BAHAGIAN REGULATORI FARMASI NEGARA
National Pharmaceutical Regulatory Agency
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Lot 36, Jalan Prof. Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor, Malaysia

Tel: +603-78835400
https://www.npra.gov.my

GMP Certificate No. M019/25

Our Ref. : KKM/NPRA.PKP/600-2/5 (61) Jld 43
Date : 21 July 2025

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confirms the following:

The Manufacturer : **Getz Pharma (Pvt) Ltd**

Site Address : **29-30, Sector 27,**
Korangi Industrial Area,
Karachi 74900,
Pakistan.

Has been inspected in accordance with Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **10-13 February 2025**, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guides.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.

(DR. AZUANA RAMLI) RPh. 1889
Director of Pharmaceutical Services

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Part II

√ Human Medicinal Products

1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS	
1.2	**Non-sterile Products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.9 Pressurized preparations 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.9 Pressurized preparations 1.5.1.13 Tablets
1.6	**Quality Control Testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate: -None-

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(DR. AZUANA RAMLI) RPh. 1889
Director of Pharmaceutical Services

Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations and Coordination
2nd Floor Building No.4 Block-B
S.M.C.H.S, Karachi
*****

Certificate No. 76/2023-DRAP (K)

Karachi the, 06th December, 2023

CERTIFICATE OF CURRENT GOOD MANUFACTURING PRACTICES (LOCAL)

It is to certify that M/s. Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi holding DML No.000284 is authorized to produce medicine of following categories and is found complying with cGMP in terms of process control, maintenance of equipment and documentation as GMP guidelines etc. as per provisions of Drugs Act, 1976 and the rules framed there under:

Formulation	Pharmaceutical Categories	Activity(ies)
Tablet	General	Mixing, Drying, Granulation, Compression, Coating, Blistering, Packing & Batch Release
Capsule	General	Mixing, Drying, Granulation, Filling, Blistering, Packing & Batch Release
Dry Powder Suspension	General	Mixing, Granulation Filling, Packing & Batch Release
Dry Powder Injectables	General	Filling, Packing, & Batch Release
Sachet	General	Mixing, Granulation, Filling, Packing & Batch Release
Liquid Injectables	General	Mixing, Filtration, Filling, Sterilization, Packing & Batch Release
Liquid Injectables	Insulin	Compounding, Filling, Packing & Batch Release
Metered Dose Inhalers (MDIs)	General / Steroidal	Manufacturing, Filling, Labeling, Packing & Batch Release
Dry Powder Inhaler Capsules	General / Steroidal	Mixing, Filling, Blistering, Packing & Batch Release

Certification is based on evaluation conducted on **10th November, 2023**

- This certificate is valid for two years from the date of issuance.
- Responsibility to maintain quality of Good Manufacturing Standard throughout the period of validity of this certificate will lie on the manufacturer itself as per Drugs Act, 1976 and the rules framed there under:
- This certificate also permits the firm to apply for registration of their products, manufactured as per valid Drug Manufacturing License issued by Drug Regulatory Authority of Pakistan, in the importing country.
- The validity will automatically cease in case of reporting of non-compliance of current Good Manufacturing Practices (cGMP) under the Drugs Act, 1976 and rules framed there under.
- This certificate is in line with the format as recommended by WHO (TRS No. 908, 2003).
- This certificate is issued on the request of M/s. Getz Pharma (Pvt) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi

GOVERNMENT OF PAKISTAN DRAP KARACHI

Signature:
Name: **Abdul Rasool Sheikh**
Designation: Additional Director
Stamp: (ABDUL RASOOL SHAIKH) Additional Director Government of Pakistan Drug Regulatory Authority of Pakistan Karachi

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
2nd Floor, USAID Building, No IV, Block B, SMCHS, Karachi
****

CERTIFICATE OF PHARMACEUTICAL PRODUCT

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

Certificate No.: **COPP-C-892998**
Exporting Country: **Islamic Republic of Pakistan**

Date of Issue: **19/06/2025**
Importing Country: **Nigeria**

1. Property Name (if applicable) and dosage form	1.1 Active ingredient(s) and amount(s) per unit dose
Getinomide Tablets 25mg	Each film-coated tablet contains: Tenofovir alafenamide fumarate equivalent to Tenofovir alafenamide.....25mg **Each film coated tablet contains:** **Tenofovir alafenamide fumarate equivalent to Tenofovir Alafenamide.....25mg** **(IN-HOUSE Specification)**

For complete composition including excipient, see attached.

