

The modalities for grant of WHO - GMP Certificate of Pharmaceutical Product by CDSCO, DGHS, Ministry of Health Family welfare , Govt. of India from 1st October, 2009

In continuation to the letter No. X.11053/1/2009-D dated 1/9/2009 issued/published (on CDSCO website) by this directorate wherein, it was decided to issue the WHO GMP (Certificate of Pharmaceutical Product) by Drugs Controller General (India) , The modalities of the scheme as decided are being clarified here as under for benefit of all concerned.

The application for grant of WHO GMP (Certificate of Pharmaceutical Product) shall be made to respective zonal/sub zonal officers as per the requirement prescribed below. The COPP will be issued by zonal/sub zonal officers on behalf of Drugs Controller General (India) after inspection and satisfactory clearance by CDSCO officers as per WHO – GMP guidelines.

The Certificate of Pharmaceutical Product will be issued only in the format recommended by WHO (Model COPP annexed)

All COPP's including additional products etc. after 1st October 2009, will be granted by DCG (I) / identified CDSCO officer on behalf of DCG(I) after following procedures mentioned in para 2.

Those who are already holding COPP shall continue to hold it till its expiry.

Initially, fees is not going to be charged for application till final decision is taken and published in this matter.

For any further Clarifications the applicant may contact respective zonal/sub zonal offices.

Following personnel under the control of DCG (I) will be acting as signatory authority for DCG (I) for the grant of COPP. This list is dynamic and changes to it will be informed and posted on CDSCO website as and when it occurs.

S. No.	Name , Designation & address of certifying authority	Jurisdiction for Certification
A. From DCG(I) office (CDSCO, HQ)		
1	Dr. Surinder Singh, Drugs Controller General (India) CDSCO, FDA Bhavan New Delhi	For whole of India
2	Dr. V. G. Somani Deputy Drugs Controller(I) CDSCO, FDA Bhavan New Delhi	For whole of India, as directed by DCG(I)
3	Mr. M. Mitra Deputy Drugs Controller(I) CDSCO, FDA Bhavan New Delhi	For whole of India, as directed by DCG(I)

4	Mr. Arvind Kukrety Asst. Drugs Controller(I) CDSCO, FDA Bhavan New Delhi	For whole of India, as directed by DCG(I)
5	Dr. S. Eswara Reddy Asst. Drugs Controller(I) CDSCO, FDA Bhavan New Delhi	For whole of India, as directed by DCG(I)
B. From Zonal/Sub zonal offices		
6	Dr. R. Ramakrishna Deputy Drugs Controller(I) CDSCO, WZ , Mumbai	All applicants in West Zone except from Gujrat state
7	Dr. D. Roy Deputy Drugs Controller(I) CDSCO, NZ, Ghaziabad	For all applicants from North Zone
8	Mrs. Shanti Gunashekar Asst. Drugs Controller(I) CDSCO, SZ, Chennai	For all applicants from South Zone except from Andhra Pradesh
9	Mrs. Rubina Bose Asst. Drugs Controller(I) CDSCO, EZ, Kolkata	For all applicants from East Zone
10	Mr. A. C. S. Rao Asst. Drugs Controller(I) CDSCO, Hyderabad	For applicants from Andhra Pradesh
11	Dr. A. Ramkishan Asst. Drugs Controller(I) CDSCO, Ahmedabad	For applicants from Gujrat
12	Mr. Soumen Mukhopadhyay Asst. Drugs Controller(I) CDSCO, EZ, Kolkata	For applicants from East Zone, when directed by DCG(I)
13	Mr. D. K. Chauhan Asst. Drugs Controller(I) CDSCO, WZ, Mumbai	For applicants from West Zone, when directed by DCG(I)

General requirements for submission of application for issue of COPP:

1. A forwarding letter/application shall be addressed to DDC(I)/ADC(I) of respective CDSCO zonal/sub zonal offices with copy of covering letter & product summary sheet to DCG(I) (WHO-cell) by authorized person only.
2. The forwarding letter/application shall be accompanied with List of products applied for grant of COPP, along with the product permission copy (manufacturing licence issued by the SLA) & notarized product summary sheet, site master file as per WHO-GMP requirement.

