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جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للشئون الصيدلية
الإدارة العامة للتسجيل
إداره اصدار شهادات التصدير والتسعيره

Code No. FM-REC-01

Certificate of Pharmaceutical Product

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

Certificate No.: 01046/2020 /H
Certificate Date: 01-July-2020
Exporting Country: Arab Republic of Egypt
Importing Country: Phillipines

1. Trade Name & Dosage Form of the product in the Exporting Country :
   Remdesivir- Eva Pharma Concentrate for solution for IV infusion
   Trade Name & Dosage Form of the product in the Importing Country:
   Remdesivir- Eva Pharma Concentrate for solution for IV infusion

1.1. Active Ingredient and amount per unit dose:
Composition Per vial (20 ml solution):

Active Ingredient:	
Remdesivir	100 mg
Inactive Ingredients:	
Betadex sulfobutyl ether sodium	6 g
Sodium hydroxide	Q.S
Hydrochloric acid	Q.S
Water for injection to	20 ml
*Nitrogen is used in production as manufacturing Auxiliary agent	

1.2. Is this product licensed in the exporting country? **As An Emergency Use Authorization License**
1.3. Is this product actually on the market in the exporting country? **Hospitals Use Only**

If answer to1.2.is yes continue to section 2A& omit section 2B
If answer to1.2.is no continue to section 2B& omit section 2A

2. A.1. Number of product licence and date of issue:33967/2020 –Date:11/06/2020
2.A.2. Name and address of the product license/marketing authorization holder:
Eva pharma for pharmaceuticals and medical appliances –
176, El Sadate St., Kafr El- Gabal- Pyramids- Giza
2.A.3. Status of the product license holder:
   a. Manufactures the finished dosage form ■
   b. Packages and/or labels dosage form manufactured by another company □
   c. Is involved in none of the above □
2.A.3.1. For categories (b) and (c) the name and address of the manufacturing site is:
2.A.4. Is a summary basis for approval appended? Yes( ) No(√)
2.A.5. Is the attached, officially approved product information complete and consonant with the license? Yes ( ) No ( ) Not Provided (√)
2.A.6. Applicant for certificate If different from license holder (name& address):
2.B.1. Applicant for certificate Name & Address:
2.B.2. Status of the applicant:
   a. Manufactures the finished dosage form □
   b. Packages and/or labels dosage form manufactured by another company □
   c. Is involved in none of the above □
2.B.2.1. For categories (b) and (c) the name and address of the manufacturing site is:

Tel.: +202 – 23684288 +202 – 23640368 +202 – 23648769 +202 – 25354100 Ext.:1413 Fax: +202 - 23684194
Website: www.eda.mohp.gov.eg Version: 1.1 Email: cpp@eda.mohp.gov.eg

is marketing authorization lacking?
quired/not requested/under consideration/refused)
Remarks:

Does the certifying authority arrange for periodic inspection of the manufacturing plant? Yes (√) No ( )

If no or not applicable, proceed to section 4

3.2.Periodicity of Routine inspection: 2Years

3.3.Has the manufacturer of this type of dosage form been inspected? Yes (√) No ( )

3.4.Do the facilities and operations conform to GMP as recommended by the World Health Organization? 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 ( )

5. Additional information of the product:

A. Package: Carton box containing Clear colorless type 1 glass vial closed with bromobutyl rubber and flip-off plastic cap with insert leaflet.
B. Shelf Life: 6 months.

Revised By: Dr. Mona Abdelaziz

Checked By: Dr. Noha

Head of
General Directorate of Registration

Dr. Hanan Amin

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