C_S = concentration of USP Acebutolol Hydrochloride RS in the *Standard solution* (µg/mL)
C_U = nominal concentration of acebutolol in the *Sample solution* (µg/mL)
M_{r1} = molecular weight of acebutolol, 336.43
M_{r2} = molecular weight of acebutolol hydrochloride, 372.89

Acceptance criteria: NMT 0.5% of any individual impurity. Disregard any peaks from the *Diluent*.

Test 2

Buffer and **System suitability:** Proceed as directed in *Test 1*.

Mobile phase: Methanol and *Buffer* (50:50)

Standard stock solution: 0.6 mg/mL of USP Acebutolol Hydrochloride RS prepared as follows. To a suitable amount of USP Acebutolol Hydrochloride RS in a suitable volumetric flask, add methanol, about 24% of the flask volume, swirl to dissolve, and dilute with *Mobile phase* to volume.

Standard solution: 1.4 µg/mL of USP Acebutolol Hydrochloride RS in *Mobile phase* from *Standard stock solution*

Sample stock solution: Nominally 2.5 mg/mL of acebutolol prepared as follows. Transfer a portion of the contents of 20 opened Capsules, equivalent to 250 mg of acebutolol, to a 100-mL volumetric flask. Add 25 mL of methanol and shake by mechanical means for 15 min. Dilute with *Mobile phase* to volume.

Sample solution: Nominally 250 µg/mL of acebutolol in *Diluent* from *Sample stock solution* prepared as follows. Centrifuge a portion of *Sample stock solution*, and transfer 10.0 mL of the clear supernatant to a 100-mL volumetric flask. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Proceed as directed in *Test 1* except for the *Injection volume* and *Run time*.

Injection volume: 70 µL

Run time: NLT 3 times the retention time of acebutolol

Analysis

Samples: *Mobile phase*, *Standard solution*, and *Sample solution*

Calculate the percentage of each impurity eluting after the acebutolol peak in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*
r_S = peak response of acebutolol from the *Standard solution*
C_S = concentration of USP Acebutolol Hydrochloride RS in the *Standard solution* (µg/mL)
C_U = nominal concentration of acebutolol from the *Sample solution* (µg/mL)
M_{r1} = molecular weight of acebutolol, 336.43
M_{r2} = molecular weight of acebutolol hydrochloride, 372.89

Acceptance criteria

Test 2: NMT 0.5% of any individual impurity. Disregard any peaks from the *Mobile phase*.

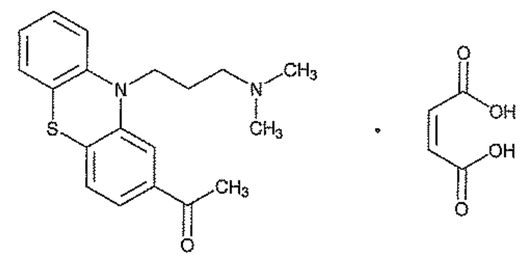
Sum of impurities from *Test 1* and *Test 2*: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.

- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Acebutolol Hydrochloride RS

Acepromazine Maleate



$C_{19}H_{22}N_2OS \cdot C_4H_4O_4$ 442.53

Ethanone, 1-[10-[3-(dimethylamino)propyl]-10*H*-phenothiazin-2-yl]-, (Z)-2-butenedioate (1:1);
10-[3-(Dimethylamino)propyl]phenothiazin-2-yl methyl ketone maleate (1:1) [3598-37-6].

DEFINITION

Acepromazine Maleate contains NLT 98.0% and NMT 101.0% of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$), calculated on the anhydrous basis.

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⟩
- **B.** The retention time of the major peak for acepromazine 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: 1 mg/mL of Acepromazine Maleate in 0.05 N hydrochloric acid

Sample solution: 0.1 mg/mL of Acepromazine Maleate in water from *Sample stock solution*

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 Acepromazine Maleate taken:

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

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