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Azaperone Injection

» Azaperone Injection is a sterile solution of Azaperone in Water for Injection, prepared with the aid of Tartaric Acid. It may contain a suitable preservative and a stabilizing agent. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{22}FN_3O$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

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

USP Reference standards ⟨11⟩—

USP Azaperone RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for azaperone, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation,* obtained as directed in the *Assay*.

pH ⟨791⟩: between 4.0 and 5.6.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase—Prepare a filtered and degassed mixture containing 6 volumes of acetonitrile and 4 volumes of 0.01 M dibasic potassium phosphate, and adjust by the addition of dilute phosphoric acid (1 in 10) to a pH of 7.8 ± 0.1. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Internal standard solution—Prepare a solution of benzophenone in methanol containing about 0.5 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Azaperone RS in methanol, and dilute quantitatively with methanol to obtain a solution having a known concentration of about 0.5 mg per mL. Combine 2.5 mL of this solution with 2.5 mL of *Internal standard solution*, dilute quantitatively with methanol to 10.0 mL, and mix.

Assay preparation—Dilute an accurately measured volume of Injection quantitatively with methanol to obtain a solution containing about 0.5 mg of azaperone per mL. Combine 2.5 mL of this solution with 2.5 mL of *Internal standard solution*, dilute quantitatively with methanol to 10.0 mL, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with 243-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the azaperone and internal standard peaks is not less than 2.7; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of azaperone ($C_{19}H_{22}FN_3O$) in each mL of the Injection taken by the formula:

$$(C)(L/D)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Azaperone RS in the *Standard preparation; L* is the labeled quantity, in mg, of azaperone in each mL of the Injection; D is the concentration, in mg per mL, of azaperone in the *Assay preparation*, based on the volume of Injection taken and the extent of dilution; and R_U and R_S are the ratios of the azaperone peak to the benzophenone peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
AZAPERONE INJECTION	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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