



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

Acepromazine Injection

General Notices

Action and use

Dopamine receptor antagonist; neuroleptic.

DEFINITION

Acepromazine Injection is a sterile solution of Acepromazine Maleate in Water for Injections. The pH of the solution is adjusted to about 5 by the addition of Sodium Hydroxide.

The injection complies with the requirements stated under Parenteral Preparations 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 volume 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 volume containing the equivalent of 20 mg of acepromazine with two 5 mL quantities of [chloroform](#) and use the combined extracts. Solution (2) is a solution of [acepromazine maleate BPCRS](#) in [chloroform](#) containing the equivalent of 0.2% w/v of acepromazine.
- C. To 5 mg of the residue obtained in test A add 2 mL of [sulfuric acid](#). A yellow colour is produced which becomes deep orange on warming for 2 minutes.
- D. To a volume of the injection containing the equivalent of 25 mg of acepromazine add 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 in a water bath. A bluish black colour develops.

TESTS

Acidity

pH, 4.5 to 5.5, [Appendix V L](#).

ASSAY

To a volume containing the equivalent of 40 mg of acepromazine add 5 mL of 1M [sodium hydroxide](#) and extract with 50 mL quantities of [chloroform](#) until the chloroform extract is colourless. Wash the extracts with the same 10 mL of [water](#) and filter through a plug of absorbent cotton previously moistened with [chloroform](#). Evaporate the combined extracts 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 $C_{19}H_{22}N_2OS$.

STORAGE

Acepromazine Injection should be protected from light.

LABELLING

The strength is stated as the equivalent amount of acepromazine in a suitable dose-volume.