THE MINISTRY OF HEALTH, VIETNAM

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate: 887/GP-QLD

Exporting (certifying) country: **VIETNAM**

Importing (requesting) country: **AS PER ANNEXURE**

Digitally signed by Sîli Oleg
Date: 2021.09.10 08:21:40 EEST
Reason: MoldSign Signature
Location: Moldova

1. Name and dosage form of product: **FERONSURE – SOLUTION FOR INJECTION – PREFILLED SYRINGE 0.5 mL**

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

Each prefilled syringe contains:

Active ingredient	**Recombinant Human Interferon alfa-2a**		**3 MIU**
Excipients:			
Sodium chloride	3.605 mg	Benzyl alcohol	4.50 mg
Ammonium acetate	0.385 mg	Water for injection	q.s 0.50 mL
Polysorbate 80	0.10 mg		

Shelf life: 24 months

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

2.A.1 Number of product License[7]: **QLSP-917-16**

Date of issue: **05th Feb 2016**

Date of review: **05th Feb 2021**

2.A.2 Product License holder (name and address):

Name: **NANOGEN PHARMACEUTICAL BIOTECHNOLOGY JSC.**

Address: **Lot I-5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, Ho Chi Minh City, Vietnam**

Tel: **(+84) 28 37309931** Fax: **(+84) 28 37309963**

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

☒ a ☐ b ☐ c

2.A.4 Is summary basic of Approval appended?[10]

☐ Yes ☒ No

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]

☐Yes ☐ No ☒ Not provided

2.A.6 Applicant for certificate (name and address)[12]:

Name: **NANOGEN PHARMACEUTICAL BIOTECHNOLOGY JSC.**

Address: **Lot I-5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, Ho Chi Minh City, Vietnam**

Tel: **(+84) 28 37309931** Fax: **(+84) 28 37309963**

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

☒ Yes ☐ No ☐ N/A[14]

If no or not applicable proceed to question 4

3.1. Periodicity of routine inspections (years): 3 years

Has the manufacture of this type of dosage form been inspected?

☒ Yes ☐ No

3.2. Do the facilities and operations conform to GMP as recommended by the World Health Organisation?[15]

☒ Yes ☐ No ☐ N/A[14]

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

☐ Yes ☐ No

If no, explain:

Address of certifying authority:

The Ministry of Health of Vietnam **Drug Administration** **138A Giang Vo Street, Hanoi City, Vietnam** Telephone number: 8424 37366483 Fax number: 8424 38234758	**Name of the authorized person:** **Signature:** BỘ Y TẾ CỤC QUẢN LÝ DƯỢC **Stamp and date:** 17/12/2019 PHÓ CỤC TRƯỞNG Nguyễn Thành Lâm

ANNEXURE

No. of certificate :

Exporting (certifying) country : **VIETNAM**

Importing (requesting) country : **THE LIST BELOW**

NAME AND ADDRESS OF THE MANUFACTURING SITE:

NANOGEN PHARMACEUTICAL BIOTECHNOLOGY JSC.

Lot I-5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, Ho Chi Minh City, Vietnam

NAME OF THE PRODUCT: **FERONSURE – SOLUTION FOR INJECTION – PREFILLED SYRINGE 0.5 mL**

Tentative list of countries to which the above product may be exported:

1. Afghanistan	33. Costa Rica	65. Italy	97. Nicaragua	129. Sudan
2. Albania	34. Croatia	66. Ivory Coast	98. Niger	130. Suriname
3. Algeria	35. Cuba	67. Jamaica	99. Nigeria	131. Swaziland
4. Angola	36. Cyprus	68. Japan	100. North Korea	132. Sweden
5. Argentina	37. Czech Republic	69. Jordan	101. Oman	133. Syria
6. Armenia	38. Denmark	70. Kazakhstan	102. Pakistan	134. Tadjikistan
7. Australia	39. Dominican Republic	71. Kenya	103. Panama	135. Taiwan
8. Austria	40. Ecuador	72. Kuwait	104. Papua New Guinea	136. Tanzania
9. Azerbaijan	41. Egypt	73. Kyrgyzstan	105. Paraguay	137. Thailand
10. Bahamas	42. El Salvador	74. Laos	106. Peru	138. Togo
11. Bahrain	43. Estonia	75. Latvia	107. Philippines	139. Tonga
12. Bangladesh	44. Ethiopia	76. Lebanon	108. Poland	140. Trinidad & Tobago
13. Barbados	45. Fiji	77. Liberia	109. Portugal	141. Tunisia
14. Belarus	46. Finland	78. Libya	110. Qatar	142. Turkey
15. Belize	47. France	79. Lithuania	111. Romania	143. Turkmenistan
16. Belorussia	48. Gabon	80. Luxembourg	112. Russia	144. UAE
17. Benin	49. Gambia	81. Madagascar	113. Rwanda	145. Uganda
18. Bhutan	50. Georgia	82. Malawi	114. Samoa	146. Ukraine
19. Bolivia	51. Ghana	83. Malaysia	115. Sao Tome	147. United Kingdom
20. Bosnia & Herzegovina	52. Greece	84. Male	116. Saudi Arabia	148. Uruguay
21. Botswana	53. Guatemala	85. Mali	117. Senegal	149. USA
22. Brazil	54. Guyana	86. Mauritania	118. Serbia & Montenegro	150. Uzbekistan
23. Brunei	55. Haiti	87. Mauritius	119. Seychelles	151. Venezuela
24. Bulgaria	56. Honduras	88. Mexico	120. Sierra Leone	152. Yemen
25. Burkina Faso	57. Hungary	89. Moldova	121. Singapore	153. Zaire
26. Burundi	58. Iceland	90. Mongolia	122. Slovakia	154. Zambia
27. Cambodia	59. India	91. Morocco	123. Slovenia	155. Zimbabwe
28. Cameroon	60. Indonesia	92. Mozambique	124. Somalia	
29. Chile	61. Iran	93. Myanmar	125. South Africa	
30. China	62. Iraq	94. Namibia	126. South Korea	
31. Columbia	63. Ireland	95. Nepal	127. Spain	
32. Congo	64. Israel	96. New Zealand	128. Sri Lanka	

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.