CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

042637

Certificate No. : MFG/WHO-COPP/INTAS-PFC/2022/14

Exporting (certifying country) : **INDIA** : Importing (requesting country) : **All countries except India**

1. Name and dosage form of product : Human Fibrinogen EP 1 G (Freeze dried powder)
Reconstitute with 50 ml of sterile WFI
FIBROGEN - I

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3] : Each package contains 1 vial with:
1725-3110 mg dried powder out of which
700-1300 mg Fibrinogen

Human Albumin	400-700 mg
L-Arginine HCL	375-660 mg
Sodium Chloride	200-350 mg
Sodium Citrate	50-100 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**

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 : **No. G/28E/1 Date : 18/12/2021**	2B.1	Applicant for certificate (name and address) : **N.A.**
2A.2	Product-License holder (Name and Address) : **Intas Pharmaceuticals Ltd.** Plot No.:496/1/A & B, Sarkhej-Bavla Highway, Village- Matoda, Taluka- Sanand, Ahmedabad-382213, Gujarat	2B.2	Status of applicant[8] : **N.A.**
2A.3	Status of product-license holder[8] : **a) Manufacturer of Dosage Form**	2B.2.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9] : **N.A.**
2A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **N.A.**	2B.3	Why is marketing authorization lacking? **N.A.**
2A.4	Is Summary Basis of Approval appended[10]? : **No**	2B.4	Remarks[13] : **N.A.**
2A.5	Is the attached, officially approved product information complete and consonant with the license[11]? : **N.A.**		
2A.6	Applicant for certificate, if different from license holder (Name and address)[12] : **N.A.**		

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14] : **Yes**
(If not or not applicable, proceed to question 4)

3.1 Periodicity of routine inspection (years) : **Once in 3 Years**

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

3.3 Does 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 in all aspects of the manufacture of the product?[16] : **N.A.**
If no, explain

This certificate is valid up to : **15/10/2023**

Address of certifying authority : Name of authorized person : **Dr. Manoj P. Gadhvi**

Food and Drugs Control Administration,
Gujarat State, Block No. 8,
1st Floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat, India.

Telephone No. : 91-79-23253417
Fax No. : 91-79-23253400

Signature :

Stamp and date :

Assistant Commissioner
Food and Drugs Control Administration
Gujarat State, INDIA.

16 JUL 2022

Digitally signed by Harea Ștefan
Date: 2022.08.14 11:28:32 BST
Reason: MoldSign Signature
Location: Moldova

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 Names (INNs) or national nonproprietary names.

3. The formula (complete composition) of the dosage form should be given on the certificate or to 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 the details of any restriction applied to the sale, distribution or administration of the product license holder.

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;
   (c) Is involved in none of the above.

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 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 regulatory 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 that the reason that the applicant has provided for not requesting registration.
   (a) The product has been developed exclusively for the treatment of conditions - particularly 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 seconds report of expert committee on specifications for Pharmaceutical Preparation (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 license holder or applicant confirms 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 this 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.