FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

KMLEVO TABLET 500mg

Levofloxacin Hemihydrate

AFH0106/25

KNVM Medicare Pvt. Ltd. - KH. No. 959, Udyog Kunj, Ghaziabad, UP, India, India

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Administrative info

Dosage Form	Tablet
Strength	500mg
Applicant's Name & Postal Address	KNVM Medicare Pvt. Ltd. - KH. No. 959, Udyog Kunj, Ghaziabad, UP, India, India
Manufacturer's Name & Address	TRIDENT LIFELINE LIMITED, 2nd Floor, North Extension, Falsawadi, Ring Road, Surat-395 003.Gujarat(INDIA), India
Local Agent	Med House Pharmaceutical Ltd, Fokal House No. 3 (first floor), official street, Adabraka, Accra, Ghana

1. Part 1

1.1 Abstract

Based on the review of the data on quality, safety and efficacy, the application for KMLEVO TABLET 500mg, used to treat bacterial infections in adults is approved.

1.2 Executive Summary

1.2.1 About the product

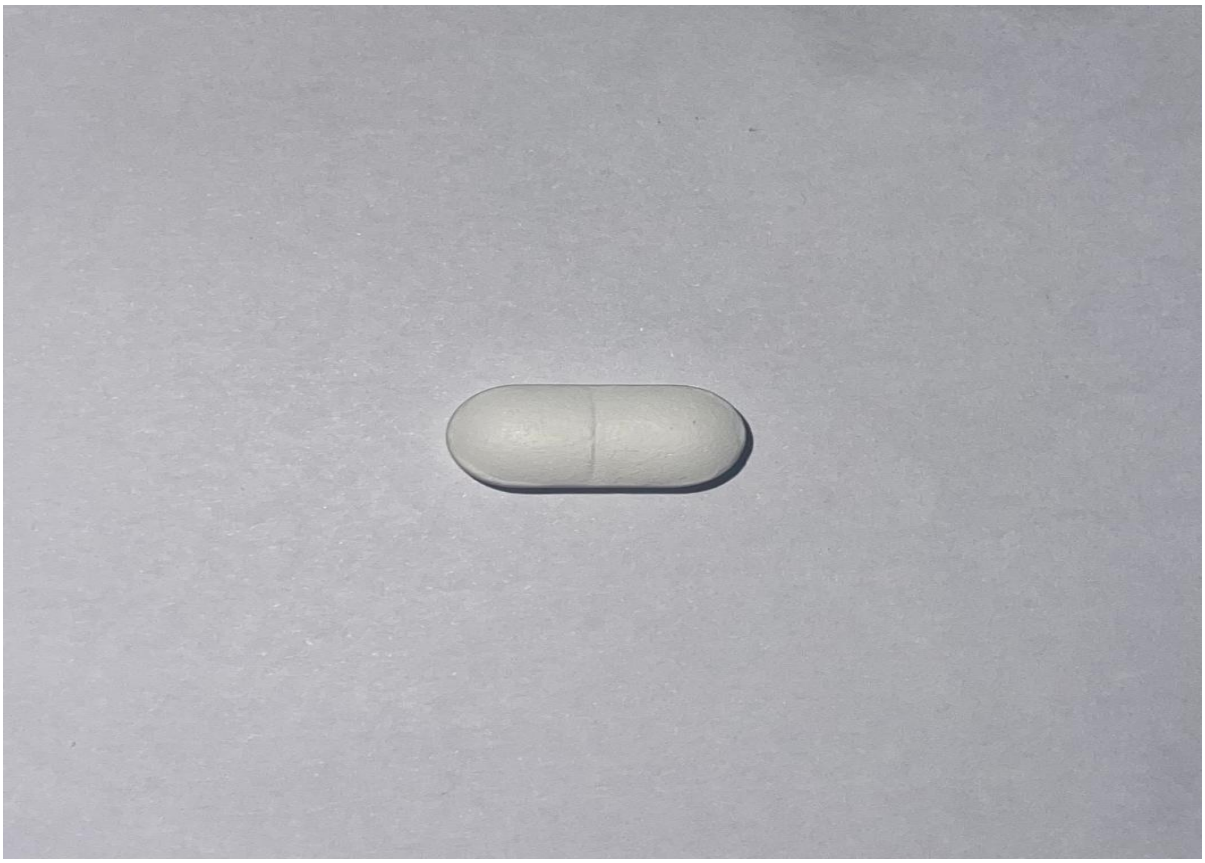
A comprehensive description of the indications and posology is given in the SmPC. This registration application concerns a generic application.

The marketing authorization has been granted pursuant to section 118 of the Public Health Act, Act 857.

