are continued till expiry.
- COPPs should be issued as per Model Certificate of Pharmaceutical Product recommended by WHO as given in WHO TRS 863.
- COPPs will be initially issued in an A-4 size white paper with black color printing having background CDSCO logo with seal as prescribed.

FORMAT FOR ISSUE OF COPPs

- COPPs/Certificates issued by SLA are not in standard format of WHO, manufacturers may approach CDSCO for fresh COPPs in the standard format for already existing products.
- For additional products / contract manufacturer products COPPs will be issued by CDSCO only from 01-10-2009.
- Additional products certification would be done upon recent inspection for the same category of drugs / dosage forms / brands / strengths etc., upon submission of suitable documents.
- In case of new category of drugs / dosage forms, or separate facility or equipment for production or qc is involved, the application will be treated as fresh grant of COPP of those applied products.

AUTHORISED PERSONNEL TO ISSUE COPPs

- COPPs will be issued DCGI and officials delegated by his responsibility to Senior Zonal, Sub Zonal and Head Quarter Officers on behalf of DCGI.
- List of delegated officers are already posted in website: www.cdsc0.nic.in
- Names of delegated officers with signatures are already communicated to WHO

DATA BASE REQUIREMENT AT CDSCO OFFICES

- All CDSCO offices have to submit the data of status of manufacturing units applied, inspected, issued, rejected, etc. on cumulative basis every month to DCGI Office in both soft and hard copies.
- Updated list of manufacturers with type of products certified as per WHO guidelines will be kept in the website.

CDSCO SUBZONE HYDERABAD

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THANK YOU