



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

NAFDAC Public Assessment Report (NAPAR)

Linezolid 600 mg tablet

Linezolid 600 mg

A4-101853

Hetero Labs Nigeria Limited

This report reflects the scientific assessment for the approval of linezolid tablet. The product was licenced in December 2025.

PART 1: ABSTRACT

Linezolid tablet, manufactured at Hetero Labs Limited, Unit-V, Jadcherla, Telangana, India, was granted marketing authorization by NAFDAC for the treatment of serious infections caused by susceptible bacteria on 18 December 2026.

Linezolid tablet is indicated for the treatment of serious infections caused by susceptible gram-positive bacteria.

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 Linezolid tablet 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 linezolid 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 Linezolid tablet has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Linezolid 600 mg tablets	Linezolid 600 mg	Film-coated tablet White to off white, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a bevelled edged. The tablets have 'H' debossed (stamped into) on one side and on the other side 'L' and '8' separated by a break line.	Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 1 x 10 tablets	1x 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

Appearance



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Linezolid 600 mg tablet

5.1.2 Therapeutic indication

Linezolid tablet is indicated for the treatment of serious infections caused by susceptible gram-positive bacteria.

5.1.3 Applicant

Hetero Labs Nigeria Limited, No.8 Wole Ogunjimi Street, Agbaoku street Opebi Road, Ikeja, Lagos State, Nigeria.

5.1.4 Pharmaceutical form

Film-coated tablet

White to off white, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a bevelled edged. The tablets have 'H' debossed (stamped into) on one side and on the other side 'L' and '8' separated by a break line.

5.1.5 Storage

Store below 30°C. Protect from moisture.

5.1.6 Shelf life

60 months

5.1.7 Product presentation

Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 1 x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

Linezolid is manufactured by Symed Labs Limited, Unit-I, Survey No.353, Domadugu (Village), Gummadidala (Mandal), Sanga Reddy (Dist)-, 502 313 Telangana, India.

The API specifications include tests for description, solubility, identification (IR, and XRPD), loss on drying, residue on ignition, heavy metals, specific optical rotation, related substances and other synthesis impurities (HPLC with UV and MS detection, and GC), assay (HPLC), enantiomeric purity (chiral HPLC; $\leq 0.08\%$), residual solvents (GC), particle size distribution and microbiological examination. Synthesis related genotoxic impurities are controlled at justified levels.

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 core tablet formulation include lactose monohydrate, maize starch, hydroxypropyl cellulose, sodium starch glycolate and magnesium stearate. The commercially sourced proprietary film-coating mixture contains hypromellose, titanium dioxide, macrogol and carnauba wax. TSE / BSE free attestations have been provided for the excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Hetero Labs Limited, Unit-V, Sy No. 439, 440, 441 & 458, TSIC Formulation SEZ, Polepally village, Jadcherla Mandal, Mahaboob Nagar (Dist) – 509301, Telangana, 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, Zyvoxid® 600 mg manufactured by Pfizer.

The product was manufactured using the wet granulation technique, followed by drying, milling, lubrication, and compression into tablets.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Zyvoxid (Pfizer) and Linezolid tablet. The profile in the three BCS media are similar.

5.4.3 Specification

The finished product specifications include tests for description, identification of the API (HPLC, UV) and colorant, average weight, water content (KF), dissolution (UV detection), uniformity of dosage units (by weight variation), related substances (HPLC), assay (HPLC), hardness, subdivision of tablets and microbiological examination.

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 36 months and store below 30°C. Protect from moisture have been accepted.

5.5 Assessment of bioequivalence

The following bioequivalence study has been performed in 2014 according to internationally accepted guidelines.

The objective of the study was to compare the bioavailability of the stated Linezolid 600 mg tablets manufactured for/by Hetero Labs Ltd., India (test drug) with the reference formulation Zyvoxid® (Pharmacia GmbH/Pfizer Pharma GmbH) and to assess bioequivalence.

The comparison was performed as a single center, open label, randomized, crossover study in healthy subjects under fasting conditions. Each subject was assigned to receive each of the following treatments in a randomized fashion:

Treatment T: Test – 1 tablet Linezolid 600 mg
(linezolid 600 mg) Batch no. LIN113001.

Treatment R: Reference – 1 tablet Zyvoxid®
(linezolid 600 mg) Batch no. V131600

An 8-day wash-out period was observed between administration of test and reference. Serial blood samples (1 pre-dose sample and 24 samples within 36 h post dose) were taken during each study period to obtain bioavailability characteristics AUC, C_{max} and t_{max} for bioequivalence evaluation. Drug concentrations for linezolid were analyzed using a validated LC-MS/MS method. The limit of quantification was stated to be about 0.125 µg/mL for linezolid.

The study was performed with 32 participants; data generated from a total of 30 subjects were utilized for analysis to establish pharmacokinetic parameters and assess bioequivalence.

Arithmetic mean and geometric mean values of the pharmacokinetic variables for linezolid as well as statistical results are summarised in the following table:

Linezolid

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean ± SD (geometric mean)	Reference (R) arithmetic mean ± SD (geometric mean)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90% CI (ANOVAlog)
t _{max} (h)	1.99 ± 1.07	1.77 ± 1.12	—	—
C _{max} (µg/mL)	13.8 ± 2.7 (13.5)	13.9 ± 2.7 (13.7)	98.7	93.6 – 104.1
AUC _{0-t} (µg·h/mL)	145 ± 32 (141)	148 ± 30 (145)	97.5	93.4 – 101.7
AUC _{0-inf} (µg·h/mL)	150 ± 37 (146)	153 ± 33 (150)	97.6	93.3 – 102.1

The results of the study show that preset acceptance limits of 80 -125 % are met by both AUC and Cmax values regarding linezolid. Accordingly, the test tablet Linezolid 600 mg meets the criteria for bioequivalence with regard to the rate and extent of absorption and is therefore bioequivalent to the reference Zyvoxid® (Pharmacia GmbH/Pfizer Pharma GmbH).

5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of linezolid tablet was acceptable for the following indication: 'for the treatment of serious infections caused by susceptible Gram-positive bacteria', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Hetero Labs Nigeria Limited, No.8 Wole Ogunjimi Street, Agbaoku street Opebi Road, Ikeja, Lagos State, Nigeria. submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Linezolid tablet.

The following are the steps for registration

October 2024	Date of receipt of application
November 2024	Date of conclusion of assessment
June 2025	Date of inspection
18 December 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Linezolid 600 mg tablet.