Change to read:

- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Acepromazine Maleate RS
  • (CN 1-May-2018)

Acepromazine Maleate Tablets

DEFINITION

Acepromazine Maleate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$).

Throughout the following procedures, protect samples, 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⟩
  Sample: To a quantity of powdered Tablets, equivalent to 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.
  Acceptance criteria: Meet the requirements
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **PROCEDURE**
  Buffer: Add 6 mL of triethylamine to 700 mL of water, and adjust with phosphoric acid to a pH of 2.5.
  Mobile phase: Acetonitrile and *Buffer* (300:700)
  Standard stock solution: 1 mg/mL of USP Acepromazine Maleate RS in 0.05 N hydrochloric acid
  Standard solution: 0.1 mg/mL of USP Acepromazine Maleate RS in water from *Standard stock solution*
  Sample stock solution: Transfer NLT 10 Tablets to a 200-mL volumetric flask, add 100 mL of 0.05 N hydrochloric acid, and sonicate for 10 min. Shake by mechanical means for 30 min, and dilute with 0.05 N hydrochloric acid to volume.
  Sample solution: Nominally 0.1 mg/mL of Acepromazine Maleate in water from *Sample stock solution*. Pass a portion of this solution through a filter of 0.5-µm or finer pore size.
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *System Suitability*.)
  Mode: LC
  Detector: UV 280 nm
  Column: 4-mm × 15-cm; 5-µm packing L7
  Flow rate: 1 mL/min
  Injection volume: 10 µL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Column efficiency: NLT 1500 theoretical plates
  Tailing factor: NMT 2.5
  Relative standard deviation: NMT 2.0%
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

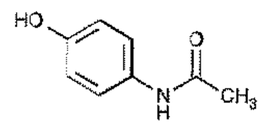
r_U = peak area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of USP Acepromazine Maleate RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **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

Acetaminophen



$C_8H_9NO_2$ 151.16

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

DEFINITION

Acetaminophen contains NLT 98.0% and NMT 102.0% of acetaminophen ($C_8H_9NO_2$), calculated on the dried basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION** ⟨197K⟩
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **PROCEDURE**
  Use low-actinic glassware for preparation of the *Sample solution*.
  Solution A: 1.7 g/L of monobasic potassium phosphate and 1.8 g/L of dibasic sodium phosphate, anhydrous
  Solution B: Methanol
  Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	99	1
•.0	99	1
•.0	•9	1
•.•	99	1
•.•	99	1

Standard solution: 0.1 mg/mL of USP Acetaminophen RS in methanol
Sample solution: 0.1 mg/mL of Acetaminophen in methanol