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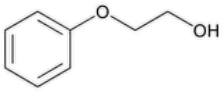
Phenoxyethanol



$C_8H_{10}O_2$ 138.16

2-Phenoxyethanol;

2-Phenoxyethyl alcohol;

Ethylene glycol, 2-monophenyl ether CAS RN®: 122-99-6.

DEFINITION

Phenoxyethanol contains NLT 98.0% and NMT 102.0% of phenoxyethanol ($C_8H_{10}O_2$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F.**▲ (CN 1-May-2020) On an undried specimen

ASSAY

• **Procedure**

Phenol solution, Standard solution, and **Chromatographic system:** Prepare as directed in the test for *Organic Impurities*.

Sample stock solution: 5 mg/mL of Phenoxyethanol in isopropyl alcohol

Sample solution: Transfer 500 µL of the *Sample stock solution* to a vial, add 1000 µL of isopropyl alcohol, crimp the vial, and mix on a vortex mixer for 15 s.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenoxyethanol ($C_8H_{10}O_2$) in the portion of Phenoxyethanol taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Phenoxyethanol RS in the *Standard solution* (mg/mL)

C_U = concentration of Phenoxyethanol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **Organic Impurities**

Phenol solution: 0.25 mg/mL of phenol in isopropyl alcohol

Standard stock solution: 5 mg/mL of USP Phenoxyethanol RS in the *Phenol solution*

Standard solution: Transfer 500 µL of the *Standard stock solution* to a vial, add 1000 µL of isopropyl alcohol, crimp the vial, and mix on a vortex mixer for 15 s.

Sample solution: Transfer 500 µL of Phenoxyethanol to a tared vial, and determine the weight of Phenoxyethanol taken. Add 1000 µL of isopropyl alcohol, crimp the vial, and mix on a vortex mixer for 15 s.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 10-m capillary coated with a 5-µm film of stationary phase G27

Temperatures

Injection port: 300°

Detector: 300°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
80	8	260	10

Carrier gas: Helium

Injection volume: 1 µL

Injection type: Split injection mode

Split flow rate: 44 mL/min

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 10 between the phenol and phenoxyethanol peaks

Relative standard deviation: NMT 2.0% for the phenoxyethanol peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of total impurities in the portion of Phenoxyethanol taken:

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

r_U = peak response of all additional peak areas in the *Sample solution*, excluding the main peak, the solvent peak, and the phenol peak

r_S = peak response of phenoxyethanol from the *Standard solution*

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

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.0%

- **Limit of Phenol**

Phenol solution, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the test for *Organic Impurities*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenol in the portion of Phenoxyethanol taken:

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

r_U = peak response of phenol from the *Sample solution*

r_S = peak response of phenol from the *Standard solution*

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

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.1%

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SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 1.105–1.110 at 20°

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store in a cool, dry place, protected from light.

• **USP Reference Standards ⟨11⟩**
USP Phenoxyethanol RS

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

Topic/Question	Contact	Expert Committee
PHENOXYETHANOL	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 31(3)

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