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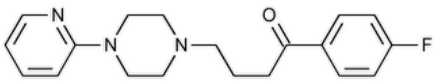
Azaperone



$C_{19}H_{22}FN_3O$ 327.40

1-Butanone, 1-(4-fluorophenyl)-4-[4-(2-pyridinyl)-1-piperazinyl]-.

4'-Fluoro-4-[4-(2-pyridyl)-1-piperazinyl]butyrophenone CAS RN®: 1649-18-9; UNII: 19BV78AK7W.

» Azaperone contains not less than 98.0 percent and not more than 102.0 percent of $C_{19}H_{22}FN_3O$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers, protected from light. Store at room temperature.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Azaperone RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020) **:** previously dried.

Melting range ⟨741⟩**:** between 92° and 95°.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Chromatographic purity—Dissolve an accurately weighed quantity of USP Azaperone RS in a mixture of acetone and methylene chloride (5:1) to obtain a solution having a concentration of 0.50 mg per mL *(Standard solution A).* Quantitatively dilute a volume of *Standard solution A* with the same solvent mixture to obtain a solution having a concentration of 0.25 mg per mL *(Standard solution B).* Prepare a test solution by dissolving an accurately weighed quantity of Azaperone in a mixture of acetone and methylene chloride (5:1) to obtain a solution containing 50 mg per mL. Separately apply 1 µL each of *Standard solution A, Standard solution B,* and the test solution to a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.2-mm layer of chromatographic silica gel mixture with chemically bonded amino groups, and allow the spots to dry. Develop the chromatograms in a solvent system consisting of a mixture of cyclohexane, acetone, and methanol (65:30:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chromatographic chamber, and allow the plate to air-dry. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots, other than any spot at the origin, observed in the chromatogram of the test solution with those of the principal spots in the chromatograms of *Standard solution A* and *Standard solution B:* the sum of the intensities of the secondary spots obtained from the test solution corresponds to not more than the intensity of the principal spot in the chromatogram of *Standard solution A* (1.0%).

Assay—Dissolve about 120 mg of Azaperone, accurately weighed, in 50 mL of a mixture of methyl ethyl ketone and glacial acetic acid (7:1). Add 3 drops of *p*-naphtholbenzein TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 16.37 mg of $C_{19}H_{22}FN_3O$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AZAPERONE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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