MALAYSIA DRUG CONTROL AUTHORITY
CERTIFICATE OF PHARMACEUTICAL PRODUCT [1]

(Superscript number refer to WHO explanatory notes)

This certificate conforms to the format recommended by the WHO (general instructions and explanatory notes attached)

Certificate No: **2139/2019**

Exporting (Certifying) country : **MALAYSIA**

Importing (Requesting) country : **UNITED ARAB EMIRATES**

1. Name and dosage form of product:
HEXBIO MCP GRANULE (ORANGE FLAVOR)

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

Active Ingredient(s)	Quantity
See Attachment	

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

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 ☐Unknown

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 with section 2B[6]

2A.1 Number of product licence[7] and date of issue : Registration No : **MAL06071166X**
Date of Issue : **29th JULY 2016**

2A.2 Product-licence holder (Name and address):

Name : **B-CROBES LABORATORY SDN BHD**
Address : **18 & 20, LINTASAN PERAJURIT 17G, TAMAN TEKNOLOGI INDUSTRI & PERUSAHAAN IPOH, 31400 IPOH PERAK MALAYSIA**

2A.3 Status of product-licence holder[8] ☑a ☐b ☐c

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9]:

2.A.4 Is Summary Basis of Approval appended?[10] ☐Yes ☑No

2A.5 Is the attached, officially approved product information provided complete and consonant with the licence?[11] ☑Yes ☐No ☐Not provided

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

Name :
Address :

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

2B.2 Status of applicant[8] : ☐a ☐b ☐c

2B.2.1 For categories b & c, the name and address of the manufacturer producing the dosage form is[9] :

2B.3 Why is marketing authorisation lacking? ☐Not required ☐Under consideration ☐Not requested ☐Refused

2B.4 Remarks[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14] ☑Yes ☐No ☐N/A
If not applicable proceed to question 4

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

3.2 Has the manufacture of this type of dosage been inspected? ☑Yes ☐No

3.3 Do the facilities and operations conform to GMP as recommended by the WHO?[15] ☑Yes ☐No ☐N/A

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the products?[16] ☑Yes ☐No
If no explain

THIS CERTIFICATE EXPIRES TWENTY FOUR MONTHS FROM THE DATE ISSUED

Address of the certifying authority : **Drug Control Authority**
National Pharmaceutical Regulatory Division (NPRA)
Ministry of Health Malaysia
Jalan Universiti, Peti Surat 319,
46730 Petaling Jaya MALAYSIA

Telephone number : **(603)-78835400**
Fax number : **(603)-79581312**

Name of authorised person : **ROSILAWATI BINTI AHMAD RPh.1413**

Stamp and date : **27th DECEMBER 2019**

Signature of authorised person :

Rosilawati binti Ahmad (RPh.1413)
Secretary
Drug Control Authority
Ministry of Health Malaysia

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth/Death Certificate is that of ROSILAWATI BINTI AHMAD who is from Ministry of Health
The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.

Mohd Tarmizi Mohd Taib
Consular Officer
Consular Division
Ministry of Foreign Affairs
Putrajaya Malaysia
02 JAN 2020

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. If no, the reason why the licence holder has elected not to market the product is Malaysia is indicated.

6. Section 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 non 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 product, the applicant. Non-completion of this section indicated 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 the product licence.

10. This refers to the document, prepared by some national regulatory authority, that summarizes the technical basis on which the product has been licenced.
11. This refers to product information approved by the competent national regulatory authority, such as 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 condition – particularly tropical diseases – not endemic in the country of export;
   (b) the product has been reformulated with the view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical product 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 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 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 product 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 or manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.