



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

NAFDAC Public Assessment Report (NAPAR)

Levofloxacin 500 mg tablets

Levofloxacin 500 mg

A4-102334

Dannyfaith Pharmacy Limited

This report reflects the scientific assessment for the approval of Levofloxacin 500 mg tablets. The product was licenced in July 2026.

PART 1: ABSTRACT

Levofloxacin tablets manufactured at Alpa Laboratories Limited, Pigdamber, Madhya Pradesh, India, was granted marketing authorization by NAFDAC for the treatment of susceptible bacterial infections on 28 July 2026.

Levofloxacin is indicated for the treatment of susceptible bacterial infections.

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 levofloxacin tablets 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 levofloxacin 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 levofloxacin have been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Levofloxacin 500 mg tablets	Levofloxacin 500 mg	Film-coated tablet Yellow, capsule-shaped, film-coated tablets. The tablets 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	Aluminum foil blister cards, each containing 10 tablets. Available in cartons of 10 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

Levofloxacin 500 mg tablet

5.1.2 Therapeutic indication

Levofloxacin tablet is indicated for the treatment of susceptible bacterial infections.

5.1.3 Applicant

Dannyfaith Pharmacy Limited, No. 23, Oseni Street, Lawanson, Lagos.

5.1.4 Pharmaceutical form

Film-coated tablet

Yellow, capsule-shaped, film-coated tablets. The tablets 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

36 months

5.1.7 Product presentation

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

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, Levofloxacin, is manufactured by Aarti Drugs Limited, Plot No. 109 – D, Mahendra Industrial Estate, Road No 29, Sion (East), Mumbai - 400 022, India.

The API specifications are in-house and adequately validated.

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 levofloxacin tablet include microcrystalline cellulose, polyvinylpyrrolidone k-30, crospovidone, colloidal silicon dioxide, magnesium stearate, purified talc, iso propyl alcohol, methylene chloride, all being pharmacopoeial controlled, and insta coat white and colour of lake of tartrazine being in-house controlled.

None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Alpa Laboratories Limited, 33/2 A.B Road, Pigdamber, Madhya 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 Tavanic 500 mg currently licensed by Sanofi Aventis.

The manufacturing method used was dry mixing, sizing, and compression. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, Tavanic 500 mg tablets (Sanofi Aventis) and levofloxacin 500 mg tablets. The profiles in the three BCS media are similar.

5.4.3 Specification

The finished product specification is based on in-house standards. The finished product specifications include description, identification, average weight of a tablet, dissolution, uniformity of dosage units, 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' have been accepted.

5.5 Conclusion

Based on the assessment of data, the benefit–risk profile of levofloxacin tablet was acceptable for the following indication: 'for the treatment of susceptible bacterial infections' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Dannyfaith Pharmacy Limited, No. 23, Oseni Street, Lawanson, Lagos State, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of levofloxacin tablet.

The following are the steps for registration

July 2026	Date of receipt of application
May 2026	Date of conclusion of assessment
July 2026	Date of inspection
28 July 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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