Saudi Public Assessment Report

(Summary Report)

Veraline®

Type of Product: Generic.

Active Pharmaceutical Ingredient(s): Norepinephrine Bitartrate.

ATC code: QC01CA03-norepinephrine.

Dosage Form: Sterile Solution for injection.

Dosage Strength: 1mg/ml.

Rout of administration: Intravenous use.

Pack Size: 20 ml (5 ampules each 4ml).

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C, Protect from light.

Reference Product in SA (if applicable): Levophed®

Marketing Authorization Holder: Verve Human Care Laboratories.

Manufacturer: 15 A, Pharmacity, Selaqui, Dehradun Uttarakhand, India.

Registration No.: Not Applicable.

Date of Decision: 16/08/2022.

Proposed Indications: Indicated for use as an emergency measure in the restoration of blood pressure in cases of acute hypotension.

Product Background

This product is considered as a known active ingredient drug for Saudi regulatory purposes, this application is submitted to follow the SFDA's regular submission regulatory pathway.

SFDA denied the marketing authorization for Veraline® (Norepinephrine Bitartratesolution 1mg/ml for injection) based on a decision that took into account the recommendations of the Quality Evaluation. The quality assessment for this product was undertaken to meet the last version of *GCC Data Requirements for Human Drugs Submission*. The assessment process and conclusion are summarised hereinafter:

Quality Aspects

Drug Substance

Norepinephrine Bitartratesolution is freely soluble in water, slightly soluble in alcohol; practically insoluble in chloroform and in ether. Polymorphism has been observed. The drug substance is manufactured by a multiple-step chemical synthesis. The structure of Norepinephrine bitartrate 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

Veraline ® is presented as a clear colourless solution filled in 4 ml USP Type- I amber glass ampoules. Each ampoule contains 4 mg of Norepinephrine Bitartrate. The composition of the drug product is insufficiently described, qualitatively and quantitatively. Inadequate pharmaceutical development data have been provided for the finished product composition and manufacturing process. The manufacturing process is not described in sufficient detail. The control methods are not fully validated according to international guidelines. Batch data do not show consistent quality of the drug product.

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.

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