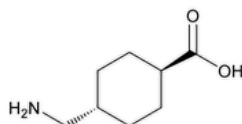


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Aug-2024
 Document Type: USP Monographs
 DocId: GUID-FEC38B38-8DD5-4B5D-B4CA-83865AC39C2B_6_en-US
 DOI: https://doi.org/10.31003/USPNF_M84413_06_01
 DOI Ref: xd1ri

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Tranexamic Acid



$C_8H_{15}NO_2$ 157.21

trans-4-(Aminomethyl)cyclohexanecarboxylic acid;

Cyclohexanecarboxylic acid, 4-(aminomethyl)-, *trans* CAS RN[®]: 1197-18-8; UNII: 6T84R30KC1.

DEFINITION

Tranexamic Acid contains NLT 98.0% and NMT 102.0% of tranexamic acid ($C_8H_{15}NO_2$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: Dissolve 11 g of [monobasic sodium phosphate](#) in 500 mL of [water](#), and add 5 mL of [triethylamine](#). Add 1.4 g of [sodium dodecyl sulfate](#) and adjust with [phosphoric acid](#) to a pH of 2.5. Dilute with [water](#) to 600 mL.

Mobile phase: [Methanol](#) and *Buffer* (40:60)

Standard solution: 1 mg/mL of [USP Tranexamic Acid RS](#) in [water](#)

Sample solution: 1 mg/mL of Tranexamic Acid in [water](#)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: NLT 2.5 times the retention time of tranexamic acid

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tranexamic acid ($C_8H_{15}NO_2$) in the portion of Tranexamic Acid taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of tranexamic acid from the *Sample solution*

r_S = peak response of tranexamic acid from the *Standard solution*

C_s = concentration of [USP Tranexamic Acid RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Tranexamic Acid in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#)

Sample: 1 g of Tranexamic Acid

Acceptance criteria: NMT 0.1%

- [CHLORIDE AND SULFATE \(221\)](#), *Chloride*

Standard solution: 0.1 mL of 0.020 N [hydrochloric acid](#)

Sample: 0.51 g of Tranexamic Acid

Acceptance criteria: The *Sample* shows no more chloride than the *Standard solution* (NMT 0.014%).

- **ORGANIC IMPURITIES**

Buffer and Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.2 mg/mL of [USP Tranexamic Acid RS](#) and 0.002 mg/mL of [USP Tranexamic Acid Related Compound C RS](#) in [water](#)

Sensitivity solution: 5 µg/mL of [USP Tranexamic Acid RS](#) in [water](#)

Standard solution: 50 µg/mL of [USP Tranexamic Acid RS](#) in [water](#)

Sample solution: 10 mg/mL of Tranexamic Acid in [water](#)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: 3 times the retention time of tranexamic acid

System suitability

Samples: *System suitability solution*, *Sensitivity solution*, and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between tranexamic acid and tranexamic acid related compound C, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual specified or unspecified impurity in the portion of Tranexamic Acid taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak response of each individual specified or unspecified impurity from the *Sample solution*

r_s = peak response of tranexamic acid from the *Standard solution*

C_s = concentration of [USP Tranexamic Acid RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Tranexamic Acid in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.025%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Tranexamic acid	1.0	1.0	—
Tranexamic acid related compound C	1.1	200.0	0.1
Aminomethylbenzoic acid ^a	1.3	166.7	0.1
cis-Tranexamic acid ^b	1.5	0.83	0.2
Ditraneamic acid amine ^c	2.1	1.0	0.1
Any individual unspecified impurity	—	1.0	0.05
Total impurities	—	—	0.2

^a 4-(Aminomethyl)benzoic acid.

^b cis-4-(Aminomethyl)cyclohexanecarboxylic acid.

^c trans,trans-4,4'-[Iminobis(methylene)]dicyclohexanecarboxylic acid.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

Sample: 1.00 g of Tranexamic Acid

Analysis: Dry the *Sample* at 105° under vacuum for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at a temperature not exceeding 30°.

Change to read:

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Tranexamic Acid RS](#)

[USP Tranexamic Acid Related Compound C RS](#)

▲(RS)-4-(Aminomethyl)cyclohex-1-enecarboxylic acid hydrochloride.

$C_8H_{13}NO_2 \cdot HCl$ 191.66▲ (CN 1-Aug-2024)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TRANEXAMIC ACID	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 45(3)

Current DocID: GUID-FEC38B38-8DD5-4B5D-B4CA-83865AC39C2B_6_en-US

DOI: https://doi.org/10.31003/USPNF_M84413_06_01

DOI ref: [xd1ri](#)