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

Public Assessment Report (PAR)

Tranexamic acid 100 mg/mL injection

Tranexamic acid 100 mg/mL

A4-101814

Tallis Pharmaceutical Company Nigeria Ltd

This report reflects the scientific assessment for the approval Of Tranexamic acid injection. The product was licenced in December 2025.

PART 1: ABSTRACT

Tranexamic acid injection, manufactured at Kamla Lifesciences Limited, Boisar, Maharashtra, India, was granted marketing authorization by NAFDAC the prevention and treatment of bleeding associated with enhanced fibrinolysis on 18 December 2025.

Tranexamic acid injection is indicated for the prevention and treatment of bleeding associated with enhanced fibrinolysis.

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 tranexamic acid 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 Tranexamic acid 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 Tranexamic acid injection has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Tranexamic acid injection	Tranexamic acid 100 mg/mL	Injection A clear colourless liquid is filled in 5 mL clear ampoule	5 ml glass ampoule available as 5 x 5 mL	5 x 5 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

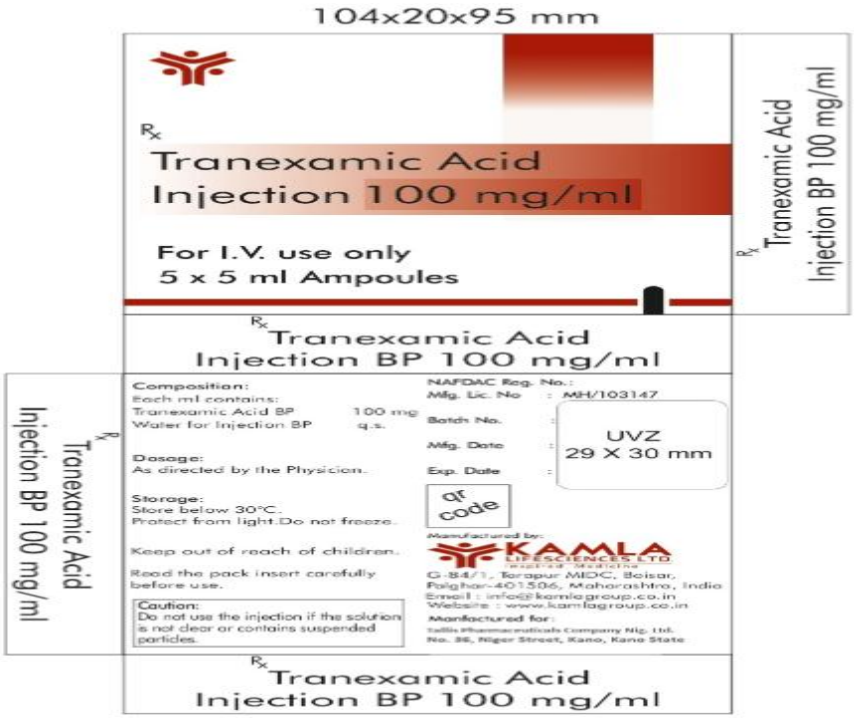
Refer to the NAFDAC Greenbook URL below for the SmPC

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

PART 4: LABELLING

Primary label

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Tranexamic acid 100 mg/mL injection

5.1.2 Therapeutic indication

Tranexamic acid injection is indicated for the prevention and treatment of bleeding associated with enhanced fibrinolysis.

5.1.3 Applicant

Tallis Pharmaceutical Co Nigeria Limited, No. 36, Niger Street Kano, Kano State, Nigeria.

5.1.4 Pharmaceutical form

Injection

A clear colourless liquid is filled in 5 mL clear ampoule.

5.1.5 Storage

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

5.1.6 Shelf life

24 months

5.1.7 Product presentation

5 mL glass ampoule available as 5 x 5 mL.

5.2 Drug Substance

5.2.1 Manufacturer

Tranexamic acid injection is manufactured by Shilpa Pharma Lifesciences Limited, Shilpa House, #12-6-214/A1, Hyderabad Road, Raichur–584 135, Karnataka, India

The API specifications are pharmacopoeial 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 tranexamic acid injection include sodium hydroxide, hydrochloric acid, water for injection 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

Kamla Lifesciences Limited, G-84/1, Tarapur Midc, Boisar Dist-Palghar Maharashtra 401506 India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Cyklokapron injection, manufactured by Pfizer Inc., United States.

The manufacturing method used are hydrogenation, isomerization, purification, and crystallization.

5.4.3 Specification

The finished product specification is based on BP pharmacopoeial and in-house. The finished product specifications include identification, assay, related impurities, sterility, pH, bacterial endotoxins, particulate matter and extractable volume. 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 ‘Do not store above 30°C. Protect from light’ have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of tranexamic acid injection was acceptable for the following indication: 'for the prevention and treatment of bleeding associated with enhanced fibrinolysis', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Tallis Pharmaceutical Co. Nigeria Limited, No. 36, Niger Street Kano, Kano State, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of tranexamic acid injection.

The following are the steps for the registration of tranexamic acid injection

November 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
July 2025	Date of inspection
18 December, 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Tranexamic acid injection