

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

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):

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

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 to 1.2.is yes continue to section 2A& omit section 2B*

*If answer to 1.2.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:

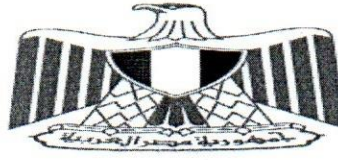
2.B.2. Status of the applicant:

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:



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is marketing authorization lacking?

(required/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. Mena Abdelaziz*

Checked By: *Dr. Noha*

Head of  
General Directorate of Registration

