DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 3090518/TS/2022 Valid UpTo: **15/06/2025**

1.Name and Dosage form of Product: Exporting(Certifying)Country: **INDIA**

CHLORAMBUCIL TABLETS USP 2mg CELKERAN 2

1.1 Active Ingredients(s)^2 and amount(s) per unit dose^3: Importing(Requesting) country **Mozambique**

Each film coated tablet contains ChlorambucilUSP2mg Excipientsq.s.
Colours: Iron oxide of yellow & Titanium Dioxide USP.

For complete qualitative composition including excipients see above^4

1.2 Is this Product licensed to be placed on the market for use in Exporting country?^5 **Yes**

1.3 Is this product actually on the marketing in the Exporting Country? **Yes**

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 continue with section 2B^6

2A.1 Number of Product Licence^7: **25/HD/AP/2003/F/CC Dated 27.05.2003**

2A.2 Product License Holder(Name and address): CELON LABORATORIES PRIVATE LIMITED. Plot. No. 2, ALEAP Industrial Estate, Gajularamaram, Medchal District 500 090, Telangana State, India.

2A.3 Status of License Holders^8 : a

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 Not Applicable

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is the Attached, officially approved production information complete and consonant with the license?^11: Not Provided

2A.6 Applicant for Certificate, if different from licence holder (name and address) No

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

3 Does the certifying authority arrange for periodic spection of the manufacturing plant in which the dosage form is produced?^14 Yes

3.1 Periodicity of routine inspection(years) Once in a Year

3.2 Has the Manufacture of this type of dosage from been inspected? Yes

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 Yes

Address of Certifying Authority.
Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India
Telephone No : 91-040-23814119 Fax No : 91-040-23814360

Name of the authorized person:
Digitally Signed By
C RAJAVARDHANA CHARY
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:25-06-2022 12:36:47 PM

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes overleaf)

Digitally signed by Harea Ştefan
Date: 2023.07.27 12:51:52 BST
Reason: MoldSign Signature