2. Part 2a: All accepted presentations (Description of all accepted presentations and dosages, as given in the product dossier)

FDA Registration Number	Product Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package Size
FDA/SD.255-020296	KMLEVO 500 MG	500mg	Film-coated tablet	Oral	Aluminum-Aluminium Blister Pack	1x10 tablets

Part 2b: Appearance of Product (Photograph of formulation (solid forms) or other product characteristics (liquid forms)



3. Part 3: Product information for the user (Patient Information Leaflet - PIL)

KMLEVO-500MG-TABLETS-LEVOFLOXACIN-PIL.pdf

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC)

KMLEVO-500-MG-TABLETS-LEVOFLOXACIN-SMPC.pdf

5. Part 5: Labelling

5.1 Particulars to appear on the Outer Packaging (Secondary Package)

- **Name of the medicinal product**

KMLEVO 500 mg tablets
Levofloxacin hemihydrate

- **Statement of active substance**

Each tablet contains 500 mg Levofloxacin Hemihydrate

- **List of excipients (excipient of safety concern)**

N/A

- **Pharmaceutical form and contents**

1 x 10 Tablets

- **Method and route of administration**

Oral use
Read the patient information leaflet before use

- **Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children

- **Other special warning(s), if necessary**

N/A

- **Expiry date**

EXP {MM/YYYY}

- **Special storage conditions**

Do not store above 30°C.

- **Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate.**

N/A

- **Name and address of the manufacturer**

TRIDENT LIFELINE LIMITED. - 2004,2nd Floor, North Extension, Falsawadi, Ring Road, Surat-395 003.Gujarat(INDIA), India

- **Manufacturer's batch number**

Batch {number}

- **(Advice on) General classification for supply**

POM

- **Instructions on use**

5.2 MINIMUM PARTICULARS TO APPEAR ON PRIMARY PACKAGE

Blister strips

- **Name of the medicinal product**

KMLEVO TABLET 500mg
Levofloxacin

- **Name of the manufacturer**

Trident lifeline limited, India.

- **Expiry date**

EXP {MM/YYYY}

- **Manufacturer's batch number**

Batch{number}

- **Other**

6. Part 6: Scientific Overview and Discussion

6.1 Introduction

KMLEVO TABLET is a white colored, Oblong Shaped, Biconvex and Film coated tablets with break line on one side and plain on other side. Each tablet contains Levofloxacin Hemihydrate 500mg. The Tablet is packed in Blister – Alu/Alu.

The excipients are: Maize starch BP, Microcrystalline cellulose, Starch (P) BP, Sodium benzoate BP, Sodium methyl Paraben BP, Sodium propyl Paraben BP, Purified talc BP, Magnesium Stearate BP, Sodium Starch Glycollate BP, Colloidal silicon Dioxide USP, Isopropyl alcohol BP, Methylene Dichloride, Titanium Dioxide.

6.2 Active Pharmaceutical Ingredient(s) (API)

The active pharmaceutical ingredient is described by the USP. Levofloxacin Hemihydrate is classified under BCS class 1 (high solubility, high permeability) It exhibits isomerism specifically chirality. Only the S-enantiomer is used therapeutically.

Manufacturing process

The manufacturing process was presented with sufficient details. The active pharmaceutical ingredient has been adequately characterized, and acceptable specifications have been adopted for the relevant materials and products (starting materials, intermediate products, solvents).

Quality control of active pharmaceutical ingredients

The pharmaceutical ingredient specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of active pharmaceutical ingredients

Stability data are provided on the active substance of 3 batches. The currently acceptable retest period is 60 months.

6.3 Finished Pharmaceutical Product

Manufacturing process

The manufacturing process consists of sifting, dry mixing, wet granulation, wet mass milling, drying, blending and Lubrication, compression and coating. The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product has been presented for at least three production-scale batches in accordance with the relevant FDA guidelines.

Control of excipients

The excipients are controlled with acceptable specifications. Certificates of analysis were submitted and reviewed and found compliant with the respective specifications.

Quality control of finished pharmaceutical products.

The finished product specifications (release and shelf-life) are adequate to control the relevant parameters for the dosage form. The test parameters include description, identification, average weight of 20 tablets, weight variation, disintegration, dissolution, related substances, residual solvent, assay and microbial enumeration tests. The proposed acceptance criteria at release and shelf-life have been justified and are considered appropriate for the quality control of the product. Batch analytical data from production scale batches manufactured at the proposed finished product manufacturing site have been reviewed. The data demonstrates compliance with the specification and also shows batch to batch consistency.

Stability of finished pharmaceutical products.

Stability data on the product have been provided on three production scale batches stored at Store below 30℃. Protect from light & moisture. The conditions used in the stability studies are according to the FDA/ICH stability guideline. The batches were stored in the proposed unit dose containers. All parameters remain within the specified limits. The proposed shelf-life of 36months and storage conditions are justified.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.

There are no substances of ruminant animal origin present in the product, nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

6.4 Summary of product safety and efficacy

No bioequivalence study has been performed. The finished product contains active ingredients eligible for a BCS-based biowaiver. Accordingly, a request for a biowaiver was submitted with the required supporting data in line with the FDA guidance and criteria for biowaivers.

7. Part 7: Steps taken for registration.

The application was submitted and assessed though the full review route. It was first approved by the FDA Ghana on Monday, 24 February 2025.

8. Part 8: Steps taken following registration.

This is a first registration. The report will be updated at the next renewal date.