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

Public Assessment Report (PAR)

Ralvet 1 g injection

Ceftriaxone sodium 1 g

A4-101465

Chuvet Pharmaceutical & Allied Ventures Limited

This report reflects the scientific assessment for the approval of Ralvet injection. The product was licensed in August 2025.

PART 1: ABSTRACT

Ralvet injection containing Ceftriaxone sodium, manufactured at Swiss Pharma Private Limited, Ahmedabad, Gujarat State, India, was granted marketing authorization by NAFDAC for the treatment of infections on 27 August 2025.

Ralvet injection is indicated for the treatment of infections such as gonorrhea, 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 Ralvet 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 Ralvet 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 Ralvet injection has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ralvet 1 g injection	Ceftriaxone Sodium	Powder for injection A white or almost white powder filled in transparent glass vial	A clear glass vial with flip off seal and grey butyl rubber stopper,	Combi-pack of 1 vial + 10 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

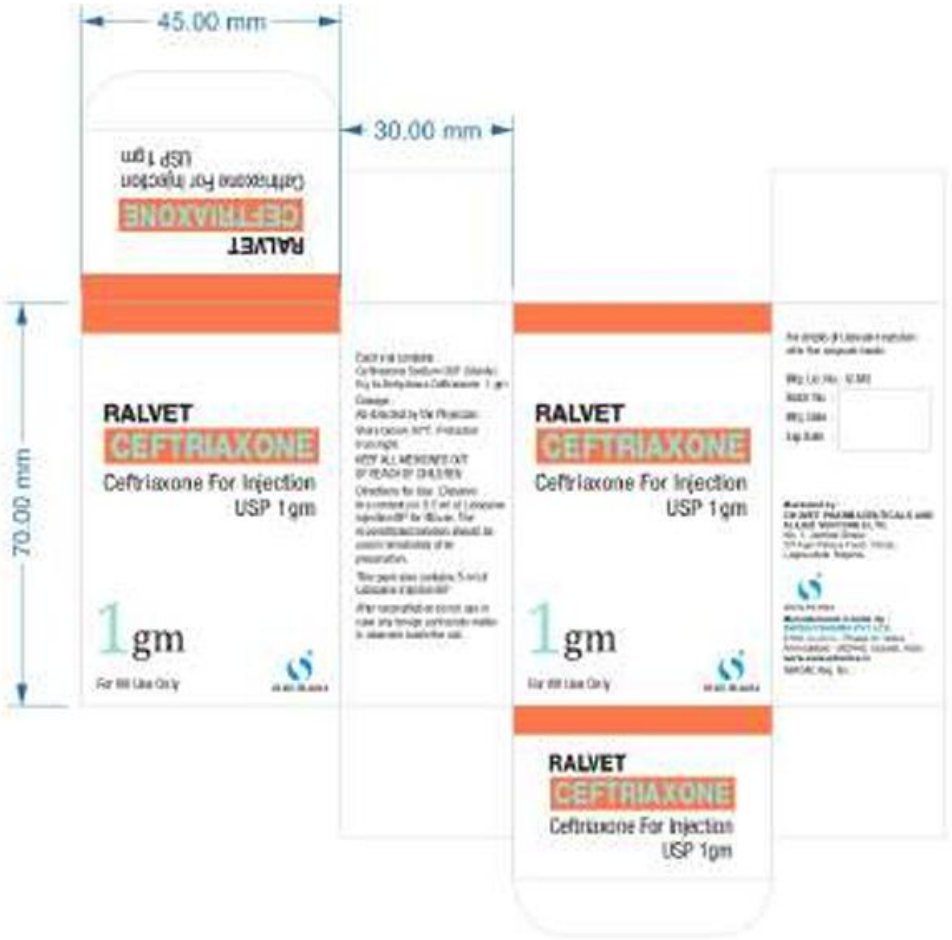
See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

To be updated

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Ralvet 1 g injection.

5.1.2 Therapeutic indication

Ralvet 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

Chuvet Pharmaceutical & Allied Ventures Limited, No.1, Jemtok Street, Off Ago-Palace Food, Okota, Lagos State.

5.1.4 Pharmaceutical form

Powder for injection
A white or almost white powder filled in transparent glass vial, available as 1 vial + 10 mL WFI

5.1.5 Storage

Do not store above 30^0C. After reconstitution, stable up to 7 days. Protect from light.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Ralvet injection contains 1 g white or almost white powder in a clear glass vial with a flip off seal and grey butyl rubber stopper and 1 clear glass ampoule of 10 mL water for injection.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient, Ceftriaxone sodium is manufactured by Nectar Lifesciences Limited. Vill. Saidpura, Teh. Dera Bassi, Distt. Mohali, Punjab India.

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

Not applicable

5.4 Drug Product

5.4.1 Drug product manufacturer

Swiss Pharma Private Limited
3709, G.I.D.C.Phase iv, Vatva, City, Ahmedabad –382445, Dist.:Ahmedabad. Gujarat State, 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 24 months and storage conditions as 'Do not store above 30^0C. After reconstitution, stable up to 7 days. Protect from light have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ralvet 1 g injection was acceptable for the following indication: for the treatment of infections such as gonorrhea, 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, Chuvet Pharmaceutical & Allied Ventures Limited, No 1, Jemtok street, off Ago- Palace food, Okota, Lagos State submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ralvet 1 g injection

The following are the steps for the registration of Ralvet injection

August 2024	Date of receipt of application
June 2025	Date of conclusion of assessment
November 2024	Date of inspection
27 August 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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