



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

Public Assessment Report (PAR)

Moxifloxacin ophthalmic solution

Moxifloxacin hydrochloride 0.5% w/v

A4-102346

Genex Life Sciences Limited

This report reflects the scientific assessment for the approval of Moxifloxacin ophthalmic solution. The product was licenced in July 2026.

PART 1: ABSTRACT

Moxifloxacin ophthalmic solution, manufactured at Axa Parenterals Limited, Delhi, India, was granted marketing authorization by NAFDAC for the treatment of conjunctivitis on 28 July 2026.

Moxifloxacin is indicated for the treatment of purulent bacterial conjunctivitis caused by susceptible strains.

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 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 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 have been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of moxifloxacin ophthalmic solution.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Moxifloxacin ophthalmic solution	Moxifloxacin hydrochloride 0.5% w/v	Ophthalmic solution Clear, yellow solution free from visible particles filled in a 5 mL transparent plastic bottle	5 mL transparent plastic (LDPE) bottle with nozzle and cap	1 x 5 mL

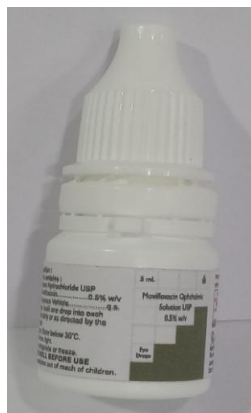
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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

Moxifloxacin ophthalmic solution

5.1.2 Therapeutic indication

Moxifloxacin ophthalmic solution is indicated for the topical treatment of purulent bacterial conjunctivitis caused by susceptible strains.

5.1.3 Applicant

Genex Life-Sciences Limited, 7 Sapara Williams Industrial Estate, Ikeja, Lagos State, Nigeria.

5.1.4 Pharmaceutical form

Ophthalmic solution

A clear, colourless, slightly viscous solution, free from particulate matter.

5.1.5 Storage

Do not store above 30°C, protect from sunlight

5.1.6 Shelf life

24 months

5.1.7 Product presentation

5 mL transparent plastic (LDPE) bottle with nozzle and cap.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, moxifloxacin hydrochloride, is manufactured by Enaltec Labs Private Limited, Manufacturing and Testing Facility, Plot Nos. 825, 826 & 827, Sector 3, Industrial Area, District Dhar, Pithampur – 454774, Madhya Pradesh, 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 moxifloxacin ophthalmic solution include boric acid, sodium chloride, sodium hydroxide, hydrochloric acid, and water for injection, 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

Axa Parenterals Limited, 703–704, Pearls Best Height-2, Netaji Subhash Place, Pitampura, Delhi, 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, Vigamox® ophthalmic solution, currently licensed by Harrow.

The manufacturing method used was mixing, filtration, filling and aseptic sterilization. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house standard and the USP monograph. The finished product specifications include identification, particulate matter, extractable volume, sterility, osmolality, organic impurities, pH, assay, and water loss. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of 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, protect from sunlight' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of moxifloxacin ophthalmic solution was acceptable for the following indication: 'for the topical treatment of purulent bacterial conjunctivitis caused by susceptible strains' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Genex Life-Sciences Limited, 7 Sapara Williams Industrial Estate, Ikeja, Lagos State, Nigeria, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of moxifloxacin ophthalmic solution.

The following are the steps for the registration of moxifloxacin ophthalmic solution

December 2025	Date of receipt of application
February 2026	Date of conclusion of assessment
May 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 ophthalmic solution.