



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

NAFDAC Public Assessment Report (NAPAR)

Glyxiga 5 mg tablets

Dapagliflozin 5 mg

A4-101877

Hetero Labs Limited

This report reflects the scientific assessment for the approval of Glyxiga. The product was licenced in January 2026.

PART 1: ABSTRACT

Glyxiga tablets containing dapagliflozin manufactured at Hetero Labs Limited, Hyderabad, Telangana, India was granted marketing authorization by NAFDAC for the management of type 2 diabetes mellitus on 27 January 2026.

Glyxiga is indicated for the improvement of glycemic control in adults with type 2 diabetes alongside diet and exercise.

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 glyxiga 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 glyxiga 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 glyxiga has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Glyxiga 5 mg tablets	Dapagliflozin 5 mg	Film-coated tablets. Pink, round, film-coated tablets. They are biconvex (rounded on top and bottom), with a flat edge. The tablets have 'D32' debossed (stamped into) on one side and 'H' debossed on the other side.	Alu-alu foil blister packs, each containing 10 tablets. Available in cartons of 1 x 10 tablets	1 x 10 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

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Glyxiga 5 mg tablets

5.1.2 Therapeutic indication

Glyxiga is indicated for the management of Type 2 diabetes mellitus as an adjunct to diet and exercise

5.1.3 Applicant

Hetero Labs Nigeria Limited, Ogunaike Way, G.R.A Ikeja, Lagos.

5.1.4 Pharmaceutical form

Film-coated tablet

Pink, round, film-coated tablets. They are biconvex (rounded on top and bottom), with a flat edge. The tablets have 'D32' debossed (stamped into) on one side and 'H' debossed on the other side.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Alu-alu foil blister packs, each containing 10 tablets. Available in cartons of 1 x 10 tablets.

5.2 Drug Substance

5.2.1 Manufacturer

Dapafliflozin is manufactured by Honour Lab Limited, Unit –III, Plot. No.4, Hetero Infrastructure Ltd., SEZ, N. Narsapuram Village, Nakkapalli Madal, Vishakapatnam.

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 glyxiga include microcrystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, magnesium stearate, film coating and purified water 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

Hetero Labs Limited, Unit-III (Formulations), Plot no 22 – 110, I.D.A, Jeedimetla, Hyderabad, Telangana, 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, Farxiga manufactured by AstraZeneca, United Kingdom.

The product is manufactured by dispensing, sifting, pre-mix blending, premix lubrication, roller compaction, milling, sifting, re-compaction/re-sizing, extra-granular excipient sifting, final lubrication, compression and film coating. All the manufacturing processes were validated

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Farxiga (AstraZeneca) and glyxiga. The profile in the three BCS media are similar.

5.4.3 Specification

The finished product specification is based on pharmacopoeial and in-house. The finished product specifications include description, identification by HPLC, average tablet weight, water content, dissolution, uniformity of dosage units, related compounds, total impurities, assay, total aerobic microbial count, total combined yeast and mould count, Escherichia coli. 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 24 months and 'Do not store above 30°C' have been accepted.

5.5 Assessment of bioequivalence

The following bioequivalence study has been performed in 2017 according to internationally accepted guidelines.

The objective of the study was to compare the bioavailability of the stated Dapagliflozin Tablets 10 mg of Hetero Labs Limited, India (test drug) with the reference formulation Farxiga® (dapagliflozin) tablets 10 mg of AstraZeneca Pharmaceuticals LP, and to assess bioequivalence.

The study was designed as an open-label, balanced, randomized, two-treatment, two sequence, two-period, single dose, two-way crossover bioequivalence study under fasting condition. A total of 56 (50 Male and 6 Female), normal, healthy, adult, human subjects were enrolled in the study. Subjects were checked out at 48.00 hours post-dose during each study period. Each subject was assigned to receive each of the following two treatments in a randomized fashion:

Treatment T: Test – 1 tablet Glyxiga
(Dapagliflozin 10 mg) Batch no. E170948A.

Treatment R: Reference – 1 tablet Farxiga®
(dapagliflozin 10 mg) Batch no. HH0134.

A wash-out period of 07 days was maintained between each study period. Plasma concentrations of Dapagliflozin were measured by validated LC-MS/MS method.

Primary (C_{max}, AUC_{0-t} and AUC_{0-inf}) and secondary (T_{max}, t_{1/2}, Kel and AUC_%Extrap_obs) PK parameters were subjected to non-compartmental model using Phoenix™ WinNonlin® - Software,

Professional Version 7.0 (Pharsight Corporation, USA). Fifty (50) data of subjects was included for PK and statistical analysis.

Arithmetic mean and geometric mean values of the pharmacokinetic variables for dapagliflozin as well as statistical results are summarised in the following tables:

Dapagliflozins

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean $\pm$ SD (geometric mean)	Reference (R) arithmetic mean $\pm$ SD (geometric mean)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90% CI (ANOVAlog)
$t_{\max}$ (h)	1.840 $\pm$ 1.025	1.937 $\pm$ 1.261	–	–
$C_{\max}$ (ng/mL)	111.66 $\pm$ 36.74 (106.85)	107.56 $\pm$ 26.81 (104.47)	102.28	96.55 - 108.35
AUC _{0-t} (ng·h/mL)	634.15 $\pm$ 136.59 (620.26)	624.88 $\pm$ 133.66 (611.42)	101.45	99.65 - 103.28
AUC _{0-inf} (ng·h/mL)	658.52 $\pm$ 137.02 (645.00)	649.25 $\pm$ 140.91 (635.09)	101.56	99.81 - 103.34

The results of the study show that preset acceptance limits of 80 -125 % are met by both AUC and C_{max} values regarding dapagliflozin. Accordingly, the test tablet Glyxiga 10 mg meets the criteria for bioequivalence with regard to the rate and extent of absorption and is therefore bioequivalent to the reference Farxiga® (AstraZeneca Pharmaceuticals LP).

5.6 Conclusion

Based on the assessment of data submitted on quality, bioequivalence, safety and efficacy, the benefit–risk profile of glyxiga was acceptable for the following indication: 'for the management of type 2 diabetes mellitus as an adjunct to diet and exercise ', 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, G.R.A Ikeja, Lagos, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Glyxiga 5mg tablets.

The following are the steps for registration

October 2024	Date of receipt of application
November 2025	Date of conclusion of assessment
February 2025	Date of inspection
27 January 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Glyxiga 5 mg tablets