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Tranexamic Acid Injection

DEFINITION

Tranexamic Acid Injection is a sterile solution of Tranexamic Acid in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of tranexamic acid ($C_8H_{15}NO_2$).

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

  Sample: Transfer the content of Injection into a beaker and heat on a hot plate at 100° for 30 min, until a paste appears. Then heat it in an oven to complete dryness at 110° for about 30 min.

  Acceptance criteria: Meets the requirements

- **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 lauryl sulfate, adjust with diluted phosphoric acid (10% w/w) to a pH of 2.5, and 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: Nominally 1 mg/mL of tranexamic acid prepared as follows. Transfer an accurately measured volume of Injection from a composite of contents from NLT 3 vials to a suitable volumetric flask, and dilute with water to volume.

  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: 2 times the retention time of tranexamic acid

  System suitability

  Sample: *Standard solution*

  Suitability requirements

  Tailing factor: NMT 2.0

  Relative standard deviation: NMT 2.0%

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of the labeled amount of tranexamic acid ($C_8H_{15}NO_2$) in the portion of Injection 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 = nominal concentration of tranexamic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **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 2 µg/mL of USP Tranexamic Acid Related Compound C RS in water

Sensitivity solution: 0.01 mg/mL of USP Tranexamic Acid RS in water

Standard solution: 0.05 mg/mL of USP Tranexamic Acid RS in water

Sample solution: Nominally 10 mg/mL of tranexamic acid prepared as follows. Transfer an accurately measured volume of Injection to an appropriate volumetric flask, and dilute with water to volume.

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: 3.3 times the retention time of tranexamic acid

System suitability

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

Suitability requirements

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

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each unspecified impurity in the portion of Injection taken:

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

r_U = peak response of each 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 = nominal concentration of tranexamic acid in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*. Disregard any impurity peaks less than 0.03%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tranexamic acid	1.0	—
Tranexamic acid related compound C[a]	1.1	—
Aminomethylbenzoic acid[a,b]	1.3	—
cis-Tranexamic acid[a,c]	1.5	—
Ditranexamic acid amine[a,d]	2.1	—
Any unspecified impurity	—	0.1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Total impurities	—	0.5

[a] For identification only. These are process impurities monitored in the drug substance and are not included in the total impurities.

[b] 4-(Aminomethyl)benzoic acid.

[c] *cis*-4-(Aminomethyl)cyclohexanecarboxylic acid.

[d] *trans*,*trans*-4,4'-[Iminobis(methylene)]dicyclohexanecarboxylic acid.

SPECIFIC TESTS

- **pH ⟨791⟩:** 6.5–8.0
- **Particulate Matter in Injections ⟨788⟩:** It meets the requirements for small-volume injections.
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.5 USP Endotoxin Units/mg of tranexamic acid
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers and store at controlled room temperature.

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 INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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