



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

Public Assessment Report (PAR)

Ceftriaxone 1 g injection

Ceftriaxone sodium

A4-101400

Kal-G Pharmacy and Stores Limited

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

PART 1: ABSTRACT

Ceftriaxone injection, manufactured at Alpa Laboratories Limited, 33/2 A.B Road, Pigdamber, Indore (MP)-India, was granted marketing authorization by NAFDAC for the treatment of infections on 30 July 2025.

Ceftriaxone injection is indicated for the treatment of infections such as gonorrhoea, meningitis, pneumonia, septicaemia, typhoid fever, and syphilis, and for surgical infection prophylaxis.

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

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ceftriaxone 1 g injection	Ceftriaxone Sodium	Powder for injection A white to pale yellow crystalline powder	15 mL USP Type III clear glass vial with grey butyl rubber stopper and flip-off aluminium seal.	1 vial + 10 mL WFI

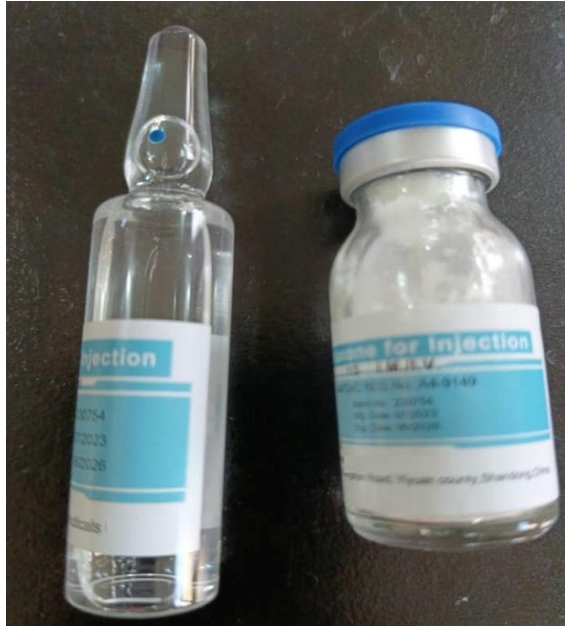
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

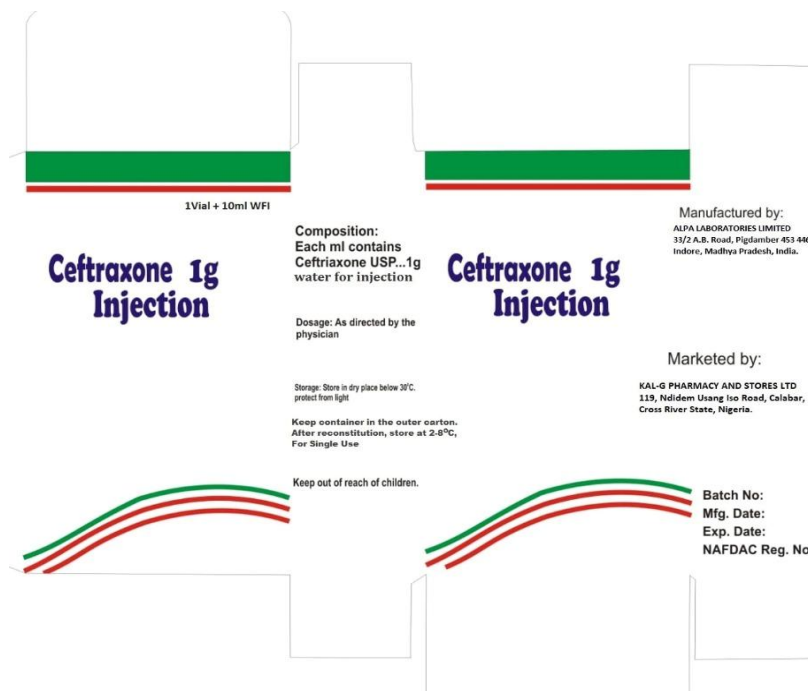
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Ceftriaxone 1 g injection

5.1.2 Therapeutic indication

Ceftriaxone 1 g injection is indicated for the treatment of infections such as gonorrhoea, meningitis, pneumonia, septicaemia, typhoid fever, and syphilis, and for surgical infection prophylaxis.

5.1.3 Manufacturer/applicant

Manufactured by Alpa Laboratories Limited, 33/2 A.B Road, Pigdambar, Indore (MP)-India, and local agent Kal-G Pharmacy and Stores Limited, 119, Ndidem Usang Isolo Road, Calabar, Cross Rivers State, Nigeria.

5.1.4 Pharmaceutical form

Powder for injection

A white to pale yellow crystalline powder. Available as 1 vial + 10 mL WFI

5.1.5 Storage

Store below 30°C. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Ceftriaxone injection is a 1 g white dry powder in a Type III clear glass vial with grey butyl rubber stopper and flip-off aluminium seal & 1 clear glass ampoule of 10 mL water for injection.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient API, ceftriaxone sodium is manufactured by Aurobindo Pharma Limited. Unit-VI, Survey No. 329/39 & 329/47, Chitkul Village, Patancheru Mandal, Medak District, Telangana, India.

The API specifications are pharmacopeial 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

Not applicable

5.4 Drug Product

5.4.1 Drug product manufacturer

Alpa Laboratories Limited√33/2 A.B Road, Pigdamber, Indore (MP)-India.

5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable parenteral formulation of ceftriaxone injection that delivers the required therapeutic activity against susceptible bacterial infections.

The manufacturing method used involved dry heat sterilization and aseptic filtration. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on pharmacopoeia. The finished product specification includes description, identification, pH, uniformity of weight of vial, crystallinity, visible particles, particulate matter, sterility, assay, uniformity of dosage units, bacterial endotoxins, and constituted solution. 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’. Have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ceftriaxone injection 1 g was acceptable for the following indication: ‘for the treatment of infections such as gonorrhoea, meningitis, pneumonia, septicaemia, typhoid fever, and syphilis, and for surgical infection prophylaxis and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, local agent Kal-G Pharmacy and Stores Limited., 119, Ndidem Usang Iso Road, Calabar, Cross Rivers State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ceftriaxone 1g injection.

The following are the steps for the registration of Ceftriaxone injection

November 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
June 2025	Date of inspection
30 July 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Ceftriaxone 1 g injection.