FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **COPP/CERT/PD/96294/2020/11/32810/164572** Valid Upto: 02 Nov 2021

Exporting Country : INDIA

Importing Country : **CHILE**

1. Name and dosage form of product : **Solivo**
Leflunomide Tablets 20 mg

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

Leflunomide Ph.Eur 20 mg	Excipients qs

For complete qualitative composition including excipients :[4] As per Annexure

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 ☐

2A.1 Number of product license:[7] **PD149 in Form 25**
and date of issue: **17 Jul 2020**

2A.2 Product License holder (Name and address) :
EMCURE PHARMACEUTICALS LTD PLOT NO. P1 AND P2, I.T.B.T. PARK PHASE-II, M.I.D.C. HINJAWADI PUNE 411057 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder :[8]
A ☒ B ☐ C ☐

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

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

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

2A.6 Applicant for certificate if different from License holder :[12]
Not Applicable

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

2B.2 Status of applicant :
A ☐ B ☐ C ☐

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

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ 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 ?
if no or not applicable proceed to question 4. Yes ☒ No ☐ Not Applicable[14] ☐

3.1 Periodicity of routine inspections(years) : **Once 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 World Health Organisation ?[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 :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959
4CME1119629420200806H88

Name of the Authorised person : J. B. MANTRI

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:06 Aug 2020

3 NOV 2020

NOTARY SURAJ DHARMARAJ KHADE GOVERNMENT OF INDIA

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE PUNE 056204 03 NOV 2020 MAHARASHTRA (INDIA)

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar, Pimpri, Pune-18. Mob-9850666405

LALIT MADHAV WAYKOLE
DEPUTY DIRECTOR

GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction 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 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 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 dosages 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 be provided only 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 must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product Licence holder. This e applicant.
ided for not requesting registration:
for the treatment of conditions – particularly tropical
improving its stability under tropical conditions:
xcipients not approved for use in pharmaceutical products
fferent maximum dosage limit for an active ingredient
ing place in a country other than that issuing the product
gis of the country of manufacture.
acture and quality control of drugs referred to the certificate
he Expert Committee on Specifications for Pharmaceutical
No.823 , 1992 , Annex 1) Recommendations specifically
mulated by the WHO Expert Committee on Biological
No . 822, 1992, Annex 1).
licence holder or applicant conforms to status (b) or (c) as
mportance when foreign contractors are involved in the
es the applicant should supply the certifying authority with
onsible for each stage of manufacture of the finished dosage
rcised 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.

(PRAKASH KUMAR)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

Annexure of Excipients

No. of certificate : COPP/CERT/PD/96294/2020/11/32810/164572 VALID UP TO :02 Nov 2021

Name of the Company : EMCURE PHARMACEUTICALS LTD PLOT NO. P1 AND P2, I.T.B.T. PARK PHASE-II, M.I.D.C. HINJAWADI PUNE 411057 MAHARASHTRA STATE, INDIA

Name and dosage form of product : Solivo Leflunomide Tablets 20 mg

Sr.No.	Ingredients	Specification	Qty/Units
1	Lactose Monohydrate (MOD. SPRY Dry Fast FLO)	Ph.Eur	99.400 mg
2	Pregelatinized Starch (Starch 1500)	Ph.Eur	30.000 mg
3	Croscarmellose Sodium (AC-DI-SOL)	Ph.Eur	6.000 mg
4	Silica Colloidal Anhydrous (Aerosil® 200PH)	Ph.Eur	1.600 mg
5	Talc (Luzenac Pharma M)	Ph.Eur	2.000 mg
6	Magnesium Stearate (Ligamed MF-2-V)	Ph.Eur	1.000 mg

NOTARY SURAJ DHARMARAJ KHADE PIMPRI - CHINCHWAD MAHARASHTRA REG. No. 6458 EXP. DATE 31/12/2021 GOVERNMENT OF INDIA

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
4CME1119629420200806H88

Name of the Authorised person : J. B. MANTRI

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:06 Aug 2020

3 NOV 2020

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE PUNE 056204 03 NOV 2020 MAHARASHTRA (INDIA)

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-9850666405

LALIT MADHAV WAYKOLE
DEPUTY DIRECTOR

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13 NOV 2020

SURAJ D. KHADE
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GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18, Mob-9850666405

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भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by LALIT MADHAV WAYKOLE
acting in the capacity of DY. DIRECTOR
bears the seal/stamp of MAHRATTA CHAMBER OF COMMERCE INDUSTRIES AND AGRICULTURE

Certified

4. at NEW DELHI, INDIA the 06-Nov-2020
5. by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
6. No MHMC0003414720

Signature

Seal / Stamp

7. is issued to EMCURE PHARMACEUTICALS LTD.

The Ministry of External Affairs accepts no responsibility for the contents of the attached documents

(पल्लवी करारा)
(PALLAVI KARARHA)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Emcure

NOTARY SURAJ DHARMARAJ KHADE PIMPRI - CHINCHWAD MAHARASHTRA REG. No. 6460 EXP. DATE: 31/07/2023 GOVERNMENT OF INDIA

cGMP Certificate

Date: 02 April 2020

Leflunomide Ph.Eur.

TO WHOMSOEVER IT MAY CONCERN

M/s. Emcure Pharmaceuticals Limited hereby declare that, the methods, facilities and controls being used for manufacture & release are and will be in conformity with Current Good Manufacturing Practices in accordance with applicable parts of 21 CFR Parts 210 and 211 and ICH Q7.

For **Emcure Pharmaceuticals Limited**

02 Apr 2020

Tushar Kulkarni
Manager QA

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE
PUNE
056209
03 NOV 2020
MAHARASHTRA (INDIA)

3 NOV 2020

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-9850666405

LALIT MADHAV WAYKOLE
DEPUTY DIRECTOR

Emcure Pharmaceuticals Limited
D-24, M.I.D.C., Kurkumbh, Tal. Daund, Dist. Pune - 413 802
Phone Nos. : 02117 - 235742 / 305000 Telefax No. : 02117 - 235743
Registered Office : Emcure House, T-184, M.I.D.C., Bhosari, Pune 411 026. INDIA
Phone Nos. : + 91 20 30610000, 27120084 Fax No. : 91 - 20 - 30610111 E.mail : corporate@emcure.co.in
CIN : U24231PN1981PLC024251

For: Chile.

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3 NOV 2020

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18, Mob-9850666405

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Country REPUBLIC OF INDIA

This public document
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acting in the capacity of DY. DIRECTOR
bears the seal/stamp of MAHRATTA CHAMBER OF COMMERCE INDUSTRIES AND AGRICULTURE

Certified
at NEW DELHI, INDIA the 06-Nov-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0003415820

Seal / Stamp
Signature
is issued to EMCURE PHARMACEUTICALS LTD

The Ministry of External Affairs accept no responsibility for the contents of the above documents

(पल्लवी करारा)
(PALLAVI KARARHA)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
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