Chlormadinone Acetate Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Chlormadinone Acetate Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of a solution of sodium lauryl sulfate (1 in 250) as the dissolution medium. 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 a solution of sodium lauryl sulfate (1 in 250) to make exactly *V′* mL so that each mL contains about 2.2 μg of chlormadinone acetate ($C_{23}H_{29}ClO_4$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Chlormadinone Acetate RS, previously dried in vacuum with phosphorus (V) oxide for 4 hours, and dissolve in ethanol (99.5) to make exactly 100 mL. Pipet 2 mL of this solution, add a solution of sodium lauryl sulfate (1 in 250) to make exactly 200 mL, and use this solution as the standard solution. Perform the test with exactly 20 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 chlormadinone acetate in each solution.

The requirements are met if Chlormadinone Acetate Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of chlormadinone acetate ($C_{23}H_{29}ClO_4$)
$= M_S \times A_T/A_S \times V'/V \times 1/C \times 9$

M_S: Amount (mg) of Chlormadinone Acetate RS
C: Labeled amount (mg) of chlormadinone acetate ($C_{23}H_{29}ClO_4$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 285nm).

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 25ºC.

Mobile phase: A mixture of acetonitrile and water (11:9).

Flow rate: Adjust the flow rate so that the retention time of chlormadinone acetate is about 10 minutes.

System suitability —

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of chlormadinone acetate are not less than 4000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the

above operating conditions, the relative standard deviation of the peak area of chlormadinone acetate is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
2 mg	45 minutes	Not less than 85%
25 mg	90 minutes	Not less than 75%