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

Public Assessment Report (PAR)

Feccox Paracetamol 300 mg/mL injection

Paracetamol 300 mg/mL

A4-101905

Feccox Pharmacy and General Enterprises Ltd

This report reflects the scientific assessment for the approval of Feccox paracetamol injection. The product was licenced in January 2026.

PART 1: ABSTRACT

Feccox Paracetamol injection containing paracetamol, manufactured at Guizhou Tiandi Pharmaceutical Company Limited, Qianxi'nan Buyi and Miao Autonomous Prefecture, Guizhou Province, China, was granted marketing authorization by NAFDAC for the symptomatic relief of fever, on 27 January 2026.

Feccox paracetamol injection is indicated for the symptomatic relief of 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 Feccox paracetamol injection 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 Feccox paracetamol injection 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 Feccox paracetamol injection has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Feccox paracetamol injection	Paracetamol 300 mg/mL	Liquid Injection A clear and almost colourless liquid filled in an amber colour glass ampoule	Amber glass ampoules	2 mLx10

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

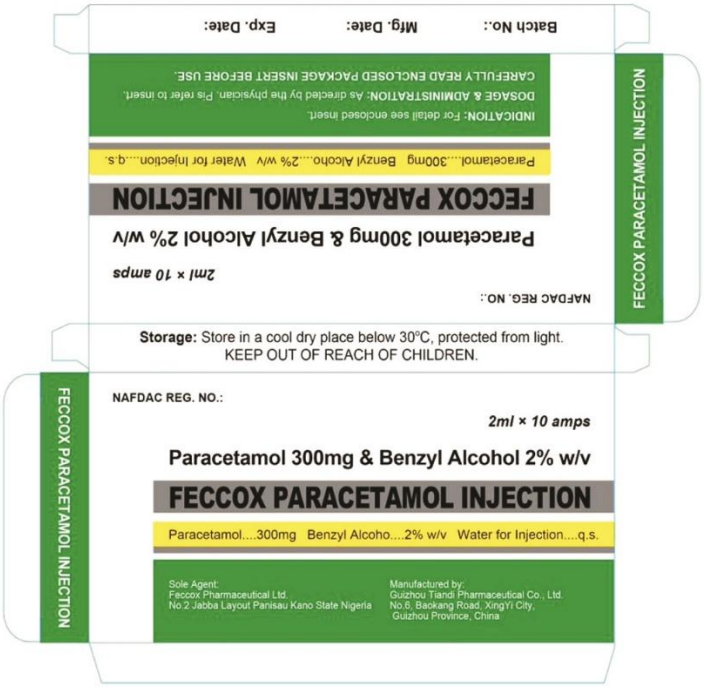
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Feccox paracetamol 300 mg/ 2mL injection.

5.1.2 Therapeutic indication

Feccox paracetamol injection is indicated for the symptomatic relief of fever.

5.1.3 Applicant

Feccox Pharmacy and General Enterprises Ltd, 2 Jabba Layout, Off Airport Road, Kano, Kano State.

5.1.4 Pharmaceutical form

Liquid injection

A clear and almost colourless liquid filled in an amber glass ampoule.

5.1.5 Storage

Do not store above 30°C

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Feccox paracetamol injection is presented as 10 x 2mL amber glass ampoule containing a clear and almost colourless liquid. Each ampoule is packed in a plastic tray, and one such tray is further enclosed in a carton along with a package insert.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, paracetamol is manufactured by Meghmani LLP**,** Plot No. CH-3, GIDC Estate, Dahej-392130, Ta. Vagra, Dist. Bharuch. Gujarat, 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 Feccox paracetamol injection include polyethylene glycol-400 BP, sodium hydrogensulfite BP, water foriInjection 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

Guizhou Tiandi Pharmaceutical Company Limited, No 6 Baokang Road, Yilong Hongxing Pharmaceutical Park, Qianxi'nan Buyi and Miao Autonomous Prefecture, Guizhou Province 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, Paranyx injection, manufactured by NYX Pharmaceuticals, India.

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

5.4.3 Specification

The finished product specification is based on In- House method. The finished product specifications include pH, extractable volume, particulate matter, bacterial endotoxin test, 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.

5.6 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Feccox paracetamol injection was acceptable for the following indication: ' for the symptomatic relief of fever ', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Feccox Pharmacy and General Enterprises Ltd, 2 Jabba Layout, Off Airport Road, Kano, Kano State submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Feccox paracetamol injection.

The following are the steps for the registration of Feccox paracetamol injection

September 2024	Date of receipt of application
November 2025	Date of conclusion of assessment
December 2025	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 Feccox paracetamol injection