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Azaperone Injection

General Notices

Action and use

Dopamine receptor antagonist; neuroleptic (veterinary).

DEFINITION

Azaperone Injection is a sterile solution of Azaperone in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of azaperone, $C_{19}H_{22}FN_3O$

90.0 to 110.0% of the stated amount.

CHARACTERISTICS

A clear, yellow solution.

IDENTIFICATION

A. To a volume containing 80 mg of Azaperone add 5 mL of 0.5M *sulfuric acid* and 20 mL of *water*. Extract the solution with 50 mL of *ether*, make the aqueous phase alkaline with 1M *sodium hydroxide* and extract with 50 mL of *ether*. Wash the ether extracts with two 10 mL-quantities of *water*, shake with *anhydrous sodium sulfate*, filter and evaporate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of azaperone *(RSV 08)*.

B. The *light absorption*, Appendix II B, in the range 230 to 350 nm of a 2-cm layer of the solution obtained in the Assay exhibits maxima at 242 nm and at 312 nm. The *absorbances* at the maxima are about 1.1 and about 0.38, respectively.

TESTS

Acidity

pH, 3.5 to 5.0, Appendix V L.

Related substances

Carry out in subdued light the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 1 volume of *ethanol (96%)* and 9 volumes of *chloroform* as the mobile phase. Apply separately to the plate 10 µL of each of the following two solutions. For solution (1) dissolve the

extracted residue obtained in Identification test A in sufficient *chloroform* to produce a solution containing 1% w/v of Azaperone. For solution (2) dilute 1 volume of solution (1) to 100 volumes with *chloroform*. After removal of the plate allow it to dry in air and examine under *ultraviolet light (254 nm)*. 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%).

ASSAY

To a volume containing 0.4 g of Azaperone add 25 mL of 0.5M *sulfuric acid* and sufficient *water* to produce 250 mL. Mix, transfer 10 mL of the solution to a separating funnel containing 10 mL of 0.05M *sulfuric acid* and shake with 20 mL of *ether*. Wash the ether layer with two 10 mL quantities of 0.05M *sulfuric acid*. Make the combined acid extract and washings alkaline with 5 mL of 1M *sodium hydroxide*, add 50 mL of *ether*, shake and allow to separate. Extract the aqueous layer with 50 mL of *ether*. Wash the two ether solutions, in succession, with a 20 mL quantity of *water* and extract each of the two ether solutions, in succession, with two 20 mL quantities and one 5 mL quantity of 0.25M *sulfuric acid*. Combine the acid extracts and add sufficient 0.25M *sulfuric acid* to produce 100 mL. To 5 mL of the resulting solution add 5 mL of *methanol* and sufficient 0.25M *sulfuric acid* to produce 100 mL. Measure the *absorbance* of the resulting solution at the maximum at 242 nm, Appendix II B. Dissolve 40 mg of *azaperone BPCRS* in sufficient *methanol* to produce 250 mL, dilute 5 mL of the resulting solution to 100 mL with 0.25M *sulfuric acid* and measure the *absorbance* at 242 nm. Calculate the content of $C_{19}H_{22}FN_3O$ in the injection from the absorbances obtained using the declared content of $C_{19}H_{22}FN_3O$ in *azaperone BPCRS*.

STORAGE

Azaperone Injection should be protected from light.