



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

NAFDAC Public Assessment Report (NAPAR)

Ziglip 50 mg tablets

Sitagliptin phosphate 50 mg

A4-102078

Zifam Pinnacle Nigeria Limited

This report reflects the scientific assessment for the approval of Ziglip 50 mg tablets. The product was licenced in April 2026.

PART 1: ABSTRACT

Ziglip–50 tablets containing Sitagliptin phosphate monohydrate, manufactured at Delta Biopharma Private Limited, Naidupeta, Andhra Pradesh, India, was granted marketing authorization by NAFDAC for the management of type 2 diabetes mellitus on 28 April 2026.

Ziglip–50 is indicated for the management of glycemia 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 ziglip–50 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 ziglip–50 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 ziglip–50 has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of ziglip–50.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Ziglip 50 mg tablets	Sitagliptin phosphate monohydrate 50 mg	Film-coated tablet White to off-white film-coated tablets. The tablets have a score line on one side and are plain on the other side.	Aluminium foil blister cards, 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

Ziglip-50 tablets

5.1.2 Therapeutic indication

Ziglip-50 is indicated for the management of glycemia in adults with type 2 diabetes mellitus.

5.1.3 Applicant

Zifam Pinnacle Nigeria Limited, No. 227, Ikorodu Ososun Road, Ilupeju, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Film-coated tablet

White to off-white, film-coated tablets. 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

Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 3 x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, sitagliptin phosphate monohydrate, is manufactured by MSN Life Sciences Private Limited, Unit-III, Sy. No. 544, 545 & 546, Bhiknoor, Kamareddy District, Telangana, India.

The API specifications are pharmacopoeial 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 ziglip-50 include microcrystalline cellulose, anhydrous calcium hydrogen phosphate, povidone, isopropyl alcohol, croscarmellose sodium, sodium stearyl fumarate, magnesium stearate 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

Delta Biopharma Private Limited, Plot No. 58, Block C, Industrial Park, Menakuru Village, Naidupeta Mandal, Tirupati District- 524126, Andhra Pradesh, India.

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 Januvia tablets currently licensed by Merck Sharp & Dohme (UK) Limited.

The manufacturing method used was granulation, sizing, and compression. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, januvia 50 mg tablets (Merck Sharp & Dohme (UK) Limited) and ziglip-50. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on the USP monograph. The finished product specifications include identification, assay, disintegration and impurities. 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 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 ziglip-50 was acceptable for the following indication: 'for the management of glycemia 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, Zifam Pinnacle Nigeria Limited, No. 227, Ikorodu Ososun Road, Ilupeju, Lagos, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of ziglip-50 tablets.

The following are the steps for registration

November 2024	Date of receipt of application
April 2026	Date of conclusion of assessment
February 2026	Date of inspection
28 April 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of ziglip-50 tablets.