



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

NAFDAC Public Assessment Report (NAPAR)

Glyda 10 mg tablets

Dapagliflozin 10 mg

A4-101941

Hetero Labs Nigeria Limited

This report reflects the scientific assessment for the approval of Glyda tablets. The product was licenced on February 2026.

PART 1: ABSTRACT

Glyda 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 24 February 2026.

Glyda is indicated for the management of 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 Glyda 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 Glyda 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 Glyda has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Glyda tablets	Dapagliflozin 10 mg	Oral tablets Pink, round, biconvex, film-coated tablets de- bossed (stamped in) with “D33” on one side and “H” on the other side.	1x10 tablets sealed in Alu-Alu blister pack in a mono carton along with a patient information leaflet	1x10 tablets

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

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

Primary label

[illegible]

Glyda is indicated for the treatment of type 2 diabetes mellitus diabetes.

5.1.3 Applicant

Hetero Labs Nigeria Limited. 8b, Wole Ogunjimi Street, Agbaoku Estate, off Opebi Road, Ikeja, Lagos, Nigeria.

5.1.4 Pharmaceutical form

It is an oral tablet that is pink, round, biconvex, film-coated tablets debossed (stamped in) with “D33” on one side and “H” on the other side.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Glyda is presented as a pink, round, film-coated tablets de-bossed with “D33” on one side and “H” on the other side with a pack size of 1x10 tablets in Alu-Alu blister pack in a mono-carton along with the patient information leaflet.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient, Dapagliflozin is manufactured by Honour Lab Limited, Unit –III, Plot No.4, Hetero Infrastructure Limited., SEZ, N. Narsapuram Village, Nakkapalli Madal, Vishakapatnam, District-531081, 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 Glyda include microcrystalline cellulose, anhydrous lactose, crospovidone, silicone dioxide, magnesium stearate, opadry II pink 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

The drug product is manufactured by 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 produce a safe, effective, stable, and high-quality product that consistently delivers the intended therapeutic effect as the innovator product, Farxiga®, marketed by AstraZeneca AB.

The manufacturing method used is blending, sifting, lubricating, 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® (Dapagliflozin) 10 mg tablets manufactured by AstraZeneca Pharmaceuticals LP, Wilmington and Glyda 10 mg tablets. The profiles in the three BCS media are similar.

5.4.3 Specification

The finished product specification is based on USP. The finished product specifications include, identification by HPLC and HPLC-PDA, average weight of tablet, water content, dissolution, uniformity of dosage units (content uniformity by HPLC), related substances, microbial enumeration tests and assay. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75% RH 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' storage condition has been accepted.

5.5 Conclusion

Based on the data submitted, the benefit–risk profile of Glyda tablets was acceptable for the following indication: treatment of type 2 diabetes mellitus/endocrinology which includes, improve blood glucose control usually alongside diet and exercises, reduce the risk of worsening heart failure, slow kidney disease progression and reduce the risk of cardiovascular complications in eligible patients including some without diabetes, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Hetero Labs Nigeria Limited. 8b, Wole Ogunjimi Street, Agbaoku Estate, off Opebi Road, Ikeja, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Glyda10 mg tablets.

The following are the steps for registration

April 2025	Date of receipt of application
December 2025	Date of conclusion of assessment
July 2025	Date of inspection
24 February 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Glyda 10 mg tablets.