Certificate of a Pharmaceutical Product

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

No. of Certificate: 2945 , Date of issue 09/01/2026 & Valid upto **28/08/2027**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **MOLDOVA**

1. Name and dosage form of product:

APROTININ INJECTION USP

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

Each ml contains:

Aprotinin	USP	10000 KIU/ML
Water for Injection	USP	q.s.

For complete qualitative composition including Excipients, see attached.

1.2 Is this product licensed to be placed on the market for use in the exporting Country? : **Yes**

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

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.

2A.1 Number of product license and date of issue:
Drugs Manufacturing License No. 1800-OSP (Form 25) & 1804-B (Form 28) granted on 15-02-2016 & valid upto 27-12-2030

2.A.2 Product license holder (name and address):
M/s Kwality Pharmaceuticals Ltd., (Unit-I), 6th Mile Stone, Vill. Nag Kalan, Majitha Road, Amritsar, Distt. Amritsar, Punjab (India).

2A.3 Status of product-license holder: **A (manufacturers the dosage form;)**

2A3.1 For categories b and c the name and address of the manufacturer producing the Dosage form are : **Not Applicable**

2A4. Is Summary Basis of Approval appended? : **Not Applicable**

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Date: 2026.03.23 10:46:13 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

2A5. Is this attached officially approved product information complete and consonant with the license? : **Yes**

2A6. Application for certificate, if different from license holder (name and address): **Not Applicable**

3. Application for certificate authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? : **Yes**

3.1 Periodicity of routine inspection (years): **Three Years**

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

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

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

Address of certifying authority:

Commissionerate, Food & Drugs Administration, Punjab,
Government Dispensary Complex, Mohali Stadium Road,
Phase-9, Mohali, District Shibzada Ajit Singh Nagar, India

Telephone & Fax Number: 0172-2666672

Name of authorized person:

Amit Duggal,
Assistant Commissioner (Drugs),
Food & Drugs Administration, Punjab

Signature

Stamp and date

Assistant Commissioner (Drugs)
Food & Drugs Administration Punjab,
Government Dispensary Complex,
Phase-9, Mohali-160062

GENERAL INSTRUCTION:

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 suitable for generation by computer. They should always be submitted in 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 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. Sections 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.
9. This information can only be provided 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 license has to be updated or it is no longer 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 Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to 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 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-license holder or applicant conforms to status (b) or (c) as described in note 8 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 world perfect from the Division of Drug Management and Policies. World Health Organization 1211 Geneva 27, Switzerland.