GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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

Certificate Number: DA/6-194/2015/ 1189 Date: 28 JAN 2023

Exporting (certifying) Country : **BANGLADESH**

Importing (requesting) Country : **SRI LANKA**

1. Name and dosage form of the Product : **HYDRASON 20 TABLET**

1.1 Active Ingredient(S) [2] and amount (S) [3] per unit dose:

Active Ingredient (S)	Amount per unit dose
Hydrocortisone USP	20.00 mg

For Complete Composition including excipients, see attached [4]

1.1 In this product licensed to be placed on the market **YES** ☑ **NO** ☐

For use in the exporting Country? [5]

1.2 Is this product actually on the market in the exporting country? **YES** ☑ **NO** ☐

1.3 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 the Product Licence[7] and date of issue:

DAR No : **309-128-072**

Date of issue : **28-11-2018**

2A.2 Product Licence holder: **Name** : **DRUG INTERNATIONAL LIMITED.**

Address: Plant : **13A & 14A, TONGI I/A, SQUIBB ROAD TONGI, GAZIPUR, BANGLADESH.**

Office : "KHWAJA ENAYETPURI (R :) TOWER" 17, Bir Uttam K. M. Shafiullah Sarak, (Green Road), Dhaka-1205, Bangladesh

2A.3 Status of the Product Licence [8] holder: **Manufacturing and Marketing of the product.**

2A.3.1 For categories b and c the name and address of the manufacturing Producing the dosage form is [9]: **N/A.**

2A.4. Is a summary basis of approval appended? [10]: **YES** ☐ **NO** ☑

2A.5 Is the attached, officially approved product information completed and consonant with the license? [11] **NOT PROVIDED**

2A.6 Applicant for certificate, if different from licence holder (name and address) [12] **N/A**

Digitally signed by Chief Executive Officer
Date: 2023.03.04 16:48:54 EET
Reason: MoldSign Signature
Location: Moldova

3. Does the certifying authority arrange for periodic inspection of the Manufacturing plant in which the dosage form is produced? [14] **YES** ☑ **NO** ☐

3.1 Periodicity of routine inspection (years): **EVERY 2 (TWO) YEARS**

3.2 Has the manufacture of this type of dosage form been inspected? **YES** ☑ **NO** ☐

3.3 Do the facilities and operation conform to GMP as Recommended By the World Health Organization? [15] **YES** ☑ **NO** ☐

4. Does the information Submitted by the applicant satisfy the Certifying Authority on all aspects of the manufacture of the product: **YES** ☑ **NO** ☐

Name of authorized person	:	**MD. EYAHYA**
Address of the certifying authority	:	**Directorate General of Drug Administration** Mohakhali, Dhaka-1212, Bangladesh
Telephone	:	+880-(2)-9880803
Fax No.	:	+880-(2)-9880854
E-mail	:	drugs@citech.net
Web-site	:	www.dgda.gov.bd

Stamp and Date:

MINISTRY OF HEALTH & FAMILY WELFARE * DIRECTORATE GENERAL OF DRUG ADMINISTRATION * DHAKA * GOVT. OF THE PEOPLES REPUBLIC OF BANGLADESH

20 JAN 2023

MD. EYAHYA
Director (CC)
For Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

Explanatory notes

1. This certificate, which is 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 then- 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 authority 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 a Summary Product Characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product license 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:
    i. the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export;
    ii. the product has been reformulated to with a view to improving its stability under tropical condition,
    iii. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    iv. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    v. any other reasons please specify.
14. Not applicable means that the manufacture is taking place in a country other than the 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 the Pharmaceutical Preparations (WHO technical Report Series, No. 822, 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.