*\*Important: please ensure that all applicable variations to this product authorisation have been finalised by the Human Products Authorisation and Registration Department before completion.*

**Certificate of a Pharmaceutical Product**

**This certificate conforms to the format recommended by the**

**World Health Organisation**

**Exporting (certifying) country: Ireland**

**Importing (requesting) country:**

1. Name and dosage form of product:

*Enter the name as it appears on the Irish Product Authorisation (PA). The name of the product in the importing country can be inserted here; also state the name by which the product is known in Ireland. Please note that each certificate may cover only one dosage form/strength. For example, if a product has two different strengths, two separate certificates will be needed.*

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

*List active ingredient(s) in the format and order that they appear on the PA. The full quantitative formulation must be provided.*

*If required, please attach the full composition for the product in a separate page to the back of this draft certificate. This composition page can list inactive ingredients/excipients and other ingredients (such as tablet/capsules polishes and printing inks) qualitatively and not quantitatively. If these elements of the composition are currently subject to, or will be subject to a Type 1A variation within the following twelve months, please note that the completion of a declaration (Appendix III) contained in the export certificate application form will be required in this case. A listing of the ingredients can be found in Section 6.1 of the SmPC.*

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

No

*Only mark as ‘No’ if the product is manufactured in Ireland but does not have a valid product authorisation and is intended for export only.*

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

Yes

No

*Please ensure that the marketing status of the product has been correctly notified to the HPRA.*

If the answer to 1.2 is ‘yes’, continue with section 2.A 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 licenceand date of issue:

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

*Ensure this information conforms in every detail with the product authorisation. If the applicant is different from the PA holder, the PA holder must provide permission to the applicant in the form of a ‘letter of authorisation’ permitting the applicant to apply on their behalf. This letter must be on the PA holder’s headed paper, stating the product or giving open authorisation for a number of products.*

2A.3 Status of product licence holder: a, b or c:

*Key in appropriate category as defined in note 8 in* ***explanatory notes****.*

2A.3.1 For categories b and c, state the name and address of the manufacturer producing the dosage form:

*This should be the name and address, as shown on the current product specific details (PSD) section of the PA, of the actual site of manufacture of the* ***final dosage form****. If more than one manufacturer must be stated, please ensure that all details are current as shown on the current PA for the product. It is not necessary to include API sites. Primary and secondary packaging sites and/or batch release sites should not be listed here but may be added as an attachment to the certificate if required (see 2A.4)*

2A.4 Is the summary Basis of Approval appended?

N/A

*The PSD is no longer issued by the HPRA so this section is now not applicable. If you wish to include a listing of either manufacturing sites and/or composition of the product this can be submitted as an attachment to the CPP. Ideally this manufacturer or composition details will have already been approved on the latest product authorisation held in our records. Alternatively, if you wish to include as an attachment to the certificate a listing of manufacturers which are the subject of a submitted Type 1A variation, or will be the subject of a Type 1A variation within the following twelve months, please complete a declaration to that effect. This declaration can be found in the export certificate application form (Appendix III). Only manufacturers performing primary and secondary packaging and/or batch release may be listed in these attachments. The actual manufacturing sites of the final dosage form should be listed under 2A.3.1.*

2A.5 Is attached, officially approved product information complete and consonant with the licence?

Yes

No

Not provided

*If you wish to attach the Summary of Product Characteristics (SPC) for the product, please answer ‘yes’, or ‘no’ if not applicable.*

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

*Only complete this if the company applying for the certificate is different from the PA holder.*

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

*Please see note at Section 1.2.*

2B.2 Status of applicant:

2B.2.1 For categories b and c, state the name and address of the manufacturer producing the dosage form:      

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks:

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

Yes

No

*The certifying authority is the HPRA. Therefore, if the HPRA has inspected the manufacturing plant in which the dosage form is produced, the answer is ‘yes’. If the HPRA did not inspect the manufacturing plant, the answer is ‘no’.*

3.1 Periodicity of routine inspection (years):

Every 3 years

N/A

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

Yes

N/A

3.3 Do the facilities and operations conform to GMP as recommended by the World

Health Organisation?

Yes

N/A

**For official HPRA use only:**

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

Yes

NoComments:

Address of certifying authority:

**Health Products Regulatory Authority**

**Kevin O’Malley House**

**Earlsfort Centre**

**Earlsfort Terrace**

**Dublin 2**

**Ireland**

**Telephone no:** 01-676-4971 **Fax no:** 01-676-4061

Name of authorised person:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<name>

A person authorised in that behalf by the said Authority

<position>

<department>

<date>

**N.B. The information contained in the certificate is a valid and true reflection of the latest available information pertaining to the product authorisation available at the time of issue.**

*\*Please remove all notes and clarifying remarks in red before submission to the Health Products Regulatory Authority.*

**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:
   1. manufactures the dosage form;
   2. packages and/or labels a dosage form manufactured by an independent company; or
   3. 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.
    1. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    2. the product has been reformulated with a view to improving its stability under tropical conditions;
    3. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    4. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    5. 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.