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Phenoxybenzamine Hydrochloride Compounded Oral Suspension

DEFINITION

Phenoxybenzamine Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of phenoxybenzamine hydrochloride ($C_{18}H_{22}ClNO \cdot HCl$).

Prepare Phenoxybenzamine Hydrochloride Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Phenoxybenzamine Hydrochloride powder	1 g
Corn Oil, *NF*, a sufficient quantity to make	100 mL

Pour the weighed *Phenoxybenzamine Hydrochloride powder* into a suitable mortar. Wet the powder with a small amount of *Corn Oil*, and triturate to make a smooth paste. Add the *Corn Oil* to make the mortar contents pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated container using the *Corn Oil* to rinse the mortar. Add sufficient *Corn Oil* to bring the preparation to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 25 mM monobasic potassium phosphate adjusted with phosphoric acid to a pH of 3.1

Mobile phase: Acetonitrile and *Solution A* (70:30)

Diluent: Prepare a mixture of 20 mL of acetonitrile and 80 mL of isopropyl alcohol in a conical flask. Add 10 g of anhydrous sodium sulfate to the flask, shake well for 1 min, and allow the sodium sulfate to precipitate to the bottom. [Note—The addition of anhydrous sodium sulfate removes trace amounts of water in the solvent.]

Standard solution: 0.5 mg/mL of phenoxybenzamine hydrochloride prepared from USP Phenoxybenzamine Hydrochloride RS in acetonitrile

Sample solution: Shake thoroughly each bottle of Oral Suspension. Transfer 0.5 mL of the Oral Suspension into a 10-mL volumetric flask, dilute with *Diluent* to volume, and mix well to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for phenoxybenzamine hydrochloride is about 5.2 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phenoxybenzamine hydrochloride ($C_{18}H_{22}ClNO \cdot HCl$) in the portion of Oral Suspension taken:

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

r_U = peak response of phenoxybenzamine hydrochloride from the *Sample solution*

r_S = peak response of phenoxybenzamine hydrochloride from the *Standard solution*

C_S = concentration of phenoxybenzamine hydrochloride in the *Standard solution* (mg/mL)

C_U = nominal concentration of phenoxybenzamine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.
- **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or controlled room temperature
- **Labeling:** Label it to indicate that it is to be well-shaken immediately before use, and to state the *Beyond-Use Date*.
- **USP Reference Standards** ⟨11⟩
  USP Phenoxybenzamine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PHENOXYBENZAMINE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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