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

Sodium Cromoglicate Eye Drops

General Notices

DEFINITION

Sodium Cromoglicate Eye Drops are a sterile solution of Sodium Cromoglicate in Purified Water.

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

Content of sodium cromoglicate, $C_{23}H_{14}Na_2O_{11}$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 230 to 400 nm of a solution of the eye drops diluted to contain 0.002% w/v of Sodium Cromoglicate exhibits two maxima at 239 and 326 nm, and a shoulder at about 260 nm.
B. To 1 mL of the eye drops add 2.5 mL of 1M *sodium hydroxide* and boil for 1 minute; a yellow colour is produced. Add 0.5 mL of *diazobenzenesulfonic acid solution*; a deep red colour is produced.

TESTS

Acidity or alkalinity

pH, 4.0 to 7.0, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using a precoated silica gel F_{254} plate (Merck silica ge 60 F_{254} plates are suitable) and a mixture of 5 volumes of *glacial acetic acid*, 50 volumes of *ethyl acetate* and 50 volumes of *toluene* as the mobile phase but allowing the solvent front to ascend 10 cm above the line of application. Apply separately to the plate 5 µL of each of the following solutions. For solution (1) use the eye drops, diluted, if necessary with *water*, to contain 2% w/v of Sodium Cromoglicate. Solution (2) contains 0.01% w/v of *1,3-bis(2-acetyl-3-hydroxyphenoxy)-2-propanol* in *dichloromethane*. After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).

ASSAY

Dilute the eye drops with *phosphate buffer pH 7.4* to give a solution containing 0.004% w/v of Sodium Cromoglicate and measure the *absorbance* of the resulting solution at the maximum at 326 nm, Appendix II B. Calculate the content of $C_{23}H_{14}Na_2O_{11}$ in the eye drops taking 164 as the value of A(1%, 1 cm) at the maximum at 326 nm.