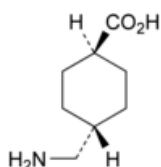


Edition: BP 2025 (Ph. Eur. 11.6 update)

Tranexamic Acid

[General Notices](#)

(Ph. Eur. monograph 0875)



$C_8H_{15}NO_2$ 157.2 1197-18-8

Action and use

Antifibrinolytic.

Preparations

[Tranexamic Acid Injection](#)

[Tranexamic Acid Mouthwash](#)

[Tranexamic Acid Oral Solution](#)

[Tranexamic Acid Tablets](#)

Ph Eur

DEFINITION

(1*r*,4*r*)-4-(Aminomethyl)cyclohexane-1-carboxylic acid.

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96 per cent).

IDENTIFICATION

Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [tranexamic acid CRS](#).

TESTS

pH ([2.2.3](#))

7.0 to 8.0.

Dissolve 2.5 g in [carbon dioxide-free water R](#) and dilute to 50 mL with the same solvent.

Related substances

Liquid chromatography ([2.2.29](#)).

Test solution Dissolve 0.200 g of the substance to be examined in [water R](#) and dilute to 20.0 mL with the same solvent.

Reference solution (a) Dilute 1.0 mL of the test solution to 100.0 mL with [water R](#). Dilute 1.0 mL of this solution to 20.0 mL with [water R](#).

Reference solution (b) Dissolve 5.0 mg of [tranexamic acid impurity D CRS](#) in [water R](#) and dilute to 50.0 mL with the same solvent.

Reference solution (c) Dilute 5.0 mL of reference solution (b) to 100.0 mL with [water R](#).

Reference solution (d) Dissolve 2.5 mg of [tranexamic acid impurity E CRS](#) in [water R](#) and dilute to 50.0 mL with the same solvent. Dilute 1.0 mL of the solution to 10.0 mL with [water R](#).

Reference solution (e) Dissolve 2.5 mg of [tranexamic acid impurity C CRS](#), 2.5 mg of [tranexamic acid impurity F CRS](#) and 7.5 mg of [tranexamic acid impurity B CRS](#) in 25 mL of [water R](#). Mix 1 mL of the solution, 1 mL of reference solution (b) and 18 mL of the test solution.

Column:

— *size:* $l = 0.25$ m, $\varnothing = 4.6$ mm;

— *stationary phase:* [end-capped octadecylsilyl silica gel for chromatography R](#) (5 μ m).

Mobile phase Dissolve 11.0 g of [anhydrous sodium dihydrogen phosphate R](#) in 500 mL of [water for chromatography R](#) and add 5 mL of [triethylamine R](#) and 1.4 g of [sodium laurilsulfate R1](#); adjust to pH 2.0 with [phosphoric acid R](#) and dilute to 600 mL with [water for chromatography R](#); add 400 mL of [methanol R2](#).

Flow rate 0.9 mL/min.

Detection Spectrophotometer at 210 nm.

Injection 40 μ L of the test solution and reference solutions (a), (c), (d) and (e).

Run time 2.5 times the retention time of tranexamic acid.

Identification of impurities Use the chromatogram obtained with reference solution (c) to identify the peak due to impurity D; use the chromatogram obtained with reference solution (d) to identify the peak due to impurity E; use the chromatogram obtained with reference solution (e) to identify the peaks due to impurities B, C and F.

Relative retention With reference to tranexamic acid (retention time = about 10 min): impurity F = about 0.3; impurity C = about 1.1; impurity D = about 1.2; impurity E = about 1.3; impurity B = about 1.5.

System suitability Reference solution (e):

— *resolution:* minimum 2.0 between the peaks due to tranexamic acid and impurity C; minimum 1.5 between the peaks due to impurities C and D.

Calculation of percentage contents:

- *correction factors:* multiply the peak areas of the following impurities by the corresponding correction factor: impurity B = 1.3; impurity C = 0.4; impurity F = 0.6;
- for impurities C and D, use the concentration of impurity D in reference solution (c);
- for impurities E and F, use the concentration of impurity E in reference solution (d);
- for impurities other than C, D, E and F, use the concentration of tranexamic acid in reference solution (a).

Limits:

- *impurity B:* maximum 0.15 per cent;
- *impurities C, D, E, F:* for each impurity, maximum 0.05 per cent;
- *unspecified impurities:* for each impurity, maximum 0.05 per cent;
- *total:* maximum 0.2 per cent;
- *reporting threshold:* 0.03 per cent.

Halides expressed as chlorides (2.4.4)

Maximum 140 ppm.

Dissolve 1.2 g in [water R](#) and dilute to 50 mL with the same solvent.

Loss on drying (2.2.32)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Sulfated ash (2.4.14)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

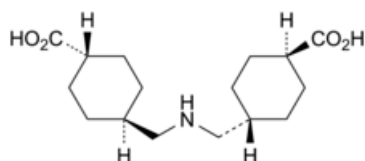
Dissolve 0.140 g in 20 mL of [anhydrous acetic acid R](#). Titrate with [0.1 M perchloric acid](#), determining the end-point potentiometrically ([2.2.20](#)).

1 mL of [0.1 M perchloric acid](#) is equivalent to 15.72 mg of C₈H₁₅NO₂.

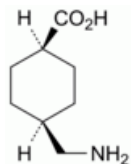
IMPURITIES

Specified impurities B, C, D, E, F.

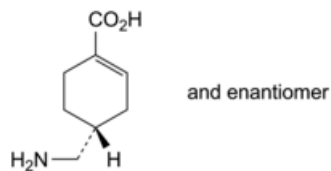
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph [Substances for pharmaceutical use \(2034\)](#). It is therefore not necessary to identify these impurities for demonstration of compliance. See also [5.10. Control of impurities in substances for pharmaceutical use](#)) A.



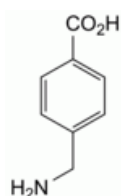
A. (1r,4r,1'r,4'r)-4,4'-[azanediylbis(methylene)]di(cyclohexane-1-carboxylic acid),



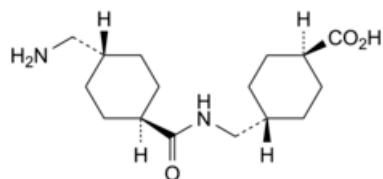
B. (1*S*,4*S*)-4-(aminomethyl)cyclohexane-1-carboxylic acid,



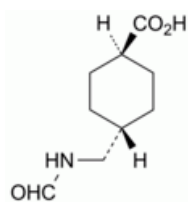
C. (4*R**S*)-4-(aminomethyl)cyclohex-1-ene-1-carboxylic acid,



D. 4-(aminomethyl)benzoic acid,



E. (1*r*,4*r*)-4-[[[(1*r*,4*r*)-4-(aminomethyl)cyclohexane-1-carboxamido]methyl]cyclohexane-1-carboxylic acid,



F. (1*r*,4*r*)-4-(formamidomethyl)cyclohexane-1-carboxylic acid.

Ph Eur