



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

Public Assessment Report (PAR)

Oliklin paracetamol injection 300 mg/2 mL

Paracetamol 300 mg/2 mL

A4-101917

Oliklin Pharmaceuticals Nigeria Ltd

This report reflects the scientific assessment for the approval of Oliklin paracetamol injection. The product was licenced in **February 2026**.

PART 1: ABSTRACT

Oliklin paracetamol injection, manufactured at Anhui Chengshi Pharmaceutical Company Limited, Bengbu Anhui province, China, was granted marketing authorization by NAFDAC for the treatment of fever, and can also be used to relieve mild and moderate pain on 24 February 2026.

Oliklin paracetamol is indicated for the treatment of fever, and can also be used to relieve mild and moderate pain.

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 Oliklin paracetamol 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 Oliklin paracetamol 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 Oliklin paracetamol has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

| Product Name | Active Ingredients | Pharmaceutical Form/Description | Packaging | Pack size |
|-------------------------------|----------------------------------|--|-------------------------------|--------------------|
| Oliklin paracetamol injection | Paracetamol 300mg/2 mL injection | Colourless or almost colourless slightly viscous clear liquid is filled in the glass ampoule | 2 mL USP Type-I Glass Ampoule | 2 mL x 10 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



扑热息痛
成品尺寸: 144x74x13mm

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Oliklin paracetamol injection 300 mg/2 mL

5.1.2 Therapeutic indication

Oliklin paracetamol injection is used for the treatment of fever, and can also be used to relieve mild and moderate pain.

5.1.3 Applicant

Oliklin pharmaceutical Nigeria Limited, Kabba street Nomansland, Kano, Nigeria

5.1.4 Pharmaceutical form

Colourless or almost colourless slightly viscous clear liquid is filled in glass ampoule.

5.1.5 Storage

Do not store above 30°C

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Oliklin paracetamol injection is colourless or almost colourless slightly viscous clear liquid filled an amber glass ampoule

5.2 Drug Substance

5.2.1 Manufacturer

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

The API specifications are pharmacopoeia 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 Oliklin paracetamol include PEG-400, anhydrous sodium sulfite, benzyl alcohol, lidocaine hydrochloride, disodium edetate and water for injection 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

Hebei Jiheng Pharmaceutical Company Limited. No.1 Weiwu Street, Hengshui City, Industrial Park, Hebei 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.

The product is manufactured by dissolving paracetamol in water for injection along with excipients, followed by pH adjustment and filtration to achieve clarity and sterility. The solution is then aseptically filled into sterile containers, sealed, and subjected to terminal sterilization, nitrogen filling process, sealing and heat sterilization.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include characteristics, identification, pH, related substances, filling volume, visible particles, particulate matter, 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’ have been accepted.

5.6 Conclusion

Based on the assessment of data submitted the benefit–risk profile of Oliklin paracetamol was acceptable for the following indication: ‘treatment of fever, and can also be used to relieve mild and moderate pain’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, oliklin pharmaceuticals Nigeria Limited, Kabba street Nomansland, kano, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Oliklin paracetamol.

The following are the steps for the registration of Oliklin paracetamol

| | |
|-------------------------|---|
| March 2025 | Date of receipt of application |
| February 2026 | Date of conclusion of assessment |
| December 2024 | Date of inspection |
| 24 February 2026 | Date of issuance of Marketing Authorization |

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Oliklin paracetamol injection.