0189426

Certificate of Pharmaceutical Product (CPP)

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

Certificate No.:**00982/2025/H**
Certificate Date: **07-May-2025**
Exporting Country: **Arab Republic of Egypt**
Importing Country: **Azerbaijan**

1. Trade Name & Dosage Form of the product in the Exporting Country: **Tenofenamide 25mg film coated tablets**
   Trade Name & Dosage Form of the product in the Importing Country: **Tenoscan 25mg film coated tablets**

1.1. Active Ingredient and amount per unit dose:

Active Ingredient	Amount per film coated tablet
Tenofovir Alafenamide hemifumarate Eq. To Tenofovir Alafenamide 25 mg	28mg

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 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 license and date of issue:
License no. **33963/2024** –Date: **22/08/2024**

2.A.2. Name and address of the product license/marketing authorization holder:
EVAPHARMA for Pharmaceutical Industries (EVAPHARMA).

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:
Eva Pharma for Pharmaceuticals and Medical Appliances (EVA Pharma),
176 El-Sadat Street, Kafr El-Gabal, Haram, Giza, Egypt

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:

Digitally signed by Sîli Oleg
Date: 2025.09.12 13:09:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Website: http://edaegypt.gov.eg Tel.: +202 - 25354100 Ext.:1203
Email: cpp@edaegypt.gov.eg Address: 21 Abdel Aziz Al Saud Street, Manial Al Rawdah, Cairo Governorate

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2.B.3. Why is marketing authorization lacking?
(not required/not requested/under consideration/refused)

2.B.4. Remarks:

3.1. 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 containing 1, 2 or 3 (AL/ AL) blisters, each of 10 film coated tablets and an inner leaflet.**

B. Shelf Life: **3 years**.

Date of Expiry: **07-May-2027**

Revised By: Dr. Amin Sabry

Checked By: Dr. Amin Sabry

Head of Central Administration
For Pharmaceutical Products
Dr. Hanan Amin

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