CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **789/MFG/WHO-GMP/DFDA/2020/154 (4)** **Valid Upto: 19.05.2022**

Exporting (certifying country) : **INDIA**

Importing (requesting country) : **As stated on Page 3**

1. Name and dosage form of the product : **Methotrexate Tablets BP 2.5 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : As stated at Page 3.

For complete 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 section 2B[6]:

2 A

A.1 Number of product licence[7] and date of issue: 616 dated 20.05.2003 Letter No. 789/(13)/MFG/DFDA/2015/2652 Dated 20/08/2015 in Form 25, under Drugs & Cosmetics Rules 1945

A.2 Product licence holder (name and address): **M/s Cipla. Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L – 147/1 to L-147/3 & L-147/A Verna Industrial Estate, Verna Goa.**

A.3 Status of product licence holder[8]: a ☒ b ☐ c ☐

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]: Not applicable

A.4 Is a summary basis of approval appended?[10] Yes ☐ No ☒

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

A.6 Applicant for certificate, if different from licence holder (name and address)[12]: Not applicable

2B NOT APPLICABLE

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

B.2 Status of applicant: a ☐ b ☐ c ☐

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

B.3 Why is marketing authorization lacking?

☐ not required ☐ not requested ☐ under consideration ☐ refused

B.4 Remarks[13]:

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question

3.1 Periodicity of routine inspections (years): **Minimum once in a year**

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

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

Yes ☒ No ☐ Not applicable[14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

Yes ☒ No ☐

If no, explain:

Address of certifying authority:
Directorate of Food & Drugs Administration,
Govt. of Goa,
"DHANWANTARI", Opp. Shrine of The Holy Cross,
Bambolim, Goa – 403 202, INDIA.
Telephone: 0832-2459230/ 2459226
Fax : 0832-2459223
Website: www.dfda.goa.gov.in

Name of authorized person: Jyoti J. Sardesai
Director

Signature:

Stamp and date: DIRECTORATE OF FOOD & DRUGS ADMINISTRATE BAMBOLIM GOA

17 APR 2020

General Instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand written.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

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 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:
(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-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:
(a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
(b) the product has been reformulated with a view to improving its stability under tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products 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 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.

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE TO CERTIFICATE NO. : **789/MFG/WHO-GMP/DFDA/2020/154 (4)**

Name of product : **Methotrexate Tablets BP 2.5 mg**

Composition : Each uncoated tablet contains:
Methotrexate BP ..... 2.5 mg
Excipients ..... q.s.

Excipients Used :

Ingredients	Std. Quantity (mg/Tablet)
Microcrystalline Cellulose (MCC for DC) (AVICEL PH 102) BP / Ph.Eur	21.075
Anhydrous Calcium Hydrogen Phosphate BP / Ph.Eur	6.375
Lactose for DC (Tablettose 80 / Super Tab) BP / Ph.Eur	12.500
Sodium Starch Glycollate (Primojel) (Type A) BP / Ph.Eur	1.800
Purified Talc BP / Ph.Eur	0.375
Magnesium Stearate (Vegetable Grade) BP / Ph.Eur	0.375

Product presentation : Tablets

Shelf life : 36 months

Pack size : 10 Tablets in Blister/Strip, 100 Tablets in HDPE bottle/Container pack.

Importing country :
Afghanistan, Albania, Algeria, Angola, Andorra, Aruba, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chile, China, Colombia, Comoros, Congo, Costa Rica, Croatia, Cook Islands, Cuba, Curacao Cyprus, Czech Republic, Democratic Republic of Congo, Denmark, Djibouti, Dominica, Dominican Republic, East Timor, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Federated States of Micronesia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea Equatorial, Guinea-Bissau , Guinee, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, Indonesia, Iran, Iraq, Ireland, Italy, Ivory Coast, Jamaica, Japan, Jamahiriya, Jordan, Kazakhstan, Kenya, Kosovo, Kiribati, Kuwait, Kurdistan, Kyrgyzstan, Laos, Latvia, Lebanon, Lesotho, Liberia, Libya, Libyan Arab Jamahiriyan Liechtenstein, Lithuania, Luxembourg, Macau, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Moldova, Monaco, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands, Netherlands Antilles, New Zealand, Nicaragua, Niger, Nigeria, Niue, North Korea, Norway, Oman, Pakistan, Palau, Panama, Palestine Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, Somaliland South Africa, South Korea, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syria, The former Yugoslav Republic of Macedonia Tadzhikistank, Taiwan, Timor Leste, Tajikistan, Tanzania, Tchad, Thailand, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States, Uruguay, Uzbekistan, Vanuatu, Vatican City, Venezuela, Vietnam, Western Sahara, West Indies, Yemen, Yugoslavia, Zambia, Zimbabwe.

DIRECTORATE OF FOOD & DRUGS ADMN.

Jyoti V. Sardesai
Director, Food & Drugs Admn.,
Bambolim, Goa