



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

NAFDAC Public Assessment Report (NAPAR)

Glinsip 50 mg tablets

Sitagliptin 50 mg

A4-102190

Hetero Labs Nigeria Limited

This report reflects the scientific assessment for the approval of Glinsip 50 mg tablets. The product was licenced on June 2026.

PART 1: ABSTRACT

Glinsip 50 mg tablets containing sitagliptin, manufactured at Annora Pharma Private Limited, Sangareddy, Telangana-502313, India, was granted marketing authorization by NAFDAC for the treatment of blood glucose control in adults with type 2 diabetes mellitus on 30 June 2026.

Glinsip 50 mg is indicated for the treatment of blood glucose control in adults with type 2 diabetes mellitus.

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 Glinsip 50 mg 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 Glinsip 50 mg 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 Glinsip 50 mg has been presented in part 5 of this report.

The detailed steps taken to approve Glinsip 50 mg by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Glinsip 50 mg.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Glinsip 50 mg tablets	Sitagliptin phosphate anhydrous	Film-coated tablet Yellow, round, film-coated tablets. The tablets have '25' debossed (stamped into) on one side and 'V1' debossed on the other side.	Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 15 tablets. Available in boxes of 2 x15 tablets.	2 x 15 tablets

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



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Glinsip 50 mg tablets

5.1.2 Therapeutic indication

Glinsip 50 mg is indicated for the treatment of blood glucose control in adults with type 2 diabetes mellitus.

5.1.3 Applicant

Hetero Labs Nigeria Limited, Ogunaiké Way, GRA Ikeja Lagos.

5.1.4 Pharmaceutical form

Film-coated tablet

Yellow, round, film-coated tablets. The tablets have '25' debossed (stamped into) on one side and 'V1' debossed on the other side

5.1.5 Storage

Store below 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Round, yellow film coated tablet debossed with '25' on one side and 'V1' on the other side available as 2x15.

5.2 Drug Substance

5.2.1 Manufacturer

Sitagliptin phosphate anhydrous is manufactured by Honour Lab Limited Unit-Iii, Plot No.4, Hetero Infrastructure Ltd., Sez, N. Narasapuram Village, Nakkapally Mandal, Visakhapatnam District – 531081, Andhra Pradesh, India (Ind).

The API specifications are in-house based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of glinsip 50 mg include microcrystalline cellulose, dibasic calcium phosphate anhydrous, croscarmellose sodium, magnesium stearate, sodium stearyl fumarate, opadry II yellow 85F520153, purified water, all being controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Annora Pharma Private Limited, Survey No. 261, Annaram village, Gummadidala Mandal, Sangareddy, Telangana-502313, 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, Januvia Tablets, manufactured by Merck & Co., Inc.

The product is manufactured by blending, sieving, lubrication, compression, and packing. All the manufacturing processes were validated.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Januvia Tablets (Merck & Co., Inc.) and Glinsip 50 mg tablets. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include description, identification by hplc & by hplc-pda, by infrared absorption, average weight of tablet (in-house), water content by kf, uniformity of dosage units (content uniformity, by hplc), dissolution (by hplc), related substance (by hplc), assay by hplc, residual solvents and microbial enumeration tests and test for specified microorganisms. 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 store below 30°C have been accepted.

5.5 Conclusion

Based on the assessment of data submitted the benefit–risk profile of Glinsip 50 mg was acceptable for the following indication: 'for the treatment of blood glucose control in adults with type 2 diabetes mellitus', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Hetero Labs Nigeria Limited, Ogunaiké Way, GRA Ikeja Lagos, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Glinsip 50 mg tablets.

The following are the steps for registration

August 2024	Date of receipt of application
April 2026	Date of conclusion of assessment
December 2025	Date of inspection
30 June 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Glinsip 50 mg tablets