



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

## Acepromazine Tablets

### General Notices

#### Action and use

Dopamine receptor antagonist; neuroleptic.

### DEFINITION

Acepromazine Tablets contain Acepromazine Maleate.

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

#### Content of acepromazine, $C_{19}H_{22}N_2OS$

92.5 to 107.5% of the stated amount.

### IDENTIFICATION

- A. To a quantity of the powdered tablets containing the equivalent of 20 mg of acepromazine add 2 mL of [water](#) and 3 mL of 2M [sodium hydroxide](#). Extract with two 5 mL quantities of [cyclohexane](#) and evaporate to dryness under reduced pressure. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of acepromazine ([RSV 01](#)).
- B. Complies with the test for [identification of phenothiazines](#), [Appendix III A](#), applying to the plate 1 µL of each of the following solutions. For solution (1) extract a quantity of the powdered tablets containing the equivalent of 20 mg of acepromazine with two 5 mL quantities of [chloroform](#). Solution (2) is a solution of [acepromazine maleate BPCRS](#) in [chloroform](#) containing the equivalent of 0.2% w/v of acepromazine.
- C. To a quantity of the powdered tablets containing the equivalent of 5 mg of acepromazine add 2 mL of [sulfuric acid](#). A yellow colour is produced which becomes deep orange on warming for 2 minutes.
- D. Dissolve as completely as possible a quantity of the powdered tablets containing the equivalent of 25 mg of acepromazine in a mixture of 3 mL of [water](#) and 2 mL of 5M [sodium hydroxide](#) and shake with three 3 mL quantities of [ether](#). Add 2 mL of [bromine solution](#) to the

aqueous solution, warm in a water bath for 10 minutes, heat to boiling and cool. Add 0.25 mL to a solution of 10 mg of [resorcinol](#) in 3 mL of [sulfuric acid](#) and heat for 15 minutes on a water bath. A bluish black colour develops.

## TESTS

### Related substances

Comply with the test for [related substances in phenothiazines](#), [Appendix III A](#), but using a mixture of 8 volumes of [diethylamine](#), 17 volumes of [butan-2-one](#) and 75 volumes of n-[hexane](#) as the mobile phase and using the following solutions. For solution (1) shake a quantity of the powdered tablets containing the equivalent of 50 mg of acepromazine with 10 mL of [chloroform](#), filter, evaporate to dryness and dissolve the residue in 5 mL of [methanol](#) containing 0.5% v/v of 13.5M [ammonia](#). For solution (2) dilute 1 volume of solution (1) to 100 volumes with [methanol](#) containing 0.5% v/v of 13.5M [ammonia](#).

## ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing the equivalent of 60 mg of acepromazine add 5 mL of [water](#) and extract with three or more 50 mL quantities of [chloroform](#) or until the chloroform extract is colourless. Evaporate to dryness and dissolve the residue in 15 mL of [acetic anhydride](#). Carry out Method I for [non-aqueous titration](#), [Appendix VIII A](#), using [0.02M perchloric acid VS](#) as titrant and [crystal violet solution](#) as indicator. Each mL of [0.02M perchloric acid VS](#) is equivalent to 6.529 mg of  $C_{19}H_{22}N_2OS$ .

## LABELLING

The quantity of the active ingredient is stated in terms of the equivalent amount of acepromazine.