Saudi Public Assessment Report

(Summary Report)

Prodein Plus®

Type of Product: Human generic drug.

Active Pharmaceutical Ingredient(s): Paracetamol, Codeine and Caffeine.

ATC code: N06BC01.

Dosage Form: Soluble tablet.

Dosage Strength: 500,8,30 mg.

Pack Size: 20.

Shelf life: 24 Months.

Storage Conditions: Store below 30°c.

Reference Product in SA: Solpadeine®

Marketing Authorization Holder: Oman Pharmaceutical Products.

Manufacturer: Oman Pharmaceutical Products.

Registration No.: 1505233640

Date of Decision: 15/05/2023

Proposed Indications:

Codeine-containing products are indicated in patients older than 12 years of age for the short term treatment of acute, moderate pain which is not relieved by paracetamol or ibuprofen alone.

Prodein Plus Soluble Tablets is indicated in the management of symptoms of headache, including migraine, toothache, backache, common cold, influenza, menstrual pain, musculoskeletal pain.

Product Background

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

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

Quality information

Drug Substance

The finished product Prodein Plus® (Soluble Tablets) containing three active ingredients:

Caffeine is a white, crystalline substance or granulesfreely soluble in (boiling) water, sparingly soluble in (20°C) water and slightly soluble in Ethanol . Caffeine's structure does not have any chiral center ,Polymorphism has been observed.

The drug substance is manufactured by a multiple-step chemical synthesis. The structure of Caffeine 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.

Codeine Phosphate is a white or almost white crystalline powder or small, colourless crystals freely soluble in water, slightly soluble or very slightly soluble in ethanol. The Codeine Phosphate's structure has five chiral center Polymorphism has been observed.

The drug substance is manufactured by a multiple-step chemical synthesis. The structure of Codeine Phosphate has been fully elucidated using several spectroscopic techniques.

The drug substance specification includes relevant tests for proper quality control in accordance with the *ICH Q6A guidlines*. Whereas the control methods are validated according to international guidelines. Appropriate stability data have been presented and justify the established re-test period.

Paracetamol which is a white or almost white crystalline powder sparingly soluble in water, freely soluble in ethanol (96%), very slightly soluble in methylene chloride . The API's structure does not have any chiral center Polymorphism has been observed.

The drug substance is manufactured by a multiple-step chemical synthesis. The structure of Paracetamol 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 a white round flat bevelled edge tablet with rough surface. Each tablet contains 500 mg of Paracetamol, 30 mg of Caffeine, and 8 mg of Codeine Phosphate. 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.

All the excipients used in the manufacture of Prodein plus 8/500/30mg are derived from the vegetable origin. As the Analytical procedures for the excipients used are based on their respective European Pharmacopoeia monographs further validation was not carried out.

Prodein plus 8/500/30mg tablets are controlled by shelf life specification. The specifications covers appropriate parameters for this dosage form as per the *ICH Q6A guidelines* allowing a proper control of the finished drug product at release and shelf-life. 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 board, containing five Laminated foil strips composed of 4 layer glassine paper/polyethylene/Aluminium foil/Polyethylene each strip contains four tablets.

Appropriate stability data have been generated in the packaging material intended for commecial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life of 24 months.

Bioequivalence Study

No comparative bioequivalence study was carried out. The exemption from *in vivo* and /or *in vitro* bioequivalence study is granted.

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