Health Canada Santé Canada

Digitally signed by Bolea Petru
Date: 2021.02.18 11:38:44 EET
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GOOD MANUFACTURING PRACTICE CERTIFICATE[1]

Exporting (certifying) country: **CANADA** No. of Certificate: **76280**

Importing (requesting) country: **TURKEY**

1. Name and dosage form of the product:

SOLUTION

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

For complete composition including excipients, see attached:[4] **No**

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **N/A**

If YES, continue with section 2A and leave section 2B blank.
If NO, leave question 1.3 and section 2A blank and continue with section 2B[6]

1.3 Is this product actually on the market in the exporting country? **N/A**

THIS CERTIFICATE DOES NOT RELATE TO ANY SPECIFIC PRODUCT.

2A.1 Number of product license and date of issue:[7]

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

2A.3 Status of license holder:[8]

2A.3.1 For categories (B) and (C) the name and address of the manufacturer producing the dosage form is:

2A.4 Is a summary basis for approval appended ?[10] **Not Applicable**

2A.5 Is the attached product information complete and consonant with the license?[11] **Not Required**

2A.6 Applicant for certificate, if different from license holder (name and address):

Canada

Health Canada Santé Canada

2B.1 Applicant for certificate (name and address):

SAOL THERAPEUTICS RESEARCH LIMITED
PETER STREET, UNIT G04
ADELAIDE CHAMBERS, DUBLIN
DUBLIN 8, IRELAND

CANADIAN REPRESENTATIVE:
REGCON SOLUTIONS (CANADA) INC.
359 JANENE COURT
MISSISSAUGA, ON
CANADA, L5A 3Z2

2B.2 Status of applicant:[8] **C**

2B.2.1 For categories (B) and (C) the name and address of the manufacturer producing the dosage form is:[9]

FABRICATING, PACKAGING, LABELLING AND TESTING SITE:
EMERGENT BIOSOLUTIONS CANADA INC.
155 INNOVATION DRIVE
WINNIPEG, MB
CANADA, R3T 5Y3

2B.3 Why is marketing authorization lacking?

2B.4 Remarks:[13] **GMP CERTIFICATE**

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14] **Yes**

If NO or NOT APPLICABLE, proceed to question 4

3.1 Periodicity of routine inspections (years): **2**

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

3.3 Do the facilities & operations conform to GMP as recommended by the WHO?[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:

Address of certifying authority

Regulatory Operations and Enforcement Branch
Health Product Compliance Directorate
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Digitally signed by Negus, Caitlin
DN: C=CA, OU=HC-SC, O=GC, CN="Negus, Caitlin", E=caitlin.negus@canada.ca
Date: 2021-02-02 14:19:34

Signature: Caitlin Negus

Date: **2021-02-01**

Name of authorized person **Caitlin Negus**

This certificate expires 1 year from the date of issue

Canada

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-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. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence 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-licence 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 licence. If the production site is changed, the licence 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-licence 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-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.