## **Quality standards**

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

# **Glycerol Suppositories**

**General Notices** 

Glycerin Suppositories

#### **DEFINITION**

Gelatin 14 g

Glycerol 70 g

Purified Water A sufficient quantity

In tropical and subtropical countries the quantity of Gelatin may be increased to an amount not exceeding 18 g.

#### **Extemporaneous preparation**

The following directions apply.

Add the Gelatin to about 30 mL of Purified Water heated nearly to boiling, then add the Glycerol previously heated to 100° and heat the mixture on a water bath for 15 minutes or until solution is complete. Adjust the weight of the product to 100 g by the addition of hot Purified Water or by evaporation on a water bath and pour into suitable moulds.

The suppositories comply with the requirements stated under Rectal Preparations and with the following requirements.

## Content of glycerol, C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>

66.5 to 73.5% w/w.

## **Disintegration**

Maximum time, 1 hour, <u>Appendix XII A2</u>.

## **ASSAY**

Dissolve a number of suppositories containing 8 g of Glycerol in 50 mL of <u>water</u> and add sufficient <u>water</u> to produce 250 mL. To 5 mL add 150 mL of <u>water</u> and 0.25 mL of <u>bromocresol purple solution</u> and neutralise with <u>0.1m sodium hydroxide VS</u> to the blue colour of the indicator. Add 1.6 g of <u>sodium periodate</u> and allow to stand for 15 minutes. Add 3 mL of <u>propan-1,2-diol</u>, shake, allow to stand for 5 minutes and titrate with <u>0.1m sodium hydroxide VS</u> to the same blue colour. Each mL of <u>0.1m sodium hydroxide VS</u> is equivalent to 9.210 mg of C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>.