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# Phendimetrazine Tartrate

$C_{12}H_{17}NO \cdot C_4H_6O_6$ 341.36

Morpholine, 3,4-dimethyl-2-phenyl-, (2*S-trans*)-, [*R*-(*R**,*R**)]-2,3-dihydroxybutanedioate (1:1);

(2*S*,3*S*)-3,4-Dimethyl-2-phenylmorpholine L-(+)-tartrate (1:1) CAS RN®: 50-58-8; UNII: 6985IP0T80.

## DEFINITION

Phendimetrazine Tartrate contains NLT 98.0% and NMT 102.0% of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$), calculated on the dried basis.

## IDENTIFICATION

***Change to read:***

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

***Change to read:***

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020)

**Sample solution:** 1 mg/mL in methanol

**Acceptance criteria:** Meets the requirements

• **C.** Identification Tests—General, *Tartrate* ⟨191⟩

## ASSAY

• **Procedure**

**Sample solution:** Transfer an accurately weighed amount of 500 mg of Phendimetrazine Tartrate to a suitable beaker, and dissolve in 50 mL of glacial acetic acid.

**Analysis:** Add 1 drop of crystal violet TS to the *Sample solution*, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 34.14 mg of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$).

**Acceptance criteria:** 98.0%–102.0% on the dried basis

## IMPURITIES

• **Residue on Ignition** ⟨281⟩**:** NMT 0.1%

• **Chloride and Sulfate,** *Chloride* ⟨221⟩

**Sample:** 1.0 g

**Acceptance criteria:** 0.035%; the *Sample* shows no more chloride than corresponds to 0.50 mL of 0.020 N hydrochloric acid.

• **Chloride and Sulfate,** *Sulfate* ⟨221⟩

**Sample:** 1.0 g

**Acceptance criteria:** 0.01%; the *Sample* shows no more sulfate than corresponds to 0.10 mL of 0.020 N sulfuric acid.

• **Organic Impurities**

**Standard solution:** An aqueous solution containing 100 mg/mL of USP Phendimetrazine Tartrate RS

**Sample solution:** 100 mg/mL of Phendimetrazine Tartrate in water

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)

**Mode:** TLC

**Adsorbent:** 0.25-mm layer of chromatographic silica gel mixture

**Application volume:** 10 µL

**Developing solvent system:** Acetone, methanol, and ammonium hydroxide (50:50:1)

**Analysis**

Develop the chromatogram in a suitable chamber with the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, air-dry, view under short-wavelength UV light, and observe the location of the spots. Expose the plate to iodine vapors in a closed chamber.

**Acceptance criteria:** Yellow spots appear at the same locations as the spots observed under UV light, and the $R_F$ value of the spot of the *Sample solution* corresponds to that of the *Standard solution*, and no other spot is obtained.

- **L-*Erythro* Isomer**

**Sample solution:** Dissolve 3.0 g of Phendimetrazine Tartrate in 25 mL of sodium hydroxide solution (1 in 20) in a suitable separator. Add 25 mL of sodium hydroxide solution (1 in 2), swirl, and allow the phendimetrazine base to separate. Discard the lower, alkaline layer, and collect the upper layer, centrifuging, if necessary, to obtain a clear liquid.

**Chromatographic system**

**Mode:** GC

**Detector:** Flame ionization

**Column:** 25-m × 0.25-mm capillary column, the inside wall of which is coated with a 0.4-µm film of liquid phase G1

**Carrier gas:** Helium

**Temperatures**

**Injection port:** 250°

**Column:** 140°

**Detector:** 280°

**Injection volume:** 1.0 µL

**Injection type:** Split ratio, 100:1

**Analysis**

**Sample:** *Sample solution*

[Note—The retention times for the D-*threo* isomer and the L-*erythro* isomer are about 8.5 and 9 min, respectively.]

Preferably using an electronic integrator, determine the areas of all peaks in the chromatogram.

Calculate the percentage of the L-*erythro* isomer in the *Sample solution* taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$ = peak area of the L-*erythro* isomer peak

$r_T$ = sum of the areas of the L-*erythro* isomer peak and the D-*threo* isomer peak

**Acceptance criteria:** NMT 0.1%

## SPECIFIC TESTS

- **Melting Range or Temperature ⟨741⟩:** 182°–188°, with decomposition, but the range between beginning and end of melting does not exceed 3°.
- **Optical Rotation, *Specific Rotation*⟨781S⟩**

**Sample solution:** 100 mg/mL in water

**Acceptance criteria:** +32° to +36°

- **pH ⟨791⟩:** 3.0–4.0, in a solution (1 in 40)
- **Loss on Drying ⟨731⟩**

**Analysis:** Dry to constant weight at 105°.

**Acceptance criteria:** NMT 0.5%

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards ⟨11⟩**

USP Phendimetrazine Tartrate RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| PHENDIMETRAZINE TARTRATE | Documentary Standards Support | SM22020 Small Molecules 2 |

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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