Quality standards

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

Lactic Acid Pessaries

General Notices

DEFINITION

Lactic Acid Pessaries are moulded pessaries containing Lactic Acid in a suitable basis.

The pessaries comply with the requirements stated under Vaginal Preparations and with the following requirements.

Content of lactic acid, C₃H₆O₃

95.0 to 105.0% of the stated amount.

ASSAY

Weigh five pessaries, melt together by warming and allow to cool, stirring continuously. Dissolve a quantity of the mass containing 1 g of Lactic Acid in 50 mL of <u>water</u>, add 50 mL of <u>0.5M sodium hydroxide VS</u>, boil gently for 5 minutes, cool and titrate the excess of alkali with <u>0.5M hydrochloric acid VS</u> using <u>phenolphthalein solution R1</u> as indicator. Each mL of <u>0.5M sodium hydroxide VS</u> is equivalent to 45.04 mg of $C_3H_6O_3$.