



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

Public Assessment Report (PAR)

Paracetamol 300 mg/2 mL injection

Paracetamol 300 mg/2 mL

A4-101373

Grace Drugs and Healthcare Limited

This report reflects the scientific assessment for the approval of Paracetamol injection. The product was licenced in June 2025.

PART 1: ABSTRACT

Paracetamol injection containing Paracetamol is manufactured at TianJin KingYork Group HuBei TianYao Pharmaceutical Co Limited, XiangYang, HuBei Province, China was granted marketing authorization by NAFDAC for the relief of pain and fever on 25 June 2025.

Paracetamol injection 300 mg/2 mL is indicated for the relief of fever and pain associated with infections, childhood illnesses, post-immunization or postoperative states, and in conditions where oral paracetamol is not suitable.

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 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 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 Paracetamol injection has been presented in Part 5 of this report.

The detailed steps taken to approve 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 Paracetamol injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Paracetamol injection 300 mg/2 mL	Paracetamol 300 mg /2 mL	Liquid solution for injection. A colourless or almost colourless slightly viscous clear liquid	Ampoules made of low borosilicate glass.	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

Paracetamol Injection 300 mg/2ml	Paracetamol Injection 300 mg/2ml For I.M. / I.V. Use Each ml contains 150 mg of Paracetamol 2ml x 10 ampoules 	
	<small>Manufactured for Grace Drugs & Healthcare Ltd. By Tianjin Kingonk Group Hualai Tianjin Pharm. Co. Ltd. No. 95, Heping Road, Wang Jing, Hubei, China</small> <small>Batch No.: Exp. Date: Mfg. Date: NAPAR/2025/09/25</small> BARCODE	
	Paracetamol Injection 300 mg/2ml For I.M. / I.V. Use Each ml contains 150 mg of Paracetamol 2ml x 10 ampoules 	Paracetamol Injection 300 mg/2ml
<small>Distributed by: Grace Drugs & Healthcare Ltd. 1A, Ogbonna Olay, Stanley, Lagos, Nigeria</small> <small>Store at temperature not exceeding 30°C. Protect from light and moisture. Keep out of reach of children. Dosage: As directed by the physician.</small>		

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Paracetamol injection 300 mg/2 mL

5.1.2 Therapeutic indication

Paracetamol injection is indicated for the relief of fever and pain associated with infections, childhood illnesses, post-immunization or postoperative states, and in conditions where oral paracetamol is not suitable.

5.1.3 Manufacturer/applicant

Manufactured by TianJin KingYork Group HuBei TianYao Pharmaceutical Co Limited No.99, HanJiang Bei Road, XiangYang City, HuBei Province, China and local agent is Grace Drugs and Healthcare Limited, 1A Ogunlana Drive, Surulere, Lagos.

5.1.4 Pharmaceutical form

Solution

Clear solution in 2mL ampoules. Available as 2 mL x 10 ampoules

5.1.5 Storage

Store below 30°C. Protect from light. Store in the original package. Do not refrigerate or freeze.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Paracetamol injection is a clear solution in 2 mL ampoules. Available as 2 mL x 10 ampoules placed in transparent tray and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient (API) paracetamol is manufactured by Anhui BBKA Likang Pharmaceutical Co Limited, High & New Technology Industries Development Zone, Bengbu City, Anhui Province (No. 6288, Donghai Avenue), 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 Paracetamol injection include propylene glycol, polyethylene glycol-400, ethanol, benzyl alcohol, disodium edentate, anhydrous sodium sulphite, water for injection. All being pharmacopoeial controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

TianJin KingYork Group HuBei TianYao Pharmaceutical Co Limited.
No.99, HanJiang Bei Road, XiangYang City, HuBei Province, China

5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable parenteral formulation of Paracetamol injection for rapid antipyretic and analgesic action in patients unable to take oral medication.

The manufacturing method used involved screening of activated carbon and dendrotoxins, nitrogen filling, and sterilization parameters. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specification includes description (character), identification, pH, Filling volume, related substances, visible particles, particulate matter, sterility, bacterial endotoxins, 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 Store below 30°C. Protect from light. Store in the original package. Do not refrigerate or freeze. Have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Paracetamol injection 300 mg/2 mL was acceptable for the following indication: ‘Paracetamol injection 300 mg/2 mL is indicated for the relief of fever and pain associated with infections, childhood illnesses, post-immunization or postoperative states, and in conditions where oral paracetamol is not suitable’, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Grace Drugs and Healthcare Limited, 1A Ogunlana Drive, Surulere, Lagos, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Paracetamol injection.

The following are the steps for the registration of Paracetamol injection.

Paracetamol 300 mg/2 mL injection
(Grace Drugs and Healthcare Ltd),
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NAPAR

September 2025

January 2024	Date of receipt of application
May 2024	Date of conclusion of assessment
May 2025	Date of inspection
30 June 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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