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/KD/108308/2021/11/37925/186432 **Valid Upto :28 Oct 2023**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **REMWIN**
REMDESIVIR FOR INJECTION 100 MG (LYOPHILIZED)

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each Vial Contains:

Remdesivir	100 mg	Excipients qs	Powder for concentrate for solution for infusion

For complete qualitative composition including excipients :[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 ☐

2A.1 Number of product license:[7] **103908A In Form 28A**
and date of issue: **15 Jul 2021**

2A.2 Product License holder (Name and address) :
SYNGENE INTERNATIONAL LIMITED. PLOT NO.C/4/10/B/2, 1ST FLOOR,PRINCE PLAZA SHOPPING COMPLEX CENTRE,GIDC AREA, ANKLESHWAR, BHARUCH, ANKLESWAR
Mfg At: KAMLA LIFESCIENCES LTD PLOT NO G-84/1 TARAPUR MIDC BOISAR PALGHAR 401506 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.

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**29 Oct 2021**

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Reason: MoldSign Signature
Location: Moldova

GENERAL INSTRUCTION:

Please refer to the guidelines for full instructions how to complete with form an information on implementation of the scheme. The forms are suitable for generation by computers. They should always be submitted as hard copy with responses printed in type rather 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, where possible, international Nonproprietary Name (INNs) or national nonproprietary names.

3. The formula (Complete composition) of the dosage from 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-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 label 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-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 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 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 of 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:

(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 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 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 7 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.

Drugs Administration, Maharashtra State, Mumbai 400051, India

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/KD/108308/2021/11/37925/186432 Valid up to: 28 Oct 2023

Name of the Product License Holder : SYNGENE INTERNATIONAL LIMITED. PLOT NO.C/4/10/B/2, 1ST FLOOR,PRINCE PLAZA SHOPPING COMPLEX CENTRE,GIDC AREA, ANKLESHWAR, BHARUCH, ANKLESWAR

OWN License Holder : KAMLA LIFESCIENCES LTD PLOT NO G-84/1 TARAPUR MIDC BOISAR PALGHAR 401506 MAHARASHTRA STATE, INDIA

Name of the Product : REMWIN

: REMDESIVIR FOR INJECTION 100 MG (LYOPHILIZED)

List of Countries For Export

Armenia	Belarus	Georgia	Kazakhstan	Mongolia	Nepal	South Africa	Thailand	Uzbekistan
Azerbaijan	Cambodia	Guinea	Moldova	Myanmar	Philippines	Sri Lanka	Ukraine	Vietnam
Bangladesh	Dominican Republic	Indonesia						

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
SNYS2491083082021102910l

Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Oct 2021