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

Labetalol Tablets

General Notices

Action and use

Alpha- and beta-adrenoceptor antagonist.

DEFINITION

Labetalol Tablets contain Labetalol Hydrochloride.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of labetalol hydrochloride, $C_{19}H_{24}N_2O_3$,HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. To a quantity of the powdered tablets containing 50 mg of Labetalol Hydrochloride add 50 mL of 0.1M *hydrochloric acid* and heat on a water bath for 30 minutes. Cool, filter, add 10 mL of *ammonia buffer pH 10.0* and extract with three 15-mL quantities of *dichloromethane*. Shake the combined extracts with 5 g of *anhydrous sodium sulfate*, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of labetalol *(RS 199)*.
B. The *light absorption*, Appendix II B, in the range 250 to 400 nm of a 0.004% w/v solution in 0.1M *sodium hydroxide* of the residue obtained in test A exhibits a maximum only at 333 nm.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 0.5 g of Labetalol Hydrochloride with 10 mL of *methanol*, filter and use the filtrate.
(2) Dilute 1 volume of solution (1) to 100 volumes with *methanol*.
(3) Dilute 1 volume of solution (2) to 2 volumes with *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF_{254}*.
(b) Use the mobile phase as described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry it in a current of warm air, heat at 105° for 30 minutes, cool and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

5 volumes of 13.5M *ammonia*, 25 volumes of *methanol* and 75 volumes of *dichloromethane*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.5%).

ASSAY

Weigh and powder 20 tablets. Shake a quantity of the powdered tablets containing 1 g of Labetalol Hydrochloride with 250 mL of 0.05M *sulfuric acid* for 30 minutes. Dilute the mixture to 500 mL with 0.05M *sulfuric acid*, mix, filter and dilute 10 mL of the filtrate to 250 mL with 0.05M *sulfuric acid*. Measure the *absorbance* of the resulting solution at the maximum at 302 nm, Appendix II B. Calculate the content of $C_{19}H_{24}N_2O_3$,HCl taking 86 as the value of A(1%, 1 cm) at the maximum at 302 nm.