Quality standards

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

Carbomer Eye Drops

General Notices

Action and use

Stabilizer in pharmaceutical products.

DEFINITION

Carbomer Eye Drops are a sterile viscous solution of Carbomer 940 or Carbomer 980 in Purified Water.

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

IDENTIFICATION

- A. Add 15 g of the eye drops to 85 mL of <u>water</u> and mix thoroughly. To 3 mL add 1 mL of <u>calcium chloride solution</u>, a fine white precipitate is produced.
- B. Add 0.5 mL of <u>thymol blue solution</u> to 10 g of the eye drops. A yellow colour is produced. Add 0.5 mL of <u>cresol red solution</u> to 10 g of the eye drops. A yellow colour is produced.

TESTS

Acidity or alkalinity

pH, 6.6 to 7.1, Appendix V L.

Apparent viscosity

75 to 125% of the declared value when determined by the following method. Empty the contents of sufficient containers to obtain 200 g of the eye drops, taking care to avoid incorporation of air bubbles, and homogenise. Allow to stand at 25° for 60 minutes. Immerse the appropriate spindle of a rotational viscometer, switch on after 5 minutes and determine the <u>viscosity</u> at 25°, <u>Appendix V H</u>, Method III, using a shear speed of 5 per second.

Clarity of solution

The eye drops are not more opalescent than <u>reference suspension III</u>, <u>Appendix IV A</u>.

LABELLING

The label states the nominal <u>viscosity</u> in millipascal seconds.

