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

Tranexamic Acid Oral Solution

General Notices

NOTE: This monograph has been developed to cover unlicensed formulations.

Action and use

Antifibrinolytic.

DEFINITION

Tranexamic Acid Oral Solution contains Tranexamic Acid in a suitable vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral solution also complies with the requirements stated under Unlicensed Medicines.

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

To a volume of the oral solution containing 0.25 g of Tranexamic Acid add 25 mL of *ethanol (96%)* and shake mechanically for 15 minutes; a cloudy white solution is produced, which may contain white lumps. Remove any lumps and filter the remaining solution using a glass fibre filter (Whatman GF/C filter is suitable). Wash the residue with 50 mL of *ethanol (96%)* and dry under vacuum at 35° for 30 minutes. The *infrared absorption spectrum* of the dried residue, Appendix II A, is concordant with the *reference spectrum* of tranexamic acid (*RS 344*).

ASSAY

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

(1) Dilute the oral solution to contain 0.05% w/v of Tranexamic Acid.
(2) 0.05% w/v of *tranexamic acid BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil ODS or Luna C18 (2) are suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.9 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 220 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

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*, adjust the pH to 2.5 with 2M *orthophosphoric acid* and add sufficient *water* to produce 600 mL. Add 400 mL of *methanol* and mix.

When the chromatograms are recorded under the prescribed conditions, the retention time of tranexamic acid is about 12 minutes.

DETERMINATION OF CONTENT

Calculate the content of $C_8H_{15}NO_2$ in the oral solution using the declared content of $C_8H_{15}NO_2$ in *tranexamic acid BPCRS*.

STORAGE

Tranexamic Acid Oral Solution should not be refrigerated.