LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

INFORMATION ONLY

Certificate of a Pharmaceutical Product[1]

This certificate conforms, in general, to the format recommended by the World Health Organisation *(explanatory notes are attached)*

No. of Certificate: **2145/11:321/2012**

Exporting (certifying) country: **Sweden**

Importing (requesting) country:

1. Name, dosage form and strength of the medicinal product:
HeliCap, capsule, hard, 37 kBq

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

Active ingredient

urea (C-14)	37,00 kBq

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product authorised to be placed on the market for use in the exporting country?[5] ☑ Yes ☐ No

If No, why is Marketing Authorisation lacking?

☐ *under consideration* ☐ *refused* ☐ *withdrawn*

2A.1 Marketing Authorisation number:[6] **19308**

Date of Marketing Authorisation: **16 April 2004**

2A.2 Marketing Authorisation Holder (name and address):

Kibion AB
Box 303
751 05 Uppsala
Sweden

2A.3 Status of the Marketing Authorisation Holder:[7]

☐ *a* ☐ *b* ☑ *c* ☐ *d (key in appropriate category as defined in note 7)*

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2A.3.1 For categories b, c and d the name and address of the manufacturing site producing the dosage form are:[8]
Institute of Isotopes Co. Ltd
Konkoly Thege út 29-33
1121 Budapest
Hungary

2A.4 Is Summary Basis of Approval appended?[9] ☑ No

2A.5 Is the attached, officially approved product information complete and consonant with the Marketing Authorisation?[10] ☑ Yes ☐ Not provided
The applicant assumes the whole responsibility for the accuracy of the translation of the text from Swedish into English.

2A.6 Applicant for certificate if different from the Marketing Authorisation Holder (name and address):[11]

Sections 3 and 4 are not relevant as the manufacture takes place in a country other than Sweden.

3. Does the certifying authority arrange for periodic inspection of the manufacturing site in Sweden in which the dosage form is produced?[12] ☐ Yes ☐ No ☐ N/A

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections: Every XX year

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

3.3 Do the facilities and operations in Sweden conform to GMP in the European Community. (The Commission: Guide to Good Manufacturing Practice for Medicinal Products in the European Community and directives 2003/94/EEC and 91/412/EEC) and as recommended by the World Health Organisation?[13] ☐ Yes ☐ No

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[14] ☐ Yes ☐ No

If no, explain:

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Address of certifying authority:
Medical Products Agency
Box 26
Dag Hammarskjölds väg 42
751 03 Uppsala
Sweden
Telephone number: ***+46 (0)18-17 46 00*** Fax number: ***+46(0)18-54 85 66***

On behalf of the Medical Products Agency

Signature:

Emilia Bayón Muñiz
Stamp and date: ***17 September, 2012***

Explanatory notes

This certificate, which is in the form recommended by WHO, establishes the status of the medicinal product and of the applicant for the certificate in Sweden. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

Whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names have been used.

The formula (complete composition) of the dosage form should be given on the certificate or be appended.

Details of the quantitative composition are preferred, but their provision is subject to the agreement of the Marketing Authorisation Holder.

When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the Marketing Authorisation.

Indicate, when applicable, if the Marketing Authorisation is provisional.

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 not involved in manufacturing, packaging or labelling but is responsible for the quality and release of the product.
(d) is involved in none of the above.

This information can be provided only with the consent of the Marketing Authorisation Holder. 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 Marketing Authorisation. If the production site is changed, the Marketing Authorisation must be updated or it will cease to be valid.

This refers to the document, prepared by some national regulatory authorities, that summarises the technical basis on which the product has been authorised. The Swedish Medical Products Agency does not prepare such a document.

This refers to product information approved by the Medical Products Agency, such as a Summary of Product Characteristics (SPC).

In this circumstance, permission for issuing the certificate is required from the Marketing

13. 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 Standardisation (WHO Technical Report Series, No. 822, 1992, Annex 1).

14. This section is to be completed when the Marketing Authorisation Holder conforms to status (b), (c) or (d) as described in note 7 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.
The Medical Products Agency does not provide attestation relevant to compliance of the manufacture with GMP when manufacture takes place in a country other than that from which the certificate is issued.
Section 2A3.1 and sections 3 to 4 are checked by the Acting Chief Pharmaceutical Inspector at the Medical Products Agency.

Complete composition

Weight/Volume: **279.00 mg**

Capsule content

Active ingredient	
urea (C-14)	37,00 kBq
Other const.	
citric acid, anhydrous	230,00 mg
ethanol (96 per cent)	0,60 mg approx.

Capsule shell

Colourant	
indigo carmine	0,02 mg approx.
titanium dioxide	2,00 mg approx.
Other const.	
gelatin	46,00 mg approx.