



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

NAFDAC Public Assessment Report (NAPAR)

Moxifloxacin hydrochloride 400 mg tablets

Moxifloxacin hydrochloride 400 mg

A4-102350

Hetero Labs Nigeria Limited

This report reflects the scientific assessment for the approval of moxifloxacin hydrochloride 400 mg tablets. The product was licenced in July 2026.

PART 1: ABSTRACT

Moxifloxacin hydrochloride tablets, manufactured at Hetero Labs Limited, Jadcherla, Telangana, India, was granted marketing authorization by NAFDAC for the treatment of susceptible bacterial infections on 28 July 2026.

Moxifloxacin hydrochloride is indicated for the treatment of susceptible bacterial infections in adult patients.

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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets 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 moxifloxacin hydrochloride have been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of moxifloxacin hydrochloride tablets.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Moxifloxacin hydrochloride 400 mg tablets	Moxifloxacin hydrochloride 400 mg	Film-coated tablet Pink, capsule-shaped, biconvex (rounded on top and bottom) film-coated tablets. They are debossed (stamped into) with '80' on one side and 'I' on the other side with a break line.	Aluminium foil on aluminium foil blister card each containing 10 tablets. Available in packs of 1x 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

Moxifloxacin Hydrochloride
Tablets 400 mg
Moxifloxacin HCl 400 mg
Comprimés de

Prescription only Medicine - List I
Médicament uniquement sur ordonnance - Liste I

HETERO

Moxifloxacin HCl Tablets 400mg
1 x 10 Tablets

Each film-coated tablet contains:
436.33 mg of Moxifloxacin HCl Ph. Eur eq. to
400 mg of Moxifloxacin.
Dosage: As directed by the physician.
Store below 30°C.
Route of administration: **Oral**
Keep out of reach of children.
See package insert for full prescribing
information.

Kenya Reg. No.: H2014/CTD1291/067
Tanzania Reg. No.: TZ14H0109
Uganda Reg. No.: S289/06/13
NAFDAC Reg. No.:
Botswana Reg. No.: PMP/PL401/60
Malawi Reg. No.:
Namibia Reg. No.:
Zambia Reg. No.:

1 x 10 Tablets

1 x 10 Tablets / Comprimés



Marketed by:
Hetero Labs Nigeria Limited,
8B, Wole Ogunjimi Street, Opebi, Road,
Ikeja, Lagos, Nigeria.

Mfg. Lic. No.: 50MN/AP/2009/F/R

Chaque comprimé pelliculé contient: 436.33 mg
de Moxifloxacin HCl Ph. Eur eq. à 400 mg de
Moxifloxacin.

Posologie: Comme dirigé par le médecin.
Conservez moins de 30°C.
Voie d'administration: **Orale**
Tenir hors de portée des enfants.
Voir la notice pour posologiques complètes
information

Manufactured by/Fabrique par:
HETERO LABS LIMITED
UNIT-V, TSIC Formulation SEZ,
Polepally Village, Jachcherla Mandal,
Mahabubnagar Dist., Telangana, India.

Comprimés de Moxifloxacin HCl 400 mg
1 x 10 Comprimés

UNVARIISH AREA
FOR BATCH CODING

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Moxifloxacin hydrochloride 400 mg tablets

5.1.2 Therapeutic indication

Moxifloxacin hydrochloride is indicated for the treatment of susceptible bacterial infections in adult patients.

5.1.3 Applicant

Hetero Labs Nigeria Limited, 10b, Olufunmilola Street, Off Toyin Street, Ikeja, Lagos State.

5.1.4 Pharmaceutical form

Film-coated tablet

Pink, capsule-shaped, biconvex (rounded on top and bottom) film-coated tablets. They are debossed (stamped into) with '80' on one side and 'I' on the other side with a break line.

The break line can be used to divide the tablet into equal doses.

5.1.5 Storage

Store below 30°C. Store in the original package in order to protect from light.

