



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

NAFDAC Public Assessment Report (NAPAR)

Saocef S 1.5 gm powder for injection

Ceftriaxone sodium/sulbactam sodium

A4-101925

Saoco Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of Saocef S for injection. The product was licenced in February 2026.

PART 1: ABSTRACT

Saocef S for injection containing Ceftriaxone sodium and Sulbactam sodium, manufactured at Shamshree Lifesciences Limited, Katha- Bhatolikalan, Baddi, India, was granted marketing authorization by NAFDAC for the treatment of moderate to severe bacterial susceptible infections on 24 February 2026.

Saocef S is indicated for the treatment of moderate to severe bacterial susceptible infections which includes, lower respiratory tract infection, urinary tract infection, biliary tract infection, abdominal cavity infection, pelvic cavity infection, skin soft tissue infection, gonorrhea, bone and joint infection.

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 Saocef S for 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 Saocef S for 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 Saocef S has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Saocef S for injection.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Saocef S for injection 1.5 gm	Ceftriaxone sodium /sulbactam sodium	Powder for injection A white or white to off white crystalline powder filled in 20 mL type III clear glass vials, sealed with grey butyl rubber plug and purple colored flip off aluminum seal.	20 mL type III clear glass vials, sealed with grey butyl rubber plug and purple colored flip off aluminum seal in a mono carton co packed with 10mL water for injection	1 vial + 10 mL ampoule

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

Saocef S ceftriaxone sodium and sulbactam sodium 1.5 gm powder for injection

5.1.2 Therapeutic indication

Saocef S for injection is used for the treatment of moderate to severe bacterial susceptible infections which includes, lower respiratory tract infection, urinary tract infection, biliary tract infection, abdominal cavity infection, pelvic cavity infection, skin soft tissue infection, gonorrhea, bone and joint infection.

5.1.3 Applicant

Saoco Pharmaceuticals Limited, 14, Johnson Street, Ilupeju Estate, off Town Planning Way, Off Coker Road Ilupeju, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Powder for injection

A white or white to off white crystalline powder filled in 20 mL type III clear glass vials, sealed with grey butyl rubber plug and purple colored flip off aluminum seal.

5.1.5 Storage

Do not store above 30°C. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Saocef S for injection is presented as a white or white to off white crystalline powder filled in 20 mL type III clear glass vials, sealed with grey butyl rubber plug and purple colored flip off aluminum seal and 10 mL WFI ampoule.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredients, ceftriaxone sodium is manufactured by Aurobindo Pharmaceuticals Limited, Plot No. 2, Maitrivihar, Ameerpet, Hyderabad Telangana, India while sulbactam sodium is manufactured by Shandong Ruiying Pioneer Pharmaceutical Company Limited, No.1777 Kunming Road, Heze City, Shandong Province, China.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

None

5.4 Drug Product

5.4.1 Drug product manufacturer

The drug product is manufactured by Shamsree Lifesciences Limited, Plot No. 11, Industrial Area, Katha- Bhatolikalan, Baddi 173205 (H.P), India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to produce a safe, effective, stable, and high-quality product that consistently delivers the intended therapeutic effect as the innovator product, Rocephin 1 g injection manufactured by F. Hoffmann-La Roche Limited, Switzerland.

The manufacturing method used was sterilization done at 121°C (NMT ±2) for 15 ± 2 minutes at 1.5 – 2.0 bar and filtration method. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on IHS and USP. The finished product specifications include identification by IR & TLC, average fill weight, water (by KF), completeness and clarity of solution,

bacterial endotoxin test, sterility, pH, particulate matter, visual particulates of constituted solution, 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 submitted, the benefit–risk profile of Saocef S for injection was acceptable for the following indication: moderate to severe bacterial susceptible infections which includes, lower respiratory tract infection, urinary tract infection, biliary tract infection, abdominal cavity infection, pelvic cavity infection, skin soft tissue infection, gonorrhea, bone and joint infection and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Saoco Pharmaceuticals Limited, 14, Johnson Street, Ilupeju Estate, off Town Planning Way, Off Coker Road Ilupeju, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Saocef S ceftriaxone sodium and sulbactam sodium 1.5 gm for injection.

The following are the steps for registration

December 2024	Date of receipt of application
December 2025	Date of conclusion of assessment
January 2026	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 Saocef S for injection.