1.2 Is this product licensed to be placed on the market for use in the exporting country? Yes ☑ No ☐

1.3 Is this product actually on the market in the exporting country? Yes ☑ No ☐

If the answer to 1.2 is Yes, continue with section 2A and omit section 2B.
If the answer to 1.2 is No, omit section 2A and continue with section 2B

2A	2B
2.A.1 Number of Product License and date of issue: Reg. No.**006378-EX** Dated:- **05 06,2017** 2.A.1 Product license holder(name and address): **GETZ PHARMA (PRIVATE) LIMITED, PLOT # 29 30 SECTOR 27, KORANGI INDUSTRIAL AREA, KORANGI KARACHI, Korangi Korangi Town.** 2.A.3 Status of the product license holder a) ☑ b) ☐ c)☐ 2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form 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 and address).:N/A	2.B.1. Applicant for certificate,(name and address): , 2.B.2. Status of applicant: (Key in appropriate categories as defined in footnote) a) ☐ b) ☐ c)☐ 2.B.2.1 For categories(b) and (c) the name and address of the manufacturer producing the dosage form is ,. 2.B.3 Why marketing authorization lacking? Not Required ☐ Not Requested ☐ Under Construction ☐ Refused ☐ 2.B.4 *Remarks:*

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced?
Yes ☑ No ☐ Not Applicable ☐
If not or not applicable, proceed to question 4.
3.1. Periodicity of routine inspections (Year): **Twice a year.**
3.2. Has the manufacturer of this type of dosage form been inspected? Yes ☑ No ☐
3.3. 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 ☐ (If no, Explain):

Address of certifying authority:
2nd Floor, USAID Building, No IV, Block B, SMCHS, Karachi
Note: Valid upto (1) Year.

Name of authorized Person: **Obaid Ali**
Designation: **Additional Director (QA & LT-I), DRAP, Islamabad**

Note: This is the system generated document and does not require any signature. This document can be verified electronically/Online through the QR code available on the document.

Explanatory Notes

- 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.
- Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
- The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- Details of quantitative composition are preferred but their provision is subject to the agreement of the product-license holder.
- When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
- Sections 2A and 2B are mutually exclusive.
- Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
- Specify whether the person responsible for placing the product on the market:
    - manufactures the dosage form;
    - packages and/or labels a dosage form manufactured by an independent company; or
    - is involved in none of the above.
- This information can only be provided 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 has to be updated or it is no longer valid.
- This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC).
- In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to be provided to the authority by the applicant.
- Please indicate the reason that the applicant has provided for not requesting registration:
    - The product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export.
    - The product has been reformulated with a view to improving its stability under tropical conditions.
    - The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
    - The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    - Any other reason, please specify.
- Not applicable means 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.
- 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).
- This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

QUALITATIVE AND QUANTITATIVE COMPOSITION

GETINOMIDE TABLETS 25mg

(TENOFOVIR ALAFENAMIDE)

Composition	Quantity (mg/Tablet)
Each Film-Coated Tablet contains:	
Active Ingredient:	
Tenofovir Alafenamide Fumarate *	** 28.04
Excipients:	
Lactose Monohydrate	70.00
Avicel PH-102 (Microcrystalline Cellulose)	91.96
Croscarmellose sodium	3.00
Magnesium stearate	1.50
Blending Materials:	
Croscarmellose sodium	4.00
Magnesium stearate	1.50
Film Coating Materials:	
Opadry Yellow 85G32558	5.00
Purified Talc ***	Q.S
Purified Water ***	28.33

Tenofovir Alafenamide Fumarate is used as Hemifumarate form.

***28.04 mg of Tenofovir Alafenamide Fumarate is equivalent to 25.0 mg of Tenofovir Alafenamide.*

****Purified Water and Purified Talc will not be appeared in the final product. Purified Talc will be used during coating to enhance smooth rolling of the tablet bed.*

Q.S = Quantity Sufficient

GOVERNMENT OF PAKISTAN DRAP KARACHI

Approved By
Fawaz Ahmed Khan
((Deputy Director R & D – Formulation and Process)