

Acepromazine Maleate Injection

» Acepromazine Maleate Injection is a sterile solution of Acepromazine Maleate in Water for Injection. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$).

Packaging and storage—Preserve in tight, light-resistant, single-dose or multiple-dose Containers for Injections as described under Injections (1), preferably of Type I glass, and store at controlled room temperature.

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

USP Reference standards (11)—

USP Acepromazine Maleate RS

USP Endotoxin RS

NOTE—Throughout the following procedures, protect test or assay specimens, the USP Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

Identification—

A: Infrared Absorption (197K)—

Test specimen—To a volume of Injection, equivalent to about 20 mg of acepromazine maleate, add 2 mL of water and 3 mL of 2 N sodium hydroxide, and extract with two 5-mL portions of cyclohexane. Combine the cyclohexane extracts, and evaporate to dryness under vacuum, using gentle heat, if necessary.

B: The retention time of the major peak for acepromazine in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Bacterial endotoxins (85): not more than 4.5 USP Endotoxin Units per mg of acepromazine maleate.

Sterility (71)—It meets the requirements when tested as directed for Membrane Filtration under Test for Sterility of the Product to be Examined.

pH (791): between 4.5 and 5.8.

Other requirements—It meets the requirements under Injections (1).

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the *Assay* under Acepromazine Maleate.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 100 mg of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$), to a 100-mL volumetric flask, dilute with 0.05 N hydrochloric acid to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under Acepromazine Maleate. Calculate the quantity, in mg, of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$) in each mL of the Injection taken by the formula:

$$1000(C/V)(r_U / r_S)$$

in which *V* is the volume, in mL, of Injection taken; and the other terms are as defined therein.

Acepromazine Maleate Tablets

» Acepromazine Maleate Tablets contain not less than 90.0 percent and not more than 110.0 per-

cent of the labeled amount of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$).

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

Labeling—Label the Tablets to indicate that they are for veterinary use only.

USP Reference standards (11)—

USP Acepromazine Maleate RS

NOTE—Throughout the following procedures, protect test or assay specimens, the USP Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

Identification—

A: Infrared Absorption (197K)—

Test specimen: To a quantity of powdered Tablets, equivalent to about 20 mg of acepromazine maleate, add 2 mL of water and 3 mL of 2 N sodium hydroxide, and extract with two 5-mL portions of cyclohexane. Combine the cyclohexane extracts, and evaporate to dryness under vacuum, using gentle heat, if necessary.

B: The retention time of the major peak for acepromazine in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay* under Acepromazine Maleate.

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the *Assay* under Acepromazine Maleate.

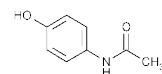
Assay preparation—Transfer not fewer than 10 Tablets, accurately counted, to a 200-mL volumetric flask. Add about 100 mL of 0.05 N hydrochloric acid, and sonicate for about 10 minutes. Shake by mechanical means for about 30 minutes, dilute with 0.05 N hydrochloric acid to volume, and mix. Quantitatively dilute an accurately measured volume of this solution with water to obtain a solution containing about 0.1 mg of acepromazine maleate per mL. Pass a portion of this solution through a filter having a 0.5-μm or finer porosity, and use the filtrate as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under Acepromazine Maleate. Calculate the quantity, in mg, of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$) in each Tablet taken by the formula:

$$(LC/D)(r_U / r_S)$$

in which *L* is the labeled quantity, in mg, of acepromazine maleate in each Tablet; *C* is the concentration, in mg per mL, of USP Acepromazine Maleate RS in the *Standard preparation*; *D* is the concentration, in mg per mL, of acepromazine maleate in the *Assay preparation*, based on the labeled quantity per Tablet, the number of Tablets taken, and the extent of dilution; and *r_U* and *r_S* are the acepromazine peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Acetaminophen



$C_8H_9NO_2$ 151.16

Acetamide, *N*-(4-hydroxyphenyl)-.
4'-Hydroxyacetanilide [103-90-2].

» Acetaminophen contains not less than 98.0 percent and not more than 101.0 per cent of $C_8H_9NO_2$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers, and store at room temperature. Protect from moisture and heat.

USP Reference standards (11)—
USP Acetaminophen RS

Identification—

A: *Infrared Absorption* (197K).

B: *Ultraviolet Absorption* (197U)—

Solution: 5 µg per mL.

Medium: 0.1 N hydrochloric acid in methanol (1 in 100).

C: It responds to the *Thin-layer Chromatographic Identification Test* (201), a test solution in methanol containing about 1 mg per mL and a solvent system consisting of a mixture of methylene chloride and methanol (4:1) being used.

Melting range (741): between 168° and 172°.

Water, *Method I* (921): not more than 0.5%.

Residue on ignition (281): not more than 0.1%.

