Quality standards

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

Aluminium Acetate Ear Drops

General Notices

DEFINITION

Aluminium Sulfate	225 g
Calcium Carbonate	100 g
Tartaric Acid	45 g
Acetic Acid (33 per cent)	250 mL
Purified Water	750 mL

Extemporaneous preparation

The following directions apply.

Dissolve the Aluminium Sulfate in 600 mL of the Purified Water, add the Acetic Acid and then the Calcium Carbonate mixed with the remainder of the Purified Water and allow to stand for not less than 24 hours in a cool place, stirring occasionally. Filter, add the Tartaric Acid to the filtrate and mix.

The ear drops comply with the requirements stated under Ear Preparations and with the following requirements.

Content of aluminium, Al

1.7 to 1.9% w/v.

CHARACTERISTICS

A clear liquid.

Weight per mL

1.06 to 1.08 g, Appendix V G.

ASSAY

Dilute 10 mL to 100 mL with <u>water</u>. To 10 mL of the resulting solution add 40 mL of 0.05M <u>disodium edetate VS</u>, 90 mL of <u>water</u> and 0.15 mL of <u>methyl red solution</u>. Neutralise by the drop wise addition of 1M <u>sodium hydroxide</u> and warm on a water bath for 30 minutes. Cool, add 1 mL of 2M <u>nitric acid</u> and 5 g of <u>hexamine</u> and titrate with 0.05M <u>lead nitrate VS</u> using 0.5 mL of <u>xylenol orange solution</u> as indicator. Each mL of 0.05M <u>disodium edetate VS</u> is equivalent to 1.349 mg of Al.

https://nhathuocngocanh.com/bp/

STORAGE

Aluminium Acetate Ear Drops should be kept in a well-filled container.

When aluminium acetate solution or Burow's Solution is prescribed or demanded a solution complying with the requirements of this monograph shall be dispensed or supplied.