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

Public Assessment Report (PAR)

Axituf injection 10 mg/mL

Atracurium besylate USP 10 mg/mL

A4-102057

Artemis Laboratories Limited

This report reflects the scientific assessment for the approval of Axituf injection. The product was licenced in 31 March 2026.

PART 1: ABSTRACT

Axituf injection containing atracurium besylate manufactured at Divine Laboratories Private Limited, Dabhasa, Vadodara, Gujarat, India, was granted marketing authorization by NAFDAC as an adjunct to general anaesthesia on 31March, 2026.

Axituf injection is indicated as an adjunct to general anaesthesia for endotracheal intubation, skeletal muscle relaxation during surgery, and facilitation of controlled ventilation.

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 Axituf 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 Axituf 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 Axituf has been presented in Part 5 of this report.

The detailed steps taken to approve Axituf by NAFDAC have been presented int part 6 of this report.

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Axituf injection	Atracurium besylate USP	Solution A clear colorless solution, in 3mL USP type-I amber colored glass ampoule with white colour ring at constriction.	Clear colorless solution, filled and sealed in 3 mL USP type-I amber colored glass ampoule with white colour ring at constriction. Available as 2 x 5 x 2.5 mL ampoule	2 x 5 x 2.5 mL ampoule

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

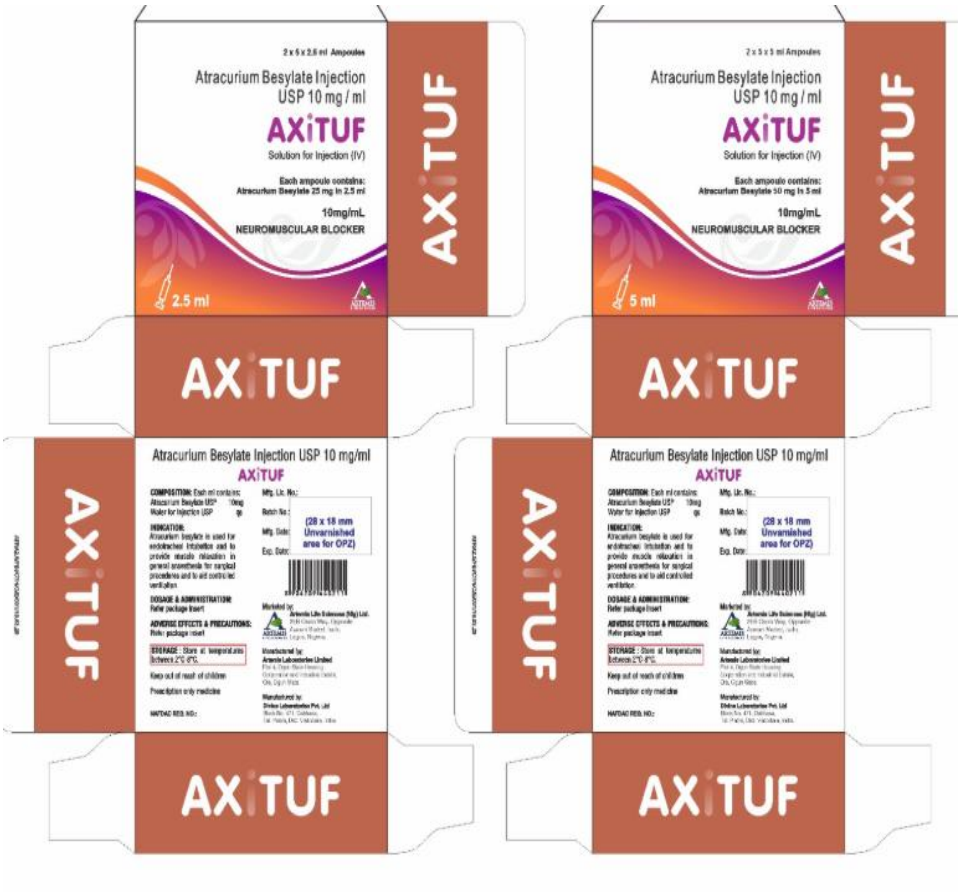
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Axituf injection 10 mg/ mL

5.1.2 Therapeutic indication

Axituf is indicated as adjunct to general anaesthesia for endotracheal intubation, skeletal muscle relaxation during surgery, and facilitation of controlled ventilation.

5.1.3 Applicant

Artemis Life Sciences Nigeria Limited, 2EB, Opposite Aswani Market, Isolo Way, Aswani Oshodi Industrial Scheme Isolo, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Solution for injection.

A clear colorless solution, filled and sealed in 3 mL USP type-I amber colored glass ampoule with white colour ring at constriction.

5.1.5 Storage

Store between 2°C to 8°C

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Axituf is presented as a clear colorless solution, filled and sealed in a 3 mL USP Type-I amber colored glass ampoule with white colour ring at constriction. Available as 2 x 5 x 2.5 mL ampoule

5.2 Drug Substance

5.2.1 Manufacturer

Atracurium besylate injection USP is manufactured by Synnat Pharma Private Limited, Plot No.60 A, Jawaharlal Nehru Pharma City, Parawada Mandal, Vishakhapatnam Dist.-531 019, Andhra Pradesh, 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

Other ingredients used in the formulation of Axituf include atracurium besylate, benzene sulphonic acids, water for injections all being pharmacopoeial controlled. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Divine Laboratories Private Limited, Block No. 471, Dabhasa, Tal. Padra, Dist. Vadodara, Gujarat – 391 440, India.

5.4.2 Pharmaceutical development

The aim of pharmaceutical development is to design a quality product and the manufacturing process to deliver the product in a reproducible manner. The information and knowledge gained from pharmaceutical development studies provide scientific understanding to support the establishing of specifications and manufacturing controls. Manufactured by Divine Laboratories Pvt. Ltd. Block no. 471, Dabhasa, Tal. Padra, Dist. Vadodara, Gujarat, India. – 391 440 The manufacturing method used was aseptic filtration and depyrogenation of glasses and this was validated to ensure the quality of the product.

5.4.3 Specification

The finished product specification is based on USP 41. The finished product specifications include identification by HPLC, pH Volume variation, average volume, organic impurities, particulate matter, bacterial endotoxins test, sterility, assay (by HPLC). The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 2°C/60%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 at 25°C ± 2°C / 60% RH have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of axituf was acceptable for is indicated as an adjunct to general anaesthesia for endotracheal intubation, skeletal muscle relaxation during surgery, and facilitation of controlled ventilation, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Artemis Life Sciences Nigeria Limited, 2EB, Opposite Aswani Market, Isolo Way, Aswani Oshodi Industrial Scheme Isolo, Lagos, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of axituf.

The following are the steps for the registration of axituf

April 2024	Date of receipt of application
January 2025	Date of conclusion of assessment
January 2025	Date of inspection
01 April 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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