



National Agency for Food & Drug Administration & Control (NAFDAC)

NAFDAC Public Assessment Report (NAPAR)

Omepep 40 mg injection

Omeprazole 40 mg

A4-102009

Sam Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of Omepep injection. The product was licenced in March 2026.

PART 1: ABSTRACT

Omepep injection containing omeprazole, manufactured at East African (India) Overseas, Selaqui, Dehradun, India, was granted marketing authorization by NAFDAC for the treatment of gastric and duodenal ulcers on 31 March 2026.

Omepep is indicated for the treatment of gastric and duodenal ulcers and the prevention of relapse of gastric and duodenal ulcers.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of omepep by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of omepep have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of omepep has been presented in part 5 of this report.

The detailed steps taken to approve omepep by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of omepep.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Omepep 40 mg for injection	Omeprazole 40 mg	A white powder for injection	Combipack of omeprazole in type 3 glass vial sealed with flip-off rubber seal along with one ampoule of 10 mL sodium chloride	1 vial +10 mL ampoule

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

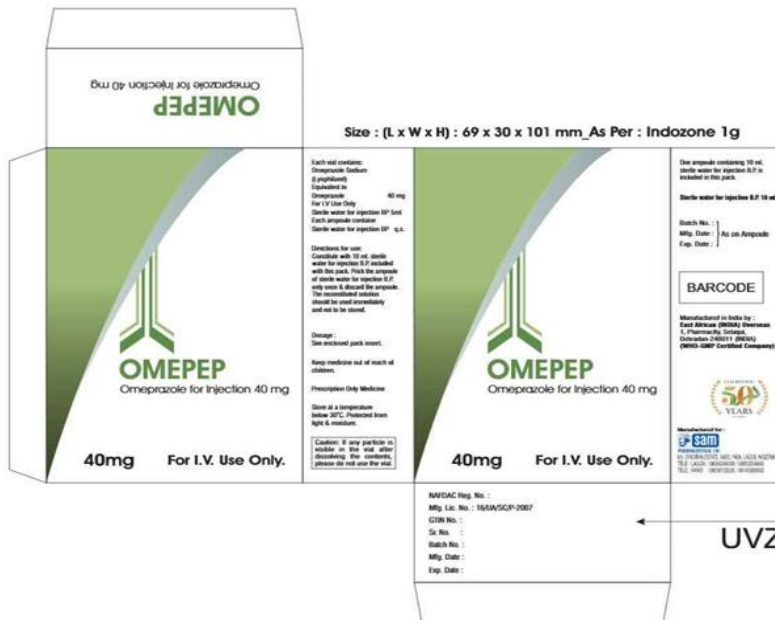
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Omepep 40 mg for injection

5.1.2 Therapeutic indication

Omepep is indicated for the treatment of gastro-oesophageal reflux disease, Zollinger-Ellison syndrome, gastric and duodenal ulcers and the prevention of relapse of gastric and duodenal ulcers.

5.1.3 Applicant

Sam Pharmaceuticals Limited, 8/9 Oyadiran Estate, Sabo Yaba, Lagos State.

5.1.4 Pharmaceutical form

A white colour powder for injection

5.1.5 Storage

Do not store above 30°C. Protect from light and moisture

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Combipack of omeprazole in type 3 glass vial sealed with flip-off rubber seal along with one ampoule of 10 mL sodium chloride.

5.2 Drug Substance

5.2.1 Manufacturer

Omeprazole is manufactured by Mac-Chem Products Private Limited, N-21 1 /2/10, M I.D C. Boisar, Dist. Thane-401 506, Maharashtra, India.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Other ingredients used in the formulation of Omepep include sodium chloride B.P all being pharmacopoeial controlled.

None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

East African Overseas, Plot no.1, Pharmacity, Selaqui, Dehradun, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Losec 40 mg omeprazole manufactured by AstraZeneca, United Kingdom.

The product is manufactured by aseptic filling and sealing of vials which followed the washing, sterilization and drying of primary packing material. All the manufacturing processes were validated

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include description, identification, assay, pH, bacterial endotoxin test and sterility test. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Do not store above 30°C. Protect from light and moisture' have been accepted.

5.6 Conclusion

Based on the assessment of data submitted on quality, safety and efficacy, the benefit–risk profile of omepep was acceptable for the following indication: 'for the treatment of gastro-esophageal reflux disease, Zollinger-Ellison syndrome, gastric and duodenal ulcers and the prevention of relapse of gastric and duodenal ulcers', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Sam Pharmaceuticals Limited, 8/9 Oyadiran Estate, Sabo Yaba, Lagos State, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of omepep.

The following are the steps for registration

August 2025	Date of receipt of application
February 2026	Date of conclusion of assessment
January 2026	Date of inspection
31 March 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Omepep injection.