Quality standards

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

Glycerol Eye Drops

General Notices

DEFINITION

Glycerol Eye Drops are a sterile solution of Glycerol in Purified Water.

The eye drops comply with the requirements stated under Eye Preparations and with the following requirements.

Content of glycerol, C₃H₈O₃

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Mix 1 mL of the eye drops with 0.5 mL of <u>nitric acid</u> and superimpose 0.5 mL of <u>potassium dichromate solution</u>. A blue ring develops at the interface of the liquids, which does not diffuse into the lower layer within 10 minutes.

TESTS

Acidity or alkalinity

pH, 4.5 to 7.5, Appendix V L.

ASSAY

Dilute a suitable volume of the eye drops with sufficient <u>water</u> to produce a solution containing 3% w/v of Glycerol. To 5 mL add 150 mL of <u>water</u> and neutralise with <u>0.1m sodium hydroxide VS</u>, using <u>bromocresol purple solution</u> as indicator. Add 1.6 g of <u>sodium periodate</u> and allow to stand protected from light for 15 minutes. Add 3 mL of <u>propan-1,2-diol</u>, shake, allow to stand protected from light for 5 minutes and titrate with <u>0.1m sodium hydroxide VS</u>. Each mL of <u>0.1m sodium hydroxide VS</u> is equivalent to 9.21 mg of C₃H₈O₃.

STORAGE

Glycerol Eye Drops should be protected from light.

Strengths available

Eye Drops containing 10, 20, 30 and 50% w/v of glycerol are available.

