# Saudi Public Assessment Report

**(Summary Report)**

## Colimate ®

**Type of Product:** Generic.

**Active Pharmaceutical Ingredient(s):** Colistimethate Sodium (USP) -Amorphous form.

**ATC code:** J01XB01.

**Dosage Form:** Lyophilized cake or powder for reconstitution.

**Route of administration:** Intravenous infusion or intramuscular administration.

**Dosage Strength:** 150 mg/vial.

**Pack Size:** 10 ml.

**Shelf life:** 24 months.

**Storage Conditions:** Store below 30°C. Protect from moisture, any final intravenous infusion solution should be freshly prepared and used for no longer than 24 hrs.

**Reference Product in SA (if applicable):** Coly-Mycin.

**Marketing Authorization Holder:** Saudi Hetero Co.

**Manufacturer:** M/s Aspiro Pharma Limited, Telangana, India (Line-1 and Line-2).

**Registration No.:** Not Applicable.

**Date of Decision**: 23/03/2021.

**Proposed Indications:** Serious infections due to selected aerobic Gram-negative pathogens.

# Product Background

This product is considered as a known active ingredient for Saudi regulatory purposes. The application for this product is submitted to SFDA as per regular regulatory pathway and assessed to follow the *GCC Data Requirements for Human Drugs Submission Content of the Dossier Version 1.3.*

**The Food and Drug Administration (SFDA) denied marketing authorization for Colimate® (Colistimethate sodium 150 mg) based on a decision that took into account the recommendations of the Quality assessment which summarised hereinafter:**

# Quality Aspects

## Drug Substance

Colistimethate sodium is a white to slightly yellow powder showing polymorphism, freely soluble in water and insoluble in acetone. The drug substance is manufactured by a multiple-step chemical synthesis ended by the drug substance with a fully elucidated structure performed using several spectroscopic techniques.

The drug substance specification includes relevant testing parameters for proper as per *ICH Q6A guideline* quality, the control methods are validated according to international guidelines and published pharmacopia. Submitted stability data had been presented properly as per The *GCC Guidelines for "Stability Testing of Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products (FPPs)* to support the established re-test period.

## Drug Product

Colimate® is available as a white to off-white lyophilized cake or powder. When constituted as directed, the solution should be clear colourless to pale yellow solution. Each vial contains 150 mg of Colistimethate Sodium. 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. They 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 which is packaged in a type-I, 10 ml tubular glass vials sealed with 20 mm grey bromobutyl slotted stopper and 20 mm parrot green color flip off aluminum seal, an appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international

guidelines. The control of the product is considered acceptable except for one testing parameter related to the limit of the total impurities level that my affect the quality of the product during the proposed shelf life.

## Bioequivalence Study

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

## Product Information

In light of the negative recommendation, the summary of product characteristics, labelling and package leaflet are not available at this stage.

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The date of revision of this text corresponds to that of the Saudi PAR. The Saudi public assessment report (Saudi PAR): provides information for public about the evaluation of medicines submitted to have marketing authorization in Saudi Arabia and the considerations that led the SFDA to approve or not approve medicine authorization. For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa