Saudi Public Assessment Report

(Quality Summary Report)

Suxamethonium Chloride Martindale®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Suxamethonium Chloride.

ATC code: NA.

Dosage Form: Solution for injection.

Dosage Strength: 50 mg/ml.

Pack Size: 10 Ampoules.

Shelf life: 18 Months.

Storage Conditions: Store in a refrigerator (2°c – 8°c).

Reference Product in SA (if applicable): Suxamethonium Chloride 50mg per ml solution for injection.

Marketing Authorization Holder: Martindale Pharmaceuticals Ltd Trading As Martindale Pharma.

Manufacturer: Macarthys Laboratories Limited T\A Martindale Pharma.

Registration No.: 0706222142.

Decision and Decision Date: Approved on 16/05/2022.

Proposed Indications: Used for muscle relaxation during general anesthesia.

Product Background

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

The SFDA approval for Suxamethonium Chloride Martindale® (Suxamethonium Chloride 50 mg/ml) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Suxamethonium Chloride is a white or almost white crystalline hygroscopic powder. Suxamethonium Chloride is freely soluble in water and slightly soluble in alcohol. Suxamethonium Chloride does not have chiral center. Polymorphism not been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Suxamethonium Chloride 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.

Drug Product

- The finished product is available as clear and colorless solutions practically free from particles. Each ampule contains 50 mg per ml of Suxamethonium Chloride. 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. Satisfactory validation data pertaining to the commercial manufacturing process are provided.
- 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 carton box, containing 10 Ampules of (2 ml) type I clear glass ampoule.

- 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.

Bioequivalence Study

A bioequivalence study is not required if the test product is an aqueous intravenous solution containing the same active substance as the reference product.

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/

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