



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

NAFDAC Public Assessment Report (NAPAR)

Panfor–stg 50/1000 mg tablets

**Sitagliptin hydrochloride/metformin hydrochloride
50 mg/1000 mg**

A4-102033

Mega Lifesciences Nigeria Limited

This report reflects the scientific assessment for the approval of Panfor–stg 50/1000 mg tablets. The product was licenced in March 2026.

PART 1: ABSTRACT

Panfor–stg tablets containing sitagliptin and metformin hydrochloride, manufactured at SAG Manufacturing S.L.U, San Agustin De Guadalix, Madrid, Spain, was granted marketing authorization by NAFDAC for the improvement of glycemic control in adults with type 2 diabetes mellitus on 31 March 2026.

Panfor–stg tablet is indicated for the improvement of glycemic control in adults with type 2 diabetes mellitus not adequately controlled on metformin.

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 panfor–stg 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 panfor–stg 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 panfor–stg has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of panfor–stg tablets.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Panfor–stg 50 mg/1000 mg tablets	Sitagliptin hydrochloride/ metformin hydrochloride 50 mg/1000 mg	Film-coated tablet Red to brown, capsule-shaped, film-coated tablets. The tablets have ‘S’ and ‘B’ debossed (stamped into) one side separated by a score line, and are plain on the other side	Clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 14 tablets. Available in cartons of 4 x 14 tablets	4 × 14 tablets

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

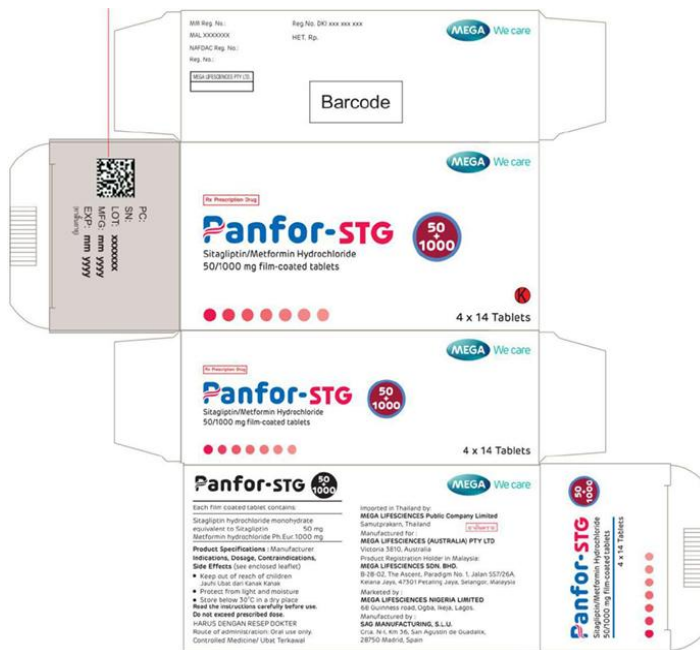
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Panfor–stg 50 mg/1000 mg tablets

5.1.2 Therapeutic indication

Panfor–stg tablet is indicated for the improvement of glycemic control in adults with type 2 diabetes mellitus not adequately controlled on metformin.

5.1.3 Applicant

Mega Lifesciences Nigeria Limited, 6b Guinness Road, Ogba, Ikeja, Lagos.

5.1.4 Pharmaceutical form

Film-coated tablet

Red to brown, capsule-shaped, film-coated tablets. The tablets have ‘S’ and ‘B’ debossed (stamped into) one side separated by a score line, 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

Clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 14 tablets. Available in cartons of 4 x 14 tablets

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredients, metformin hydrochloride and sitagliptin hydrochloride, are manufactured by SAG Manufacturing S.L.U., Carretera Nacional 1, Kilometer 36, San Agustin Del Guadalix, 28750, Madrid, Spain, and Benechim S.R.L., Zoning Nord, Rue René Magritte, 163, 7860 – Lessines, Belgium, respectively.

The API specifications for metformin hydrochloride are pharmacopoeial based, while the API specifications for sitagliptin hydrochloride are in-house.

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 panfor–stg tablets include povidone, microcrystalline cellulose, crospovidone, sodium stearyl fumarate, ready-to-use coating material 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

SAG Manufacturing S.L.U., Carretera Nacional 1, Kilometer 36, San Agustin Del Guadalix, 28750, Madrid, Spain.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Janumet tablets currently licensed by Merck Sharp & Dohme BV, The Netherlands.

The manufacturing method used was granulation, tableting, and packaging. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, Janumet tablets (Merck Sharp & Dohme BV, The Netherlands) and panfor–stg. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on in-house standards. The finished product specifications include identification, dissolution, assay and impurities. 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 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of panfor–stg tablet was acceptable for the following indication: ‘for the improvement of glycemic control in adults with type 2 diabetes mellitus not adequately controlled on metformin’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Mega Lifesciences Nigeria Limited, 6b Guinness Road, Ogba, Ikeja, Lagos, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of panfor–stg tablets.

The following are the steps for registration

November 2024	Date of receipt of application
April** 2026	Date of conclusion of assessment
December 2025	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 Panfor–stg tablets.