EP-8

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. Bhopal, dated

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This one page certificate conforms to the format recommended by the World Health Organization (general instruction and explanatory notes attached)

Certificate

On the basis of the inspection carried out on dated 3 we certify 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 :

2 Manufacturer's licence number :

3 Table 1:

Dosage Form	Category(ies)	Activity(ies)
Bulk Drugs ~~as Per List Enclosed along with COPP issued~~	As Per C.O.P.P. Issued	Production, packing & Labelling Quality Control, Synthesis. Purification

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 until dated 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 :

Name and function of responsible person : Licencing Authority

Signature

Stamp and Authority
Licensing Authority
Food & Drugs Administration
Madhya Pradesh.

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CHIEF EXECUTIVE DIRECTOR
INDO-OVERSEAS CHAMBER OF COMMERCE AND INDUSTRY

APP. UNDER NOTARIES ACT 1952 DELHI

ATTESTED PLOT

NOTARY

1. This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical products Moving in international Commerce.

Explanatory notes :

(5) This certificate, which is in the format recommended by WHO certificate the status of the Site listed in point 1 of the certificate.

(6) The certification number should be traceable within the regulatory authority issuing the certificate.

(3.) Where the regulatory issues a licence for the site this number should be specified record `not applicable` in case where there is no legal framework for the issuing of a licence.

(4.) Table 1

List the dosage forms, staring materials, categories and activities. Examples give below.

Examples 1 :

Pharmaceutical Products	Category(ies)	Activity(ies)
Bulk Drugs	As Per C.O.P.P. Issued	Production, packing & Labelling Quality Control, Synthesis, Purification

Examples 2 :

Pharmaceutical Product(s)`	Category(ies)	Activity(ies)
Starting material(s)3		
		Production, packing & Labelling Quality Control, Synthesis, Purification

2. Pharmaceutical Products. Any medicine intended for human use or veterinary product administered to food producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

3. Starting Materials : Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

To,

CHIEF EXECUTIVE DIRECTOR
INDO-OVERSEAS CHAMBER OF COMMERCE AND INDUSTRY

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OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

NO. **Bhopal, Dated**

To,

Sub: Revalidation of Certificate of Pharmaceutical Products.

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Please find enclosed herewith the Certificate of Pharmaceutical Products under WHO-GMP Certification Scheme under Certificate /alid upto 6 in respect of Bulk Drugs granted as per list enclosed under licence 4 in Form 28 as Per recommendation by the office of the Joint Drug Controller. (I) CDSCO West Zone, Mumbai's Vide Letter N 013.

Encl: AS Above.

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH
Bhopal, Dated

Endt. NO. .

CC to :

1 The Joint Drug Controller (India).CDSCO. West Zone,4th floor. Central FDA Bhawan, GMSD Compound, Bellasis Road, MUMBAI Central MUMBAI-400 008 with reference to your referred letter please.

2. Drugs Inspector, information .

DOCUMENTARY LEGALIZEISE
CHIEF EXECUTIVE DIRECTOR
INDO-OVERSEAS CHAMBER OF COMMERCE AND INDUSTRY

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

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No. of Certificate ---
Valid upto

Exporting (Certifying) Country : India
Importing (requesting) Country : As per Appendix II

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

1. **Name and dosage form of product :** **As per Annexure – A**

1.1 Active Ingredient(s) [2] and amount(s) per unit dose [3] Refer Appendix I for complete qualitative composition including expedients [4]

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] Yes / no (Key is an appropriate)

1.3 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 licence [7] and date of issue	2B.1 Applicant for certificate (Name & Address) Not Applicable
2A.2 Product Licence holder (name & address) (Name & Address)	2B.2 Status of Applicant Not Applicable a / b / c / (Key in appropriate category as defined in note 8)
2A.3 Status of licence holder [8] a / ~~b / c~~ (Key in appropriate category as defined in note 8)	2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are Not Applicable
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage from are [9] : Not Applicable	2B.3 Why is marketing authorization lacking? : Not Applicable
2A.4 Is Summary Basis of Approval appended ? [10] : ~~Yes~~ / no (Key in as appropriate)	2B.4 Remarks [11] : Not Applicable
2A.5 Is the attached officially approved product information complete and consonant with the licence? [11] : ~~Yes / no~~ / not provided (Key in as appropriate)	
2A.6 Applicant for certificate if different from licence holder (name & address) [12] Not Applicable	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? Yes / ~~no / not applicable~~ (Key in as appropriate)
If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (Years) : Once in a year

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 confirm to GMP as recommended by the World Health Organization ? [13] : Yes / ~~no / not applicable~~ (Key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of product undertaken by another party? [14] Yes /no (Key in as appropriate)
if no, explain
N.A.

Address of certifying authority : Office of the controller, Food & Drugs Administration, Madhya Pradesh, Bhopal, Madhya Pradesh, India.

Telephone Number

Name of authorized person Signature Stamp and date

LICENSING AUTHORITY
FOOD & DRUGS ADMINSTRATION, MADHYA PRADESH

Licensing Authority
Food & Drugs Administration
(M) Madhya Pradesh

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