FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

UROFAST 3g GRANULES

Fosfomycin Tromethamine

AFH0183/22

Laboratoires Frilab SA - 17 rue des Pierres du Niton 1207 Geneva, Switzerland

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Administrative info

Dosage Form	Granules
Strength	3g
Applicant's Name & Postal Address	Laboratoires Frilab SA - 17 rue des Pierres du Niton 1207 Geneva , Switzerland
Manufacturer's Name & Address	Labiana Pharmaceuticals, S.L.U - C/ Casanova, 27-31, 08757, Corbera de Llobregat, Barcelona, Spain
Local Agent	Pharmasymbiosis – LC 31 V.C.R.A.C. Crabbe Avenue, Tesano, Accra, Ghana

1. Part 1

1.1 Introduction

Based on the review of the data on quality, safety and efficacy, the application for UROFAST 3g Granules which is indicated for the treatment of acute, uncomplicated cystitis in women and female adolescents, 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 claiming essential similarity with the innovator (Alexi).

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

2. Part 2: All accepted presentations (including photo)

3. Part 3: Product information for the user (Patient Information Leaflet - PIL) – annex 1

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC) – annex 2

5. Part 5 Scientific Overview and Discussion

5.1 Introduction

The finished pharmaceutical product (FPP) is Urofast Granules for Oral Solution containing Fosfomycin Trometamol. The granule for oral solution is packed in sachet. Each sachet contains 8g of granules with Fosfomycin Tromethamine 3g.

The excipients are: sucrose, saccharin sodium, mandarin flavour and orange flavour.

5.2 Active Pharmaceutical Ingredient(s) (API)

The active pharmaceutical ingredient is Fosfomycin trometamol, an established Active Pharmaceutical Ingredient (API) described in the European Pharmacopoeia. The API is white or almost white powder, very soluble in water and very hygroscopic. The structure of the API contains two stereogenic centres and the drug substance is the 2R,3S isomer. The drug substance is obtained as a single crystalline form and is consistently manufactured having the same solid-state form.

Manufacturing process

The manufacturing process was presented with sufficient details. The active pharmaceutical ingredient has been adequately characterised and acceptable specifications have been adopted for solvents and reagents.

Quality control of drug substance

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

Stability of drug substance

Stability data have been provided on the active substance for six (6) batches stored at 25°c. The currently acceptable retest period is 24 months when stored at 25°c.

5.3 Finished Pharmaceutical Product (FPP)

Pharmaceutical development

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant FDA/ICH guidelines. The choice of excipients, packaging and manufacturing is justified. The main development studies concerned the characterization of the reference product and the development of the manufacturing process. The product contains the same active ingredients with the same concentrations/strengths as that of the reference product. The physicochemical characteristics are similar to the reference product. Similarity has adequately been demonstrated.

Manufacturing process
The manufacturing process consists of mixing of the API and excipients, stirring, drying, sieving, and final mixing with additional excipients (mandarin and orange flavour). The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product have been presented for at least three production scale batches in accordance with the relevant FDA guidelines.

Control of excipients
The excipients comply with the requirements of official compendia. These specifications are acceptable.

Microbiological attributes
The drug product is routinely tested for compliance with the limits of the microbial limits test (MLT).

Quality control of drug product
The finished product specifications are adequate to control the relevant parameters for the dosage form. The specification includes the following; appearance, identification, uniformity of dosage, water content, loss on drying, pH, solubility, assay, related substances, total aerobic microbial count, total combined yeast or mould count and E. coli. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. Batch analytical data from at least three production scale batches from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of drug product
Stability data on the product have been provided on three production scale batches stored at 30°c. 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 with the specified limits. The proposed shelf-life of 36 months 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.

5.4 Summary of product safety and efficacy

Urofast 3g Sachets for oral solution has been shown to conform to the same relevant standards of quality, efficacy and safety as those required of the reference product. According to the submitted data on quality and bioavailability, Urofast 3g Sachets for oral solution is pharmaceutically and therapeutically equivalent and thus interchangeable with the reference product (Alexi Granules for Oral Solution) for which benefits have been proven in terms of clinical efficacy. The clinical safety of Urofast 3g sachets for oral solution is considered acceptable when guidance and restrictions stated in the summary of product characteristics (SmPC) are considered. Refer to the SmPC for data on clinical safety.

6. Part 6 Benefit Risk Assessment

Based on FDA's assessment of data on quality, safety and efficacy the team of assessors considered that the benefit–risk profile of Urofast 3g sachets for oral solution was acceptable.

7. Part 7: Steps taken for registration.

The application was processed through the reliance route.