CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization

No. of Certificate: DD/794/49C/2022/-1-105-1 **Valid Upto** : **04.03.2025**

Exporting (certifying) country **: India**

Importing (requesting) country **: As per Annexure – 2**

1. Name and dosage form of product **: ONCOGINASE**
   L-Asparaginase for Injection 10000IU/vial

1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] **: Composition:**
Each lyophilized vial contains:
L-Asparaginase ……..10000 IU

For complete qualitative composition including excipients, see attached[4] **Annexure – 1**

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **: 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 section 2B[6]

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Date: 2023.07.28 11:44:11 EEST
Reason: MoldSign Signature
Location: Moldova

2A.1 Number of product licence[7] and date of issue : **DD/794 Dated 30/12/2019**

2A.2 Product license holder (Name & Address) : **Bruck Pharma Pvt. Ltd.**
Survey No. 188/1 to 6, 189/1, 190/2 to 4,
Atiyawad, Dabhel, Daman – 39210

2A.3 Status of product-license Holder :[8] : a

2A.3.1 For categories b and c, the name and address of the manufacturer producing the dosage form are[9] **:** Not applicable

2A.4 Is Summary Basis of Approved appended? :[10] **:** NO

2A.5 Is the attached, officially approved product information complete and consonant with the license? :[11] **:** Not applicable

2A.6 Applicant for certificate if different from license holder (name and address)[12] **:** Not applicable

2B.1 Applicant for certificate (Name and address): **:** NA

2B.2 Status of applicant **:** NA

2B.2.1 For categories (b) and (c) the name and address of the Manufacturer producing the dosage form are[9] **:** NA

2B.3 Why is marketing authorization lacking? **:** NA

2 B.4 Remark [13]: **:** NA

LICENSING AUTHORITY
U.T. OF DAMAN & DIU

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] **: Yes**
If no or not applicable, proceed to question 4.

3.1 Periodicity of routine inspections (years) : Yearly

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 Organisation?[15] : Yes

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

If no, explain **:** Not Applicable

Address of Certifying authority :
Drug Licensing Authority,
Administration of Daman & Diu, drugs Control Dept.,
Primary Health Center, Daman (UT) – 396 220
Telephone No.: 0091-0260-2230470
Fax No. : 0091-0260-2230570

Name of Authorized Person: Dr V K DAS

Signature
Stamp and Date

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

15 MAR 2022

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 Non-proprietary Names (INNs) or national non-proprietary 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 mutually exclusive.

7. Indicate, when applicable, if the licence in 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 dosages 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 agree 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 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 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 or 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 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 WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No, 822m 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 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.

ANNEXURE-II

No. of Certificate: DD/794/49C/2022/-1-105-1 **Valid Upto : 04.03.2025**

Name and dosage form of product : ONCOGINASE (L-Asparaginase for Injection 10000IU/vial)

List of countries/Institution to which the above product will be Exported/Locally supplied.

Afghanistan	Brunei	Ecuador	Hong-kong	Lithuania	Nigeria	Sierra Leone	Togo
Albania	Brunei Darussalam	Egypt	Hungary	Luxembourg	North Korea	Singapore	Tongo
Algeria	Bulgaria	El Salvador	Iceland	Macao	Norway	Slovakia	Trinidad & Tobago
Andorra	Burkina Faso	England	India	Macedonia	Oman	Slovenia	Tunisia
Anglia	Burundi	Equatorial Guniea	Indonesia	Madagascar	PAHO	Solomon Island	Turkey
Angola	Cape Verde	Eritrea	iran	Malawi	Pakistan	Somalia	Turkmenistan
Anguilla	Cambodia	Estonia	Ireland	Malaysia	Palau	South Africa	Turks and Calicos
Antigua	Cameroon	Ethiopia	israel	Maldives	Palestine	South Korea	Tuvalu
Antigua & Barbuda	Canada	Fiji	Italy	Mali	Panama	South Sudan	Uganda
Argenitna	Cape Verde	Fiji Island	Ivory Coast	Malta	Papua New Guinea	Spain	Ukraine
Armenia	Cayman Island (E)	Finland	Jamaica	Marshal Island	Paraguay	Sir Lanka	UNHCR
Aruba	Central African Republic	France	Japan	Mauritania	Peru	St. Kitties	UNICEF
Australia	Chad	French Guiana	Jordan	Mauritius	Philippines	St. Kitties and Nevi	United Arab Emirates
Austria	Chile	Gabon	Kazakhstan	MCGM	Poland	St. Lucia	United Kingdom
Azerbaijan	China	Gambia	Kenya	Mexico	Portugal	St. Vincent	United State
Bahamas	Colombia	Georgia	Kiribati	Micronesia	Puerto Rico	St. Maarten	UNOPS
Bahrain	Comoros	Germany	korea	Moldova	Qatar	St. Vincent and the Grenadines	United Kingdom
Bangladesh	Congo	Ghana	kosovo	Monaco	R.D.Congo	Sudan	Uruguay
Barbados	Costa Rica	Global Fund	kurdistan	Mongolia	Rep. of Congo	Sultanate of Oman	Uzbekistan
Belarus	Croatia	Grand Cayman	Kuwait	Monstserrat	Reunion	Sultanate of Oman	Vanuatu
Belgium	Cuba	Greece	Kyrgyzstan	Morocco	Romania	Suriname	Vatican City
Belize	Curacao	Grenada	Lao PDR	Mozambique	Romania	Swedan	Venezuela
Belorussia	Cyprus	Guatemala	Loas	Myanmar	RITES	Switzerland	Vientiane
Benin	Czechia	Guinea	Latvia	Namibia	Russia	Syria	Vietnam
Bermuda	Czechoslovakia	Guinea-Bissau	Lebanon	Namibia	Rwanda	Taiwan	Western Samoa
Bhutan	Denmark	Guyana	Leone	Nauru	Samaoa	Tajikistan	WHO
Bolivia	Djibouti	Haiti	Leone	Nepal	Sao Tome and Principe	Tanzania	Yemen
Bosnia	Dominica	Herzegovina	Lesotho	Netherlands	Saudi Arabia	Tehad	Yugoslavia
Bosnia and Herzegovina	Dominican Republic	Holland	Liberia	New Zealand	Senegal	Thailand	Zaire
Botswana	DR. Congo	Holy See	Libya	Nicaragua	Serbia	The Netherlands	Zambia
British Virgin	East Timor	Honduras	Liechtenstein	Niger	Seychelles	Timor Leste	Zimbabwe

Address of Certifying authority :
Drug Licensing Authority,
Administration of Daman & Diu, drugs Control Dept.,
Primary Health Center, Daman (UT) – 396 220
Telephone No.: 0091-0260-2230470
Fax No. : 0091-0260-2230570

Name of Authorized Person: Dr V K DAS
Signature
Stamp and Date
15 MAR 2022
DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण