CERTIFICATE OF A PHARMACEUTICALS PRODUCT

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

Certificate No : **MFG/WHO GMP/COPP/2023/7850239770**

Valid Up To :**12/10/2026**

Exporting (Certifying) Country : **India**

Importing (Requesting) Country : **Syria**

1 Name and dosage form of products : (Brand Name if any) : **IMIPENEM AND CILASTATIN FOR INJECTION USP**

1.1 Active ingredient(s)[2]and amount(s) per unit dose[3]: **Each vial contains**

Composition	Ingredients	Standards	Strength	UOM	Equivalent to
API	Sterile Imipenem	USP	0		Anhydrous Imipenem 500 mg
API	Sterile Cilastatin Sodium	USP	0		Cilastatin 500 mg

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

1.3 Is the product actually on the market in the exporting country? **Yes**

2A.1	No. of Product license[7]and Date of issue **Product License in Form 28 bearing no. G/28/1581 Date of Issue : 06/10/2017**	2B.1	Applicant for certificate (name and address): **Not Applicable**
2A.2	Product License holder :(Name and address) **BROOKS STERISCIENCE LIMITED, VILLAGE.- MANGLEJ, NARESHWAR ROAD, OFF NH-8, TALUKA.- KARJAN, DIST.- VADODARA, GUJARAT (INDIA)- 391 210**	2B.2	Status of Applicant: **Not Applicable**
2A.3	Status of Product-license holder[8]: **manufactures the dosage form**	2B.2.1	For categories b & c have the name and address of the Manufacturer producing the dosage form are: **Not Applicable**
2A.3.1	For category b and c the name and address of the manufacturer producing the dosage form are[9] **Not Applicable**	2B.3	Why is marketing authorization lacking? **Not Applicable**
2A.4	Is Summary Basis of Approval appended[10]? **Not Applicable**	2B.4	Remarks:[13] **Not Applicable**
2A.5	Is the attached, officially approved product information complete and consonant with the license[11]? **Not Applicable**	2B.5	Applicant for certificate, if different from license holder:[12] **Not Applicable**
2A.6	Applicant for certificate, if different from license holder:[12] **No**		

3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced[14]? **Yes**

3.1 Periodicity of routine inspection (years) : **Once in a Year**

3.2 Has the manufacturer of this type of dosage form been inspected? **Yes**

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organization[15]? **Yes**

4 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the products[16]? **Not Applicable**

Address of Certifying Authority :

The Commissioner
Food & Drugs Control Administration,
Gujarat State, Jivraj Mehta Bhavan,
Block No. 8, 1st Floor, Gandhinagar (INDIA)
Tel:+91-79232-53 417,
Fax: +91-79232-253400

Name & Signature :

(This Document is Digitally Signed)

RAVAT H. L.

Deputy Commisioner
Food & Drugs Control Administration
Gujarat State - Gandhinagar

Date of Issue : **16-Dec-2023**

General Instructions

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the Scheme. The forms are available for generation by computer. They should always be submitted as hard copy, with responses presented in type rather than hand written.

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 Names (INNS) or national nonproprietary names.
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 sale, 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 in 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 licenced.
11. This refers to product information approved by the competent national regulator, 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 third-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. The 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 diskette in WordPerfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.