Proforma for Product summary sheet:

S. 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		Process Validation	Analytical Method Validation	Cleaning Validation /verification	Annual Product Review	If permitted by DCGI Y/N/N A
			Accelerated	Real time					
			Acc	R. T.					
1	Example Tablet	20 (Commercial)	6 M	36 M	Completed	Completed	Completed	Not Completed	Y
2									
3									

3. List of major/master documents like master validation plan, quality manuals, specifications, master formula records maintained by firm and list of SOP's (to indicate the documentation system of firm)
4. Manufacturing layout (it is preferred if men and material flow, pressure flow drawing are also given)
5. HVAC schematics and details of areas (Where in clearly specify the filtration level & classification of core areas & rooms as required in section 3.3 of SMF) and Water system – Schematic diagrams along with the components
6. List of personnel (with designation, qualification & experience), List of equipments, instruments, utilities along with make and model & capacity.
7. List of primary & secondary Impurity and Reference standards/cultures available with the firm (relevant to the applied products for grant of COPP).

-Sd-

(Dr. Surinder Singh)
Drugs Controller General (India)

Model Certificate of a Pharmaceutical Product (as per WHO GMP guidelines)

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).

No. of Certificate: -----

Exporting (certifying) country: -----

Importing (requesting) country: -----

1. Name and dosage form of product:

1.1 Active ingredient(s)² and amount(s) per unit dose:³

For complete qualitative composition including excipients, see attached⁴.

1.2 Is this product licensed to be placed on the market for use in the exporting country?⁵

Yes/No (key in as appropriate)

1.2 Is this product actually on the market in the exporting country?

Yes/no/unknown (key in as appropriate)

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.⁶

2A.1 Number of product licence⁷ and date of issue:

2A.2 Product-licence holder (name and address):

2A.3 Status of product-licence holder:⁸ a/b/c (key in appropriate category as defined in note 8)

2A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹

2A.4 Is Summary Basis of Approval appended?¹⁰

yes/no (key in as appropriate)

2A.5 Is the attached, officially approved product information complete and consonant with the licence?

Yes/no/not provided (key in as appropriate)

2A.6 Applicant for certificate, if different from licence holder (name and address):¹²

2B.1 Applicant for certificate (name and address):

- 2B.2 Status of applicant: a/b/c (key in appropriate category as defined in note 8)
2B2.1 For categories b and c the name and address of the manufacturer producing the dosage form are: ⁹

- 2B.3 Why is marketing authorization lacking?
Not required/not requested/under consideration/refused (key is as appropriate)

2B.4 Remark: ¹³ -----

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes/no/not applicable¹⁴ (key in as appropriate)

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years):-----

- 3.2 Has the manufacture of this type of dosage form been inspected? Yes/no (key in as appropriate)

- 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? ¹⁵

Yes/no (key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? ¹⁶

Yes/no (key in as appropriate)

If no, explain: -----

Address of certifying authority:

Telephone number: ----- Fax number: -----

Name of authorized person:

Signature:

Stamp and date:

General Instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Name (INNs) or national nonproprietary name.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the safe, distribution or administration of the product that is specified in the product licence.
6. Section 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
 - (a) Manufactures the dosage form;
 - (b) Packages and/or labels a dosage form manufactured by an independent company;or
 - (c) Is involved is none of the above.
9. This information can be provided only with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11. This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
 - (a) the product has been developed exclusively for the treatment of conditions- particularly tropical diseases-not endemic in the country of export;
 - (b) the product has been reformulated with a view to improving its stability under tropical conditions;

 - (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
 - (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
 - (e) any other reason, please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This Section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The Layout for this Model Certificate is available on WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.