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

Public Assessment Report (PAR)

Ndonol eye drops 0.5% w/v

Timolol maleate BP 0.5% w/v

A4-101570

Ndozz Pharmaceutical Nigeria Limited

This report reflects the scientific assessment for the approval of Ndonol eye drops. The product was licenced in September 2025.

PART 1: ABSTRACT

Ndonol eye drops containing timolol maleate, manufactured at Alpa Laboratories Limited, Indore, India, was granted marketing authorization by NAFDAC for the treatment of high intraocular pressure (IOP) in the eye such as in ocular hypertension and glaucoma on 24 September 2025.

Ndonol eye drops is indicated for the treatment of high intraocular pressure (IOP) in the eye such as in ocular hypertension and glaucoma.

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 Ndonol eye drops 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 Ndonol eye drops 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 Ndonol eye drops has been presented in Part 5 of this report.

The detailed steps taken to approve Ndonol eye drops by NAFDAC have been presented in Part 6 of this report.

No action or steps have been taken following the marketing authorization of Ndonol eye drops.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredient	Pharmaceutical form/Description	Packaging	Pack size
Ndonol 0.5% w/v eye drops	Timolol maleate BP 0.5% w/v	A clear colourless to pale yellow solution filled in sealed white 10 mL plastic container.	10 mL Opaque white plastic bottle with a white colour screw cap.	10 mL plastic bottle.

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

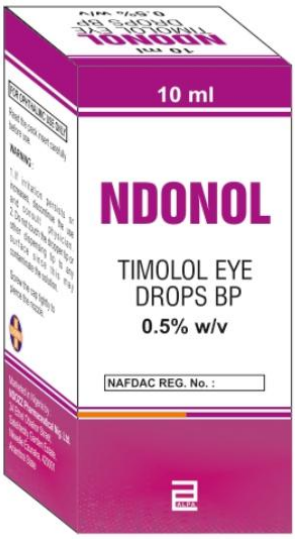
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Ndonol eye drops 0.5%w/v

5.1.2 Therapeutic indication

Ndonol eye drops is indicated for the treatment of high intraocular pressure (IOP) in the eye such as in ocular hypertension and glaucoma.

5.1.3 Applicant

Ndozz Pharmaceutical Nigeria Limited, 34 Ethel Obiakor Street, Satelite City Garden Estate, Nkwelle Ezunaka Anambra State, Nigeria.

5.1.4 Pharmaceutical form

A clear colourless to pale yellow solution filled in sealed white 10 mL plastic container.

5.1.5 Storage

Do no store above 30ºC. Store in the original packaging. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Ndonol eye drops is presented as 10 mL opaque white plastic bottle with a white colour screw cap containing a filled clear colourless to pale yellow solution packed in a printed mono carton along with a leaflet.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, timolol maleate BP is manufactured by Slfavltor S.r.1. - Via Livelli, 1 - 26852 Casaletto Lodigiano, Frazione Mairano - (LO) Italy.

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 Ndonol eye drops include benzalkonium chloride BP, sodium hydroxide BP and water for injection, all being controlled by pharmacopoeial. 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, Indore (MP)-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, Timoptic currently licensed by Bausch & Lomb**,** USA**.**

The manufacturing method used was steam sterilization followed by filtration. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include identification by IR, particulate contamination visible, extractable volume, pH, sterility, related substances, and assay. 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 36 months and 'Do not store above 30°C, store in the original packaging, protect from light' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ndonol eye drops was acceptable for the following indication 'for the treatment of high intraocular pressure (IOP)' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Ndozz Pharmaceutical Nigeria Limited, 34 Ethel Obiakor Street Satelite City Garden Estate, Nkwelle Ezunaka Anambra State, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ndonol eye drops.

The following are the steps for the registration of Ndonol eye drops.

October 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
July 2025	Date of inspection
24 September 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Ndonol eye drops.