Chloride (221)—Shake 1.0 g with 25 mL of water, filter, and add 1 mL of 2 N nitric acid and 1 mL of silver nitrate TS: the filtrate shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid (0.014%).

Sulfate (221)—Shake 1.0 g with 25 mL of water, filter, add 2 mL of 1 N acetic acid, then add 2 mL of barium chloride TS: the mixture shows no more sulfate than corresponds to 0.20 mL of 0.020 N sulfuric acid (0.02%).

Sulfide—Place about 2.5 g in a 50-mL beaker. Add 5 mL of alcohol and 1 mL of 3 N hydrochloric acid. Moisten a piece of lead acetate test paper with water, and fix to the underside of a watch glass. Cover the beaker with the watch glass so that part of the lead acetate paper hangs down near the pouring spout of the beaker. Heat the contents of the beaker on a hot plate just to boiling: no coloration or spotting of the test paper occurs.

Heavy metals, *Method II* (231): 0.001%.

Free *p*-aminophenol—Transfer 5.0 g to a 100-mL volumetric flask, and dissolve in about 75 mL of a mixture of equal volumes of methanol and water. Add 5.0 mL of alkaline nitroferricyanide solution (prepared by dissolving 1 g of sodium nitroferricyanide and 1 g of anhydrous sodium carbonate in 100 mL of water), dilute with a mixture of equal volumes of methanol and water to volume, mix, and allow to stand for 30 minutes. Concomitantly determine the absorbances of this solution and of a freshly prepared solution of *p*-aminophenol, similarly prepared at a concentration of 2.5 µg per mL, using the same quantities of the same reagents, in 1-cm cells, at the maximum at about 710 nm, with a suitable spectrophotometer, using 5.0 mL of alkaline nitroferricyanide solution diluted with a mixture of equal volumes of methanol and water to 100 mL as the blank: the absorbance of the test solution does not exceed that of the standard solution, corresponding to not more than 0.005% of *p*-aminophenol.

Limit of *p*-chloroacetanilide—Transfer 1.0 g to a glass-stoppered, 15-mL centrifuge tube, add 5.0 mL of ether, shake by mechanical means for 30 minutes, and centrifuge at 1000 rpm for 15 minutes or until a clean separation is obtained. Apply 200 µL of the supernatant, in 40-µL portions, to obtain a single spot not more than 10 mm in diameter to a suitable thin-layer chromatographic plate (see *Chromatography* (621)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Similarly apply 40 µL of a Standard solution in ether containing 10 µg of *p*-chloroacetanilide per mL, and allow the spots to dry. Develop the chromatogram in an unsaturated chamber, with a solvent system consisting of a mixture of solvent hexane and acetone (75:25), until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots in the chromatogram by examination under short-wavelength UV light: any spot obtained from the solution under test, at an *R_f* value corresponding to the principal spot from the Standard solution, is not greater in size or

intensity than the principal spot obtained from the Standard solution, corresponding to not more than 0.001% of *p*-chloroacetanilide.

Readily carbonizable substances (271)—Dissolve 0.50 g in 5 mL of sulfuric acid: the solution has no more color than *Matching Fluid A*.

Assay—Dissolve about 120 mg of Acetaminophen, accurately weighed, in 10 mL of methanol in a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Acetaminophen RS, in the same medium, at a concentration of about 12 µg per mL in 1-cm cells, at the wavelength of maximum absorbance at about 244 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of C₈H₉NO₂ in the Acetaminophen taken by the formula:

$$10C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Acetaminophen RS in the Standard solution; and *A_U* and *A_S* are the absorbances of the solution of Acetaminophen and the Standard solution, respectively.

Acetaminophen Capsules

» Acetaminophen Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of acetaminophen (C₈H₉NO₂).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

USP Reference standards (11)—
USP Acetaminophen RS

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

B: Triturate an amount of the contents of the Capsules, equivalent to about 50 mg of acetaminophen, with 50 mL of methanol, and filter: the clear filtrate (test solution) responds to the *Thin-layer Chromatographic Identification Test* (201), a solvent system consisting of a mixture of methylene chloride and methanol (4:1) being used.

Dissolution (711)—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of C₈H₉NO₂ dissolved from UV absorption at the wavelength of maximum absorbance at about 249 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Acetaminophen RS in the same *Medium*.

Tolerances—Not less than 75% (Q) of the labeled amount of C₈H₉NO₂ is dissolved in 45 minutes.

Uniformity of dosage units (905): meet the requirements.

Assay—

Mobile phase—Prepare a suitable degassed mixture of water and methanol (3:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

Standard preparation—Dissolve an accurately weighed quantity of USP Acetaminophen RS in *Mobile phase* to obtain a solution having a known concentration of about 0.01 mg per mL.