



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

Public Assessment Report (PAR)

Marley Diclofenac sodium 75 mg/3 mL injection

Diclofenac sodium 75 mg/3mL

A4-101565

Marleyshree Pharmaceutical Company Nigeria Limited

This report reflects the scientific assessment for the approval of Marley Diclofenac sodium injection. The product was licenced in September 2025.

PART 1: ABSTRACT

Marley Diclofenac sodium injection, manufactured at TianJinKingYork Group HuBeiTianYao Pharmaceutical Company Limited, XiangYang, HuBei Province, China, was granted marketing authorization by NAFDAC for the relieve of pain, inflammation, swelling, and stiffness on 24 September 2025.

Marley Diclofenac sodium is indicated for the relief of pain, inflammation, swelling, and stiffness.

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 Marley Diclofenac sodium 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 Marley Diclofenac sodium 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 Marley Diclofenac sodium has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Marley Diclofenac sodium.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Marley Diclofenac sodium 75 mg/3 mL injection	Diclofenac sodium 75mg/3mL	injection almost colourless clear liquid	10 x 3 mL Low borosilicate glass ampoules containing almost colourless clear liquid placed in tray and packed in a printed mono carton	10 x 3 mL ampoules

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

Marley Diclofenac sodium 75 mg/3 mL injection

5.1.2 Therapeutic indication

Marley Diclofenac sodium injection is used for the relieve of pain, inflammation, swelling, and stiffness.

5.1.3 Applicant

Marleyshree Pharmaceutical Company Nigeria Limited, Plot 83, Zungeru Road, Kano, Nigeria.

5.1.4 Pharmaceutical form

An injection containing an almost colourless clear liquid in a low borosilicate glass ampoule.

5.1.5 Storage

Do not Store above 30°C

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Marley Diclofenac sodium injection is presented as 10 x 3 mL in a low borosilicate glass ampoule containing almost colourless liquid. They are placed in a tray and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

Diclofenac sodium is manufactured by Henan Dongtai Pharmaceutical Company Limited, East Changhong Road, Tangyin County, Anyang City, Henan Province.

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 Marley Diclofenac sodium injection include lysine hydrochloride, propylene glycol, benzyl alcohol, disodium edetate, anhydrous sodium sulfite, 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

TianJin KingYork Group HuBeiTianYao Pharmaceutical Company Limited, No.99, HanJiangBei Road, XiangYang City, HuBei Province, China.

5.4.2 Pharmaceutical development

The objective of pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in terms of efficacy to the reference product, Voltarol® (75 mg/3 mL), produced by Novartis Pharmaceuticals.

The manufacturing method used was dry sterilization. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on ICHQ6A guidelines for injectables. The finished product specifications include identification, average net volume, extractable volume, pH, bacterial endotoxin test, sterility, particulate matter, 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 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' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Marley Diclofenac sodium injection was acceptable for the following indication: 'for the relieve of pain, inflammation, swelling, and stiffness', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Marleyshree Pharmaceutical Company Nigeria Limited. Plot 83, Zungeru Road, Kano, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Marley Diclofenac sodium injection.

The following are the steps for the registration of Marley Diclofenac sodium injection

September 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
July 2025	Date of inspection
24 September 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Marley Diclofenac sodium injection.