



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

NAFDAC Public Assessment Report (NAPAR)

Fennmet 50 mg/1000 mg tablets

Vildagliptin/metformin hydrochloride 50 mg/1000 mg

A4-102053

Fenn Pharma Limited

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

PART 1: ABSTRACT

Fennmet containing Vildagliptin/metformin hydrochloride, manufactured at Shukra Pharmaceuticals Limited, Rakanpur Sola-Santej Road, Ta. Kalol, Dist. Gandhinagar, Gujarat, India was granted marketing authorization by NAFDAC for the management of type 2 diabetes mellitus on 31 March 2026.

Fennmet 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 fennmet 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 fennmet 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 fennmet has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Fennmet 50 mg/1000 mg tablets	Vildagliptin/metformin hydrochloride 50 mg/1000 mg	Film-coated tablet A yellow capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a score-line on one side and are plain on the other side.	Alu-alu blister packs, each containing 10 tablets. Available in cartons of 3 x 10 tablets	3 x 10 tablets

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

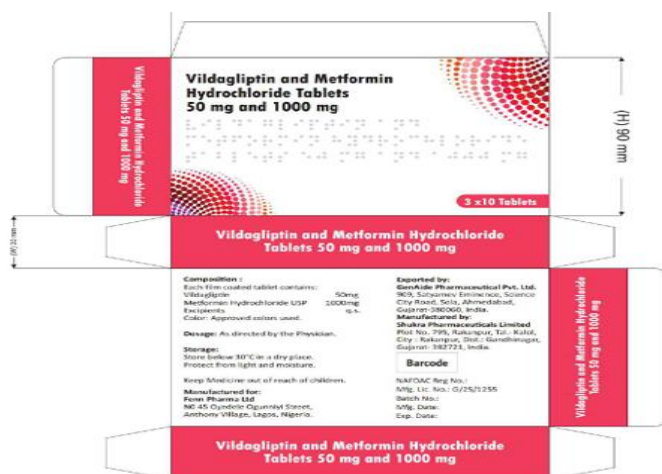
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Fennmet tablet

5.1.2 Therapeutic indication

Fennmet is indicated for the management of type 2 diabetes mellitus.

5.1.3 Applicant

Fenn Pharma Limited, 45 Oyedele Ogunniyi Street, Anthony Village, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Film- coated tablet

A yellow capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a score-line on one side and are plain 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 blister packs, each containing 10 tablets. Available in cartons of 3 x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

Vildagliptin is manufactured by Alembic Pharmaceuticals Limited, Panelav, P.O. Tajpura, Taluka-Halol District-Panchmahal,-389350, Gujarat, India.

Metformin is manufactured by Aarti Drugs Limited, Plot No. G- 60, M.I.D.C. Tarapur, Palghar, District Thane – 401506, Maharashtra, India.

The API specifications are both pharmacopoeial and 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 fennmet include sodium starch glycolate, P.V.P.K-30, microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide, titanium dioxide, yellow oxide of iron, isopropyl alcohol, methylene dichloride 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

Shukra Pharmaceuticals Limited, Plot No. 795, Rakanpur Sola-Santej Road, Ta. Kalol, Dist. Gandhinagar, Gujarat, 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, Galvus-Met manufactured by Novartis Pharma AG, Switzerland.

The product is manufactured by dry mixing, wet granulation, 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 Galvus-Met (Novartis) and fennmet. 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, disintegration time and assay. 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.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of fennmet was acceptable for the following indication: 'for the management of type 2 diabetes mellitus', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Fenn Pharma Limited, 45 Oyedele Oggunniyi Street, Anthony Village, Lagos, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of fennmet.

The following are the steps for registration

October 2025	Date of receipt of application
November 2025	Date of conclusion of assessment
October 2023	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 Fennmet tablets.