5.1.6 Shelf life

48 months

5.1.7 Product presentation

Aluminium foil on aluminium foil blister card each containing 10 tablets. Available in packs of 1x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, moxifloxacin hydrochloride, is manufactured by Hetero Drugs Limited Unit-I, Sy. No. 213, 214 and 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District -502 313, 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 core tablet formulation include microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, povidone and magnesium stearate, all being pharmacopoeial controlled. The commercially sourced proprietary film-coating mixture contains hypromellose, titanium dioxide, macrogol/PEG, iron oxide red and iron oxide yellow. BSE/TSE compliance declarations were provided for all excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Hetero Labs Limited, Unit V, Survey Nos. 439, 440, 441 & 458, Telangana State Industrial Infrastructure Corporation Formulation Special Economic Zone, Polepally Village, Jadcherla Mandal, Mahaboob Nagar District – 509301, Telangana, 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 Avalox[®] currently licensed by HSG.

The manufacturing method used was Wet granulation to overcome the poor flowability observed in trial batches. The formulation and process parameters were optimised, targeting the dissolution profiles of the comparator product. Appropriate in-process controls were set to ensure batch-to-batch reproducibility.

5.4.3 Specification

The finished product specification includes appropriate tests for description, identification of the API (HPLC, TLC, UV) and colorants, average weight, water content (KF), uniformity of dosage units (by weight variation), dissolution (UV detection), related compounds (HPLC), assay (HPLC) and microbial limits. 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 ‘Store below 30°C. Store in the original package in order to protect from light.’ have been accepted.

5.5 Assessment of bioequivalence

The following bioequivalence study has been performed in 2011 according to internationally accepted guidelines.

The objective of the study was to compare the bioavailability of moxifloxacin hydrochloride, manufactured by Hetero Labs Limited, India (test drug) with the reference formulation Avalox[®] (Bayer Schering Pharma) and to assess bioequivalence.

The bioequivalence study was conducted using a randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Moxifloxacin hydrochloride 400 mg tablets of Hetero Labs Limited, Hyderabad, India and Avalox[®] (moxifloxacin hydrochloride) 400 mg tablets of Bayer Schering Pharma, UK, in healthy human adult subjects, under fasting conditions (study no. 2562/11).

Subjects received a single dose of either the test product (moxifloxacin 400 mg, Batch No. J100072) or the reference product (Avalox®, moxifloxacin hydrochloride 400 mg, Batch No. ITA07RB), with a 5-day washout period between treatments. Serial blood samples were collected pre-dose and at 25 time points up to 60 hours post-dose during each study period. Plasma moxifloxacin concentrations were determined using a validated LC-MS/MS method. Pharmacokinetic parameters, including AUC, C_{max} and t_{max}, were assessed for bioequivalence. Of the 36 subjects enrolled, data from 35 subjects were included in the pharmacokinetic and bioequivalence analyses.

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

Moxifloxacin

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)	2.11 ± 1.12	1.95 ± 0.96	–	–
C _{max} (µg/mL)	1.92 ± 0.40 (1.89)	1.95 ± 0.46 (1.91)	99.1	95.3 – 103.0
AUC _{0-t} (µg·h/mL)	28.3 ± 4.5 (27.9)	27.9 ± 4.5 (27.6)	101.3	99.4 – 103.3
AUC _{0-inf} (µg·h/mL)	29.6 ± 4.7 (29.3)	29.3 ± 4.7 (29.0)	101.1	99.1 – 103.0

The results of the study show that preset acceptance limits of 80 -125 % are met by both AUC and C_{max} values regarding moxifloxacin. Accordingly, the test tablet, moxifloxacin meets the criteria for bioequivalence with regard to the rate and extent of absorption and is therefore bioequivalent to the reference Avelox® (Bayer Schering Pharma). Moxifloxacin hydrochloride tablet has been shown to be bioequivalent with Avalox® (Bayer Schering Pharma).

5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of moxifloxacin hydrochloride 400 mg tablet was acceptable for the following indication: ‘for the treatment of susceptible bacterial infections in adult patients’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Hetero Labs Nigeria Limited, 10b, Olufunmilola Street, Off Toyin Street, Ikeja, Lagos State, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of moxifloxacin hydrochloride tablet.

The following are the steps for registration

February 2025	Date of receipt of application
October 2025	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 Moxifloxacin hydrochloride tablet.