September 2022

Public assessment summary report

Name of the Finished Pharmaceutical Product	Isoniazid tablet 300mg and Isoniazid tablet 100 mg
Manufacturer of Prequalified Product	MACLEODS PHARMACEUTICAL LIMITED(DAMAN) Plot No.25-27, Survey No.366, Premier Industrial Estate Kachigam,Daman396210(U.T.)
Active Pharmaceutical Ingredients	Isoniazide

1. Introduction

This is a summary of the public assessment report for Isoniazid 100 mg and 300 mg tablets. Isoniazid 100 mg and 300 mg tablets are a 'generic' medicine. This means that these medicines are similar to a reference medicine called Isozid 100 mg tablets. Isoniazid is an antibiotic, which kills the bacterium that causes tuberculosis.

2. Assessment of quality

Active pharmaceutical Ingredient (API)

Isoniazid white or almost white, crystalline powder or colourless crystals. It is freely soluble in water, sparingly soluble in alcohol.

Finished pharmaceutical product (FPP)

Pharmaceutical development and manufacture:

The objective of the development programme was to formulate a safe efficacious, stable dosage form bioequivalent to the reference product. Suitable pharmaceutical development data have been provided for this application. The submitted in vitro dissolution profile has been acceptable.

Manufacture of the product

A satisfactory description of the manufacturing process and batch formulae for product has been provided. The manufacturing process has been validated with full scale production scale batches and result found to be acceptable.

Specifications:

The finished product specification is satisfactory. Test methods have been described and adequately validated as appropriate. Batch data have been provided that complies with the release specification. Certificate of analysis have been provided for the standard used.

Other ingredients:

All excipients comply with their respective pharmacopoeia monographs.

Stability testing:

Finished product stability studies were performed in accordance with current guidelines on batches of finished product packaging proposed for marketing. The data from these studies support a shelf life of 48 months.

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3. Assessment of bioequivalence

The 90% confidence intervals of the test/ reference ratio for AUC, and Cmax values lie within the acceptance limits of 80.00% to 125.00%, in line with the guideline for medicine registration. Thus, the data support the claim that the applicant's test product Isoniazid tablet 300 mg is bioequivalent to the reference product Isozid 100 mg tablets(Fatol Arzneimittel GmbH, Schiffweiler, Germany).

As the 100 mg and 300 mg strength test products meets the biowaiver criteria specified in the current bioequivalent guidance, the results and conclusions of the bioequivalence study with the 300 mg tablet strength can be extrapolated to the 100 mg strength tablet.

4. Conclusion

Based on assessment of data on quality, bioequivalence the assessors considered that the benefit–risk profile of isoniazid was acceptable for the following indication: treatment of tuberculosis, caused by *Mycobacteriumtuberculosis* .