الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Saudi Public Assessment Report

(Summary Report)

## Triova®

**Type of Application:** New Drug Application

**Type of Product:** Human Generic Drug.

**Active Pharmaceutical Ingredient(s):** Tiotropium

**ATC code:** R03BB04

**Dosage Form:** Inhalation powder, hard capsule

**Dosage Strength:** 13 mcg.

**Pack Size:** 30

**Shelf life:** 24 months.

**Storage Conditions:** Store below 30°C.

**Reference Product in SA (if applicable):** Spiriva

**Marketing Authorization Holder:** MS Pharma Saudi (MSPS)

**Manufacturer:** Laboratorios Liconsa S.A

**Registration No.:** 2103245066

**Date of Decision:** 21/03/2024

**Proposed Indications:**

Triova® 13mcg inhalation powder, hard capsules is indicated as a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD).

Triova® 13mcg inhalation powder, hard capsules is indicated for use in adults.

## Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway .

**The SFDA approval for Triova® is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:**

## Quality Aspects

## Drug Substance

- Tiotropium Bromide Methanol Solvate is a white to yellowish-white mixture of powder and isolated crystals. Tiotropium Bromide Methanol Solvate is sparingly soluble in water, freely soulble in methanol and dimethylformamide and slightly soulble in acetone. Polymorphism has been observed.
- The drug substance is manufactured by a (multiple-step) chemical synthesis.
- The structure of Tiotropium Bromide Methanol Solvate has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

## Drug Product

- The finished product is available as Colorless and transparent, size 3 capsules, containing white powder for inhalation. Each capsule contains 0.0156 mg of Tiotropium Bromide (0.013 mg of Tiotropium). 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 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 drug 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 2 HDPE bottles with screw-cap closure, (PP) Plastic cap with inviolable safety ring (PE) and a desiccant capsule containing silica gel and an inhalation device. Each bottle contains 15 capsules
- 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 shelf life.

# Clinical Aspects

## Bioequivalence Study

Ratio and 90.20 % Confidence Intervals (CI) of Triova® (Tiotropium bromide) 10 µg hard capsule versus Spiriva® (Tiotropium bromide) 18 µg hard capsule:

| **Pharmacokinetic Parameter** | **Point Estimate** | **90% CI** |
|---|---|---|
| $C_{max}$ (pg/mL) | 96.45% | 87.26% - 106.60% |
| $AUC_{0-t}$ (pg/mL) | 106.36% | 101.33% - 111.64% |

Based on the results obtained in this study, Triova® (Tiotropium bromide) 10 µg of Laboratorios Liconsa, S.A., Spain is **bioequivalent** to Spiriva® (Tiotropium bromide) 18 µg of Boehringer Ingelheim International GmbH, Germany under fasting Conditions.

# Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

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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 at (SDI or Summary Saudi-PAR report).

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