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Tranexamic Acid Tablets

General Notices

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

EAG/Panel/Working Party	Medicinal Chemicals 2
Contact Details	helen.corns@mhra.gov.uk rachael.feltham@mhra.gov.uk sophie.cherrington@mhra.gov.uk bpcom@mhra.gov.uk
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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Identification** tests B and C omitted **Dissolution** new test added **Related substances** limits revised, additional impurities and quantitative limits introduced **Assay** titration replaced with LC procedure **Impurities** impurities E and F added

Action and use

Antifibrinolytic.

DEFINITION

Tranexamic Acid Tablets contain Tranexamic Acid.

The tablets comply with the requirements stated under Tablets and with the following requirements.

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 0.5 g of Tranexamic Acid with 5 mL of *water*, mix with the aid of ultrasound and filter (a 0.45-µm nylon filter is suitable). Evaporate 2 mL of the filtrate 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

Dissolution

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of 0.01M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

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

(1) After 30 minutes withdraw a sample of the medium and filter, dilute with sufficient dissolution medium, if necessary, to produce a solution expected to contain 0.056% w/v of Tranexamic Acid.
(2) 0.05% w/v of *tranexamic acid BPCRS* in *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped 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.

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*.

When the chromatograms are recorded under the prescribed conditions, the retention time of tranexamic acid is about 9 minutes.

DETERMINATION OF CONTENT

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

LIMITS

The amount of tranexamic acid released is not less than 75% (Q) of the stated amount.

Related substances

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

(1) Shake a quantity of the powdered tablets containing 1 g of Tranexamic Acid with 100 mL, filter and use the filtrate.
(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

The chromatographic conditions described under Dissolution may be used. Allow the chromatography to proceed for 3 times the retention time of tranexamic acid.

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%.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in *water*.

(1) Shake a quantity of the powdered tablets containing 0.5 g of Tranexamic Acid with 200 mL and dilute to produce 250 mL. Filter and use the filtrate.
(2) 0.2% w/v of *tranexamic acid BPCRS*.
(3) 1% w/v of *tranexamic acid impurity standard BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due 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 tablets 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.