

Certificate of Pharmaceutical Product (CPP)

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

Certificate No.: 00902/2024/H

Certificate Date: 20-March-2024

Exporting Country: Arab Republic of Egypt

Importing Country: Yemen

1. Trade Name & Dosage Form of the product in the Exporting Country: Tecavir 1 mg film coated tablets

Trade Name & Dosage Form of the product in the Importing Country: Tecavir 1 mg film coated tablets

1.1. Active Ingredient and amount per unit dose:

Active Ingredient	Amount per film coated tablet
Entecavir monohydrate (Eq.to 1mg Entecavir)	1.06 mg

1.2. Is this product licensed in the exporting country?

Yes (✓) No ()

1.3. Is this product actually on the market in the exporting country?

Yes (✓) No ()

*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 license and date of issue:

License no. 26798/2010 - Date: 7/10/2010 Submitted for re-registration

2.A.2. Name and address of the product license/marketing authorization holder:

**Eva pharma for pharmaceuticals and medical appliances –
176 E Sadat st. from El mansouriya Canal - Kafr El Gabal - El 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:

2.B.3. Why is marketing authorization lacking?

(not required/not requested/under consideration/refused)

2.B.4. Remarks:



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Certificate No.: 00902/2024/H

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 Manufacturer of the product?

Yes (✓) No ()

5. Additional information of the product:

A. Package: Carton Box contains 1, 2 or 3 (AL/AL) blisters, each of 10 film coated tablets with leaflet.

B. Shelf Life: 2 years.

Date of Expiry: **20-March-2026**

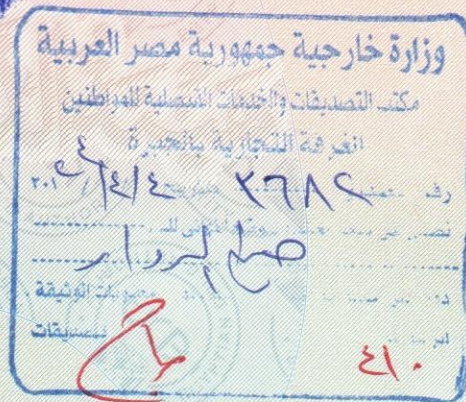
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Head of Central Administration
For Pharmaceutical Products

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Page 2

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