



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

Ethambutol Tablets

[General Notices](#)

Action and use

Antituberculosis drug.

DEFINITION

Ethambutol Tablets contain Ethambutol Hydrochloride.

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

Content of ethambutol hydrochloride, $C_{10}H_{24}N_2O_2 \cdot 2HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Extract a quantity of the powdered tablets containing 50 mg of ethambutol hydrochloride with 5 mL of [methanol](#), filter and evaporate the filtrate to dryness. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of ethambutol hydrochloride ([RS 134](#)).

B. Shake a quantity of the powdered tablets containing 0.1 g of ethambutol hydrochloride with 10 mL of [water](#), filter and add to the filtrate 2 mL of a 1% w/v solution of [copper\(II\) sulfate](#) followed by 1 mL of 1M [sodium hydroxide](#). A blue colour is produced.

2-Aminobutanol

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using [silica gel G](#) as the coating substance and a mixture of 10 volumes of 13.5M [ammonia](#), 15 volumes of [water](#) and 75 volumes of [methanol](#) as the mobile phase. Apply separately to the plate 2 µL of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 0.50 g of ethambutol hydrochloride for 5 minutes with sufficient [methanol](#) to produce 10 mL. Solution (2) contains 0.050% w/v of [2-aminobutan-1-ol](#) in [methanol](#). After removal of the plate, allow it to dry in air, heat at 110° for 10 minutes, cool, spray with [ninhydrin solution R1](#) and heat at 110° for 5 minutes. Any spot corresponding to 2-aminobutanol in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%).

ASSAY

Weigh and powder 20 tablets. Add 20 mL of 2M [sodium hydroxide](#) to a quantity of the powdered tablets containing 0.2 g of ethambutol hydrochloride, mix with the aid of ultrasound for 5 minutes and extract with three successive 25 mL quantities of a mixture of 3 volumes of [chloroform](#) and 1 volume of [propan-2-ol](#). Filter each extract successively through the same filter consisting of [anhydrous sodium sulfate](#) on an absorbent cotton plug moistened with a mixture of 3 volumes of [chloroform](#) and 1 volume of [propan-2-ol](#) and wash the plug with 10 mL of the same solvent mixture. Add 100 mL of [anhydrous acetic acid](#) to the combined extracts and washings and carry out Method I for [non-aqueous titration](#), [Appendix](#)

VIII A, using 1-naphtholbenzein solution as indicator. Each mL of 0.1M perchloric acid VS is equivalent to 13.86 mg of $C_{10}H_{24}N_2O_2 \cdot 2HCl$.