



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

NAFDAC Public Assessment Report (NAPAR)

Tranexamic acid 500 mg tablet

Tranexamic acid 500 mg

A4-102184

Annygod Pharma Co Limited

This report reflects the scientific assessment for the approval of Tranexamic acid 500 mg tablet. The product was licenced on June 2026.

PART 1: ABSTRACT

Tranexamic acid tablets, manufactured at Merit Organic Limited, Sarigam, Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of postpartum hemorrhage and heavy menstrual bleeding. antifibrinolytic agent on 30 June 2026.

Tranexamic acid is indicated for postpartum hemorrhage and heavy menstrual bleeding. antifibrinolytic agent.

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 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 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 has been presented in part 5 of this report.

The detailed steps taken to approve Tranexamic acid 500 mg tablet 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.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Tranexamic acid 500 mg tablet	Tranexamic acid	Film-coated tablet White, capsule-shaped, film-coated tablets. The tablets have a score line on one side and are plain on the other side.	Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 1 x 10 tablets	1 x 10 tablets

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

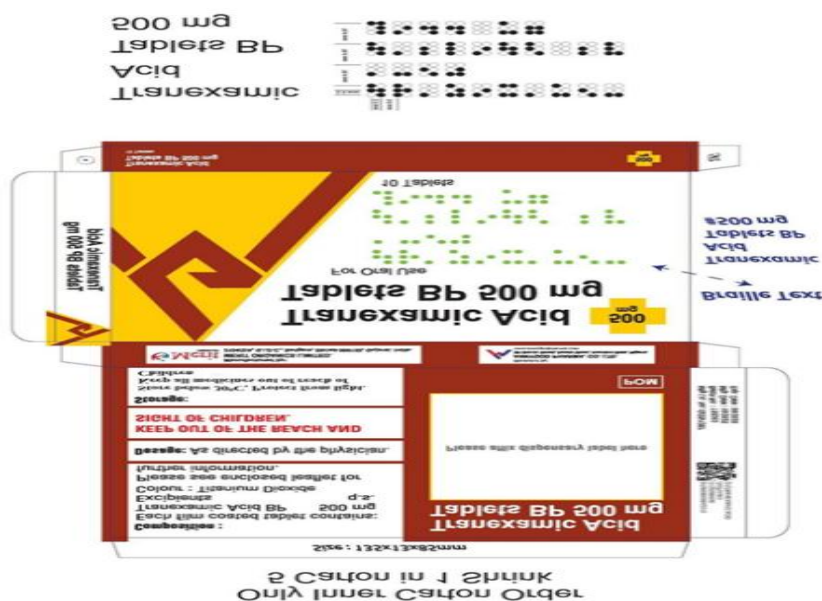
See: <https://greenbook.nafdac.gov.ng/>

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 500 mg tablet

5.1.2 Therapeutic indication

Tranexamic acid 500 mg tablet is indicated for postpartum hemorrhage and heavy menstrual bleeding. antifibrinolytic agent.

5.1.3 Applicant

Annygod Pharmaceutical Co. Limited, 28, Ukwulu Street, Awada, Obosi, Anambra State.

5.1.4 Pharmaceutical form

Film-coated tablet

White, capsule-shaped, film-coated tablets. The tablets have a score line on one side and are plain on the other side.

5.1.5 Storage

Do not store above 30°C

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 1 x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

Tranexamic acid 500 mg tablet is manufactured by Ami Lifesciences Private Limited, Block No.82/B, ECP Road, AT & PO. Karakhadi-391450, Taluka-Padra, District-Vadodara, Gujarat, India.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Other ingredients used in the formulation of Tranexamic acid 500 mg tablet include pregelatinized starch, microcrystalline cellulose, aerosil, PVPK 30, purified water, talcum, magnesium stearate, croscarmellose sodium, microcrystalline cellulose, 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

Merit Organic Limited, 2104/2/A, G.I.D.C, Sarigam, Bhilad-396 155, Gujarat. 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 tablet, manufactured by Pfizer.

Tranexamic acid 500 mg was manufactured using the wet granulation method, followed by compression, film coating, and packaging.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product cyklokapron tablet (Pfizer) and Tranexamic acid 500 mg tablet. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include description, identification, average weight, uniformity of dosage unit, assay, related substances, disintegration. 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 have been accepted.

5.5 Conclusion

Based on the assessment of data submitted the benefit–risk profile of Tranexamic acid 500 mg tablet was acceptable for the following indication: 'for postpartum hemorrhage and heavy menstrual bleeding. antifibrinolytic agent.', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Annygod Pharmaceutical Co. Limited, 28, Ukwulu Street, Awada, Obosi, Anambra State submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Tranexamic acid 500 mg tablet.

The following are the steps for registration

March 2025	Date of receipt of application
May 2026	Date of conclusion of assessment
May 2026	Date of inspection
30 June 2026	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 500 mg tablet.