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

Public Assessment Report (PAR)

Jopar paracetamol infusion 1 g/100 mL

Paracetamol 1 g/100 mL

A4-101733

Jopar Brothers Pharmaceutical Limited

This report reflects the scientific assessment for the approval of Jopar paracetamol infusion. The product was licenced in November 2025.

PART 1: ABSTRACT

Jopar paracetamol infusion containing paracetamol, manufactured at Shandong Qidu Pharmaceutical Company Limited, Zibo City, Shandong Province, P.R. China, was granted marketing authorization by NAFDAC for the management of mild to moderate pain and fever on 26 November 2025.

Jopar paracetamol infusion is indicated for the management of mild to moderate pain and reducing fever.

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 Jopar paracetamol infusion 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 Jopar paracetamol infusion 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 Jopar paracetamol infusion has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Jopar paracetamol infusion.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Jopar paracetamol infusion	Paracetamol 1 g/100 mL	Colourless solution in a transparent glass bottle	Soda lime glass bottle sealed with butyl rubber stoppers and aluminum-plastic flip-off caps	1 x 100 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

Jopar paracetamol infusion 1 g/100 mL.

5.1.2 Therapeutic indication

Jopar paracetamol infusion is used for the short-term management and treatment of mild to moderate pain and fever.

5.1.3 Applicant

Jopar Brothers Pharmaceutical Limited, Dr. Abdullahi Umar Ganduje Pharmaceutical Complex, Kanawa International Market, Kano, Kano State Nigeria

5.1.4 Pharmaceutical form

Colourless solution in a 100 mL transparent glass bottle.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Jopar paracetamol infusion is a colourless liquid filled in a 100 mL soda lime glass bottle sealed with butyl rubber stopper and aluminum-plastic flip-off cap.

5.2 Drug Substance

5.2.1 Manufacturer

Paracetamol is manufactured by Hebei Jiheng (Group) Pharmaceutical Company Limited, No. 1 Weiwu Street Industrial Park, Hengshui City, Hebei Province, China.

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 Jopar paracetamol infusion include mannitol BP, cysteine hydrochloride BP, disodium hydrogen phosphate BP, sodium hydroxide BP, hydrochloric acid BP and water for injection BP, all being pharmacopoeial controlled. None of the excipients are derived from human or animal origin. TSE / BSE free certificates have been provided for the excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Shandong Qidu Pharmaceutical Company Limited, No. 17, Hongda Road, Linzi District, Zibo City, Shandong Province, P.R. China.

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, Paracetamol Baxter infusion manufactured by Baxter Holding B.V, Utrecht, Netherlands.

The product is manufactured by Nitrogen filling process, sealing and heat sterilization following the depyrogenation of the glass bottles, rubber stoppers and aluminum caps. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include identification by HPLC, pH, osmolality, particulate matter, visible particles, bacterial endotoxins, sterility and extractable volume. 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 Jopar paracetamol infusion was acceptable for the following indication: 'short-term management and treatment of mild to moderate pain and fever', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Jopar Brothers Pharmaceutical Limited, Dr. Abdullahi Umar Ganduje Pharmaceutical Complex, Kanawa International Market, Kano, Kano State Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Jopar paracetamol infusion.

The following are the steps for the registration of Jopar paracetamol infusion

August 2024	Date of receipt of application
November 2024	Date of conclusion of assessment
October 2024	Date of inspection
26 November 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Jopar paracetamol infusion