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# Tranexamic Acid Injection

General Notices

Tranexamic Acid Infusion

*Details for the public consultation of this monograph are as follows:*

| EAG/Panel/Working Party | Medicinal Chemicals 2 |
|---|---|
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| **Deadline for Comment** | 30th September 2026 |
| **Target Publication Date (subject to change)** | BP 2028 |
| **Notes** | Revised monograph<br>If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.<br>**Identification** sample preparation amended<br>**Acidity or alkalinity** test omitted<br>**Related substances** limits revised, additional impurities and quantitative limits introduced<br>**Impurities** impurities E and F added |

**Action and use**

Antifibrinolytic.

## DEFINITION

Tranexamic Acid Injection is a sterile solution of Tranexamic Acid in a suitable vehicle.

*The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.*

**Content of tranexamic acid, $C_8H_{15}NO_2$**

95.0 to 105.0% of the stated amount.

# IDENTIFICATION

Evaporate a volume of injection containing 0.1 g of Tranexamic Acid at 60° for 2 hours. Stir gently and dry for a further hour. After drying, the *infrared absorption spectrum* of the crystals, Appendix II A, is concordant with the *reference spectrum* of tranexamic acid (*RS 344*).

# TESTS



**Related substances**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in *water*.

(1) Dilute the injection, if necessary, with sufficient *water* to produce a solution containing 1% w/v of Tranexamic Acid.
(2) Dilute 1 volume of solution (1) to 500 volumes.
(3) 0.001% w/v of *4-aminomethylbenzoic acid* (impurity D).
(4) 1% w/v of *tranexamic acid impurity standard BPCRS* (containing impurities A, C and D) and 0.001% w/v each of *tranexamic acid impurity B EPCRS*, *tranexamic acid impurity E EPCRS* and *tranexamic acid impurity F EPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.9 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 220 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 3 times the retention time of tranexamic acid.

MOBILE PHASE

40 volumes of *methanol* and 60 volumes of solution A.

*Solution A* Dissolve 11.0 g of *anhydrous sodium dihydrogen orthophosphate* in 500 mL of *water*, add 5 mL of *triethylamine* and 1.4 g of *sodium dodecyl sulfate* and adjust to pH 2.5 with *orthophosphoric acid*. Dilute to produce 600 mL with *water*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the *resolution* between the peaks due to tranexamic acid and impurity C is at least 2.0.

CALCULATION OF IMPURITIES

For impurities A, B, E and F, use the concentration of tranexamic acid in solution (2).

For impurities C and D, use the concentration of impurity D in solution (3).

For any other unspecified impurity, use the concentration of tranexamic acid in solution (2).

For the reporting threshold, use the concentration of tranexamic acid in solution (2).

For peak identification, use solutions (3) and (4).

Tranexamic acid retention time: about 9 minutes.

Relative retention: impurity F, about 0.4; impurity C, about 1.1; impurity D, about 1.2; impurity B, about 1.35; impurity E, about 1.45 and impurity A, about 1.9.

Correction factors: impurity E, multiply by 0.4; impurity F, multiply by 0.2.

LIMITS

— impurity B: not more than 0.2%;

— impurity A: not more than 0.1%;

— unspecified impurities: for each impurity, not more than 0.10%;

— total impurities: not more than 0.8%;

— reporting threshold: 0.05%.

**Bacterial endotoxins**

Carry out the *test for bacterial endotoxins*, Appendix XIV C. The endotoxin limit concentration is less than 35 IU per mL.

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in *water*.

(1) Dilute the injection, if necessary, with sufficient *water* to produce a solution containing 0.2% w/v of Tranexamic Acid.
(2) 0.2% w/v of *tranexamic acid BPCRS*.
(3) 1% w/v of *tranexamic acid impurity standard BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3) the *resolution* between the peaks corresponding to tranexamic acid and impurity C is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of tranexamic acid, $C_8H_{15}NO_2$, in the injection from the chromatograms obtained and using the declared content of $C_8H_{15}NO_2$ in *tranexamic acid BPCRS*.

## IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B, C, D, E and F listed under Tranexamic Acid.