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

Public Assessment Report (PAR)

Diclofenac 0.1% w/v eye drops

Diclofenac sodium BP 0.1% w/v

A4-101874

Pharma Aid Limited

This report reflects the scientific assessment for the approval of Diclofenac eye drops. The product was licenced in January 2026.

PART 1: ABSTRACT

Diclofenac eye drops, manufactured at Alpa Laboratories Limited, Pigdamber, Indore (Madhya Pradesh), India, was granted marketing authorization by NAFDAC for the relief of eye pain and for managing traumatic ocular inflammation on 27 January 2026.

Diclofenac eye drops is indicated for the relief of eye pain and for managing traumatic ocular inflammation.

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

The detailed steps taken to approve diclofenac 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 diclofenac eye drops.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Diclofenac 0.1% w/v eye drops	Diclofenac sodium BP 0.1% w/v	Eye drops A clear colourless to pale yellow solution filled in 10 mL white plastic container with white screw cap and sealed.	10 mL white plastic bottle with white cap and white plug.	1 x 10 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

Diclofenac 0.1% w/v eye drops

5.1.2 Therapeutic indication

Diclofenac eye drops is indicated for the relief of eye pain and for managing traumatic ocular inflammation.

5.1.3 Applicant

Pharma Aid Limited**,** No. 302, Ijegun Road, Lagos State.

5.1.4 Pharmaceutical form

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

5.1.5 Storage

Do not store above 30°C, protect from light.

5.1.6 Shelf life

36 months.

5.1.7 Product presentation

Diclofenac eye drops is presented as a 10 mL white plastic bottle with white screw cap containing a clear, colourless to pale yellow solution, which is sealed and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, diclofenac sodium, is manufactured by Aarti Drugs Limited, Plot No. G - 60, Maharashtra Industrial Development Corporation, Tarapur, Palghar Taluka, District Thane - 401 506, Maharashtra, 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 diclofenac eye drops include disodium EDTA BP, potassium dihydrogen phosphate BP, sodium sulphite BP, benzalkonium chloride (50% solution) BP, propylene glycol BP, sodium hydroxide BP, beta hydroxypropyl cyclodextrins BP and water for injections BP, 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

Alpa Laboratories Limited, 33/2 A.B Road, Pigdamber, Indore (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, Voltaren ophthalmic eye drops.

The manufacturing method used was dissolution, steam sterilization, and filtration. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is in-house. The finished product specifications include description, identification, particulate matter, pH, average extractable volume, sterility 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 at 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, protect from light' have been accepted.

5.5 Conclusion

Based on the assessment of data of data submitted, the benefit–risk profile of diclofenac eye drops was acceptable for the following indication: 'for the relief of eye pain and for managing traumatic ocular inflammation', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Pharma Aid Limited, No 302 Ijegun Road, Lagos State, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of diclofenac eye drops.

The following are the steps for the registration of diclofenac eye drops

November 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
July 2022	Date of inspection
27 January 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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