Mabuterol Hydrochloride Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Mabuterol Hydrochloride Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. Start the test, withdraw not less than 20 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL of the filtrate, pipet *V* mL of the subsequent filtrate, add water to make exactly *V'* mL so that each mL contains about 28 mg of mabuterol hydrochloride ($C_{13}H_{18}ClF_3N_2O \cdot HCl$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Mabuterol Hydrochloride RS, previously dried at 60ºC for 3 hours under reduced pressure not exceeding 0.67 kPa using phosphorus (V) oxide as a desiccant, and dissolve in water to make exactly 200 mL. Pipet 2 mL of this solution, add water to make exactly 100 mL. Then, pipet 2 mL of this solution, add water to make exactly 200 mL, and use this solution as the standard solution. Perform the test with exactly 200 μL each of the sample solution and standard solution as directed under Liquid Chromatography <*2.01*> according to the following conditions, and determine the peak areas, A_T and A_S, of mabuterol of both solutions.

The requirements are met if Mabuterol Hydrochloride Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of mabuterol hydrochloride ($C_{13}H_{18}ClF_3N_2O \cdot HCl$)

$$= M_S \times A_T/A_S \times V'/V \times 1/C \times 90$$

M_S: Amount (mg) of Mabuterol Hydrochloride RS

C: Labeled amount (μg) of mabuterol hydrochloride ($C_{13}H_{18}ClF_3N_2O \cdot HCl$) in 1 tablet

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 244 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40ºC.

Mobile phase: Adjust the pH of a mixture of water and methanol (3:2) to 3.0 with perchloric acid.

Flow rate: Adjust the flow rate so that the retention time of mabuterol is about 6 minutes.

System suitability−

System performance: When the procedure is run with 200 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of

mabuterol are not less than 2000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 200 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of mabuterol is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
25 μg	15 minutes	Not less than 80%
50 μg	15 minutes	Not less than 80%

Mabuterol Hydrochloride RS Mabuterol Hydrochloride. Purify by the following method to meet the following requirements.

Purification method−Recrystalize mabuterol hydrochloride 3 times in 2-propanol, wash with petroleum ether, and dry the crystals so obtained under reduced pressure at 60ºC for 3 hours using phosphorus (V) oxide as a desiccant.

Absorbance <2.24> $E_{1cm}^{1\%}$ (245 nm): 369 − 373 (after drying, 10 mg, diluted methanol (1 in 2), 500 mL). $E_{1cm}^{1\%}$ (306 nm): 109 − 113 (after drying, 10 mg, diluted methanol (1 in 2), 500 mL). Use the sample dried in a desiccator (reduced pressure, phosphorus (V) oxide, 60ºC) for 3 hours for the test.

Content: not less than 99.0%. Assay−Weigh accurately about 0.2 g of Mabuterol Hydrochloride RS, previously dried, dissolve in 80 mL of acetic anhydride, and titrate <2.50> with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 34.72 mg of $C_{13}H_{18}ClF_3N_2O \cdot HCl$