CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

This certificate conforms to the format recommended by the **WORLD HEALTH ORGANISATION**
(General instructions and explanatory notes attached)

No. of Certificate: Mfg/WHO COPP/Swiss Parenterals/2025/ 017450
Exporting (Certifying) country: **INDIA**
Importing (requesting) country: **KOSOVO**

1. Name and dosage form of products: **CEFTAZIDIME AND AVIBACTAM FOR INJECTION 2.5 GM**

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

Each Vial Contains:
Ceftazidime with Sodium Carbonate USP
(As Ceftazidime Pentahydrate)
Equivalent to Ceftazidime 2000 mg
Avibactam Sodium
Equivalent to Avibactam 500 mg

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country? Yes ☒ No ☐ Unknown ☐

If the answer to 1.2 is yes, continue with section 2 A and If the answer to 1.2 is no. Continue section 2 B [6]

2A.1 Number of product license[7]: **G/28/1446** In Form No. **28** And date of issue: **08/04/2025**	2B. 1 Applicant for certificate (name and address) N.A.
2A.2 Product license holder: (Name and address) **SWISS PARENTERALS LTD. (Unit - II)** Plot No. 402,412-414, Kerala Industrial Estate, GIDC, Near Bavla, Ahmedabad - 382 220, Gujarat, India.	2B. 2 Status of applicant: N.A. a ☐ b ☐ c ☐ 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are
2A.3 Status of product – license Holder [8] : Manufactures of Dosage Forms a ☒ b ☐ c ☐	2B.3 Why is marketing authorization lacking? N.A. Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are [9] : N.A	2B. 4 Remarks: [13] N.A.
2A. 4 Is summary basis of Approval appended? [10] Yes ☐ No ☒	
2A.5 Is the attached officially approved product information complete and consonant with the license ?[11] Yes ☐ No ☐ Not Provided ☒	
2A. 6 Applicant for certificate if different from license holder [12] : Not Applicable	

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

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

Yes ☒ No ☐ Not applicable [14] ☐

If no or not applicable proceed to question 4

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

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

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

Yes ☐ No ☐ Not applicable ☒

If no, explain: _____

This Certificate Valid Up to **2 years From The Date of Issue**

Address of certifying authority:
The Commissioner Food & Drug Control Administration
1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA
Tel: 91-79-232 53417 Fax: 91-79-232 53400

Name of the Authorized Person: **Shri. H.L. Ravat**

Signature:

Stamp and date: 21 APR 2025

Joint Commissioner
Food & Drugs Controls Administration
Gujarat State

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 form and different strength 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-license 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 license.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the license 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.

d) 9. This information can be provided only with the consent of the product-license 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 license. If the production site is changed the in the License 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 regulator, authority, such as a Summary of Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product license 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 count-to, 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 is 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 manufacturer.

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 Export 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 Export Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16. The Section is to be completed when the product-license 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 Word Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.