Saudi Public Assessment Report

Finate®

Active Pharmaceutical Ingredient(s): Micronized Fenofibrate

ATC code/CAS no.: C10 AB 05

Pharmaceutical/Dosage Form: Capsules

Dosage Strength: 200mg

Marketing Authorization Holder: Jamjoom Pharmaceuticals Company

Shelf life: 24 Months

Storage conditions: Do not store above 30° C.

Registration No.: 1110211116

Decision and Decision Date: Approved on 20/2/1443 H

Table of Contents

1. Terms, Definitions, Abbreviations 3

2. Background 4

2.1 Submission Details 4

2.2 Regulatory Background 4

2.3 Product Information 4

3. Scientific discussion about the product: 5

3.1 Quality Aspects 5

3.1.1 Drug Substance 5

3.1.2 Drug Product 5

3.2 Clinical Aspects 6

3.2.1 Bioequivalence study 6

4. Risk Management Plan 7

5. Overall Conclusion 8

6. Appendix 9

A. Artwork 9

1. Terms, Definitions, Abbreviations

Terms	Definitions
AUC	Area Under the curve
C.I.	Confidence Intervals
GCP	Good Clinical Practice
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HDL	High-Density Lipoprotein
KSA	Kingdom of Saudi Arabia
SDI	Saudi Drug Information System
SFDA	Saudi Food and Drug Authority
SPC	Summary of Product Characteristics
INN	International Nonproprietary Names
USAN	United States Adopted Names

2. Background

2.1 Submission Details

Type of submission: Human Generic Drug

Reference product in SA: LIPANTHYL 200mg micronised caps

Pharmacological Class: Fibrates, Lipid modifying agents

Submitted Indication: Indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following:

- Treatment of severe hypertriglyceridaemia with or without low High-Density Lipoprotein (HDL) cholesterol.
- Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.
- Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled.

Submitted Dosage: 200mg

2.2 Regulatory Background

This product is considered a human generic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the regulatory pathway normal submission.

2.3 Product Information

The officially approved Summary of Product Characteristics (SPC) can be accessed via Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

3. Scientific discussion about the product:

3.1 Quality Aspects

3.1.1 Drug Substance

Fenofibrate is white or almost white, crystalline powder. Fenofibrate is very soluble in methylene chloride, slightly soluble in ethanol (96%) and practically insoluble in water. Fenofibrate does not have any chiral centers. Polymorphism has been observed. The drug substance is manufactured by multiple-step chemical synthesis. The structure of Fenofibrate has been fully elucidated using several spectroscopic techniques. The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to international guidelines. Appropriate stability data have been presented and justify the established re-test period.

3.1.2 Drug Product

The finished product is available as orange cap/ orange body, hard gelatin capsules of size `1` imprinted with `Jamjoom` on the cap and `FNO200` on the body in black containing white to off white granular powder. Each 200 mg capsule contains 200 mg of Fenofibrate. The composition of the drug product is adequately described qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and the manufacturing process.

The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.

The drug product specification covers appropriate parameters for this dosage form, which allow for proper control of the finished product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.

The drug product is packaged in a carton box containing 3 Alu-PVC/PVDC Blisters containing 10 capsules per blister.

Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the proposed shelf life.

3.2 Clinical Aspects

3.2.1 Bioequivalence study

A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Finate® (Fenofibrate) 200mg of Jamjoom Pharmaceuticals Company, KSA, and Lipanthyl® (Fenofibrate) 200mg of Recipharm Fontaine, France, in normal, healthy human adult subjects, under Fed condition. The study was conducted in accordance with Gulf Cooperation Council (GCC) Guidelines for Bioequivalence, standards of Good Clinical Practice (GCP) and Good Laboratory Practices (GLP).
Blood samples were taken pre-dose (0.0) and at a specified time points up to 120 hours after administration of test or reference product. Plasma levels of Fenofibrate were detected by a validated LC-MS/MS method.

Twenty-nine (29) volunteers completed the study, and all data were analyzed. No significant protocol deviations were reported. There were no serious adverse events reported in the study. The ratio and 90% confidence Intervals (C.I.) of test versus reference for fenofibrate are tabulated below:

Table 1: Ratio and 90% Confidence Intervals (C.I.) of Test versus Reference for Fenofibrate:

Pharmacokinetic Parameter	Point Estimate	90% Confidence Intervals (%)
C_{max}	99.1682	94.5046 – 104.0619
AUC_{0-t}	101.7825	98.5055 – 105.1686
$AUC_{0-\infty}$	101.9779	98.6017 – 105.4698

Based on the results obtained in this study, Finate® (Fenofibrate) 200mg of Jamjoom Pharmaceuticals Company, KSA, is **bioequivalent** to Lipanthyl® (Fenofibrate) 200mg of Recipharm Fontaine, France, under Fed Conditions.

4. Risk Management Plan

Artwork and Trade Name assessment (Artwork available in appendix)

Proposed trade Name	Dosage Form
Finate™	Capsules

Look –alike/Sound-alike (LA/SA) Error Risk Potential:

Finate™ name LA/SA confusion risk potential has been assessed based on the evaluation of LA/SA similarities from our data sources (SFDA registered Drug List, Martindale, ISMP Confused Drug Name List, INN International Nonproprietary Names and USAN United States Adopted Names STEM) and the pharmaceutical characteristic of the product:

LA/SA for Product name	SFDA	Shared File/ Excel Sheet	Martindale	Stem Book 2018
Finate™	NO	NO	NO	NO

Trade Name Recommendation:

Based on the submitted data, the proposed name Finate™ is accepted.

Outer and Inner Package:

Based on the submitted data, the proposed artwork is accepted.

5. Overall Conclusion

Based on a review of data on quality, safety and efficacy, SFDA considered that the benefit/risk profile of Finate was favorable and decided to grant the marketing authorization of Finate as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following:

- Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol.
- Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.
- Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled.

6. Appendix

A. Artwork

Carton Dimensions 88 x 66 x 28mm

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR.

New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published only at SDI.

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa