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## Tranexamic Acid Mouthwash

### [General Notices](#)

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

### Action and use

Antifibrinolytic.

### DEFINITION

Tranexamic Acid Mouthwash contains Tranexamic Acid in a suitable vehicle.

*The mouthwash complies with the requirements stated under Oromucosal Preparations and with the following requirements. Where appropriate, the mouthwash 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 mouthwash 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](#)).

### TESTS

#### Acidity or alkalinity

pH, 6.5 to 8.0, [Appendix V L](#).

### ASSAY

To a volume of the mouthwash containing 0.1 g of Tranexamic Acid add 50 mL of [water](#) and adjust the pH of the solution to 7.0 with either 0.1M [sodium hydroxide](#) or 0.1M [hydrochloric acid](#). Add 25 mL of [formaldehyde solution](#), previously adjusted to pH 7.0, and 20 mL of [0.1M sodium hydroxide VS](#). Titrate immediately with [0.1M hydrochloric acid VS](#), determining the end point [potentiometrically](#). Repeat the operation without the preparation being examined. The difference between the titrations represents the amount of sodium hydroxide required. Each mL of [0.1M sodium hydroxide VS](#) is equivalent to 15.72 mg of  $C_8H_{15}NO_2$ .

