



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

NAFDAC Public Assessment Report (NAPAR)

**Amoxicillin/potassium clavulanate 1000 mg/200 mg powder for
injection**

Amoxicillin sodium/ potassium clavulanate 1000 mg/200 mg

A4-101954

Elevate Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of Amoxicillin /potassium clavulanate for injection. The product was licenced in February 2026.

PART 1: ABSTRACT

Amoxicillin/potassium clavulanate injection, manufactured at Mackur Laboratories Limited, Zac, Degham, Gandhinagar, Gujarat India, was granted marketing authorization by NAFDAC for the treatment of infections caused by bacteria susceptible organisms in adults and children on 24 February 2026.

Amoxicillin/potassium clavulanate injection is indicated for a wide range of bacterial susceptible infections in adults and children.

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 amoxicillin/potassium clavulanate 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 amoxicillin/potassium clavulanate 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 amoxicillin/clavulanate has been presented in part 5 of this report.

The detailed steps taken to approve amoxicillin and potassium clavulanate injection by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of amoxicillin/potassium clavulanate injection.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Amoxicillin/potassium clavulanate injection 1000 mg/200 mg	Amoxicillin sodium/potassium clavulanate 1000 mg/200 mg	Powder for injection Almost white or yellowish, crystalline powder.	Clear glass vial USP type III with 20 mL plastic ampoule of sterilised water for injection in a carton	1 vial + 20 mL ampoule

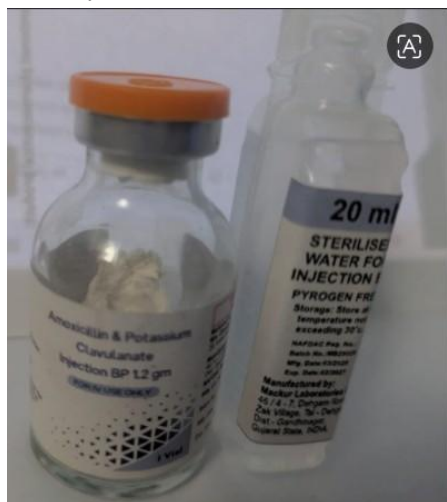
3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

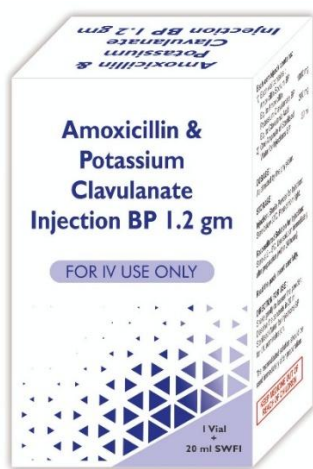
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Amoxicillin/potassium clavulanate 1000 mg/200 mg powder for injection

5.1.2 Therapeutic indication

Amoxicillin/ potassium clavulanate injection is indicated for a wide range of susceptible bacterial infections in adults and children, including severe ear, nose and throat infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections, bone and joint infections, intra-abdominal and female genital infections, and for the prophylaxis of infections associated with major surgical procedures.

5.1.3 Applicant

Elevate Pharmaceuticals Limited, 29, Irone Avenue, Aguda Surulere, Lagos.

5.1.4 Pharmaceutical form

Powder for injection

Almost white or yellowish, crystalline powder

5.1.5 Storage

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

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Amoxicillin/potassium clavulanate injection is presented in a clear glass vial USP type III alongside with a 20 mL plastic ampoule of sterilised water for injection in a carton.

5.2 Drug Substance

5.2.1 Manufacturer

Amoxicillin trihydrate is manufactured by DSM Sinochem Pharmaceuticals India Private Limited, Bhai Mohan Singh Nagar, Toansa, Tehsil: Balachaur, Nawanshahr-144533 Punjab, India, and potassium clavulanate is manufactured by Shandog New Times Pharmaceutical Company Limited. No.1 North Outer Ring. Fei country, Shandong Province. P.R China.

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Not applicable

5.4 Drug Product

5.4.1 Drug product manufacturer

Makhur Laboratories Limited 46/47, village Zac, Tal- Degham, District: Ghandinagar –382330, Gujarat India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to develop a safe, effective, stable, and high-quality pharmaceutical product that is pharmaceutically equivalent to and therapeutically comparable with the innovator product, Augmentin 1.2 g injection manufactured by GSK PLC, London, ensuring consistent quality, safety, efficacy, and performance throughout its shelf life.

The manufacturing method was done using aseptic conditions. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include description, identification by IR & TLC, pH, related substances, uniformity of weight, uniformity of dosage units, assay, particulate matter, bacterial endotoxin, and sterility. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in 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 sunlight have been accepted.

5.6 Conclusion

Based on the assessment of data, the benefit–risk profile of amoxicillin/potassium clavulanate injection was acceptable for the following indication: ‘for the treatment of a wide range of susceptible bacterial infections in adults and children, including severe ear, nose and throat infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections, bone and joint infections, intra-abdominal and female genital infections, and for the prophylaxis of infections associated with major surgical procedures’, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Elevate Pharmaceuticals Limited, 29, Irone Avenue, Aguda Surulere, Lagos submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of amoxicillin & potassium clavulanate 1.2g injection.

The following are the steps for registration

March, 2025	Date of receipt of application
August 2025	Date of conclusion of assessment
April, 2025	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 Amoxicillin/potassium clavulanate injection.