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Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-CF707DD1-7E1D-4DEE-8028-B0E7EF06E11A_4_en-US
DOI: https://doi.org/10.31003/USPNF_M62990_04_01
DOI Ref: al817

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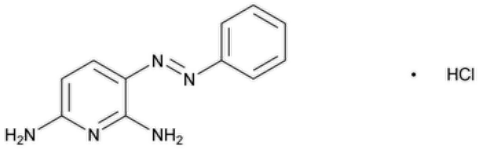
Phenazopyridine Hydrochloride



• HCl

$C_{11}H_{11}N_5 \cdot HCl$ 249.70

2,6-Pyridinediamine, 3-(phenylazo)-, monohydrochloride;

2,6-Diamino-3-(phenylazo)pyridine monohydrochloride CAS RN®: 136-40-3; UNII: 0EWG668W17.

DEFINITION

Phenazopyridine Hydrochloride contains NLT 98.0% and NMT 102.0% of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$), 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)

Medium: Sulfuric acid in alcohol (1 in 360)

Sample solution: 5 µg/mL of Phenazopyridine Hydrochloride in *Medium*

Acceptance criteria: Meets the requirements

• **C.** The retention time of the phenazopyridine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **D.** Identification Tests—General, *Chemical Identification Tests, Chloride* ⟨191⟩**:** Meets the requirements

ASSAY

• **Procedure**

Solution A: 20 mM ammonium acetate in water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
2	95	5
15	50	50
20	50	50
28	30	70

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Time (min)	Solution A (%)	Solution B (%)
33	30	70
35	95	5
40	95	5

Diluent: Acetonitrile and water (10:90)

Standard solution: 0.03 mg/mL of USP Phenazopyridine Hydrochloride RS in *Diluent*

Sample solution: 0.03 mg/mL of Phenazopyridine Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$) in the portion of Phenazopyridine Hydrochloride 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 Phenazopyridine Hydrochloride RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Water-Insoluble Substances**

Sample: 2 g of Phenazopyridine Hydrochloride

Analysis: Dissolve the *Sample* in 200 mL of water, heat to boiling, and then heat in a covered container on a steam bath for 1 h. Filter through a tared, fine-porosity, sintered-glass crucible, wash thoroughly with water, and dry at 105° to constant weight.

Acceptance criteria: The weight of the residue does not exceed 0.1% of the weight of Phenazopyridine Hydrochloride taken.

- **Organic Impurities**

Solution A, Solution B, Mobile phase, and **Diluent:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.25 µg/mL each of USP Phenazopyridine Hydrochloride RS and 2,6-diaminopyridine in *Diluent*

Standard solution: 0.0005 mg/mL of USP Phenazopyridine Hydrochloride RS and 0.001 mg/mL of 2,6-diaminopyridine in *Diluent*

Sample solution: 0.5 mg/mL of Phenazopyridine Hydrochloride in *Diluent*

Chromatographic system: Proceed as directed in the *Assay* except for the *Detector*.

Detector: UV 240 nm

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5 for the phenazopyridine peak, *Standard solution*

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Relative standard deviation: NMT 3.0% for the phenazopyridine peak, *Standard solution*

Signal-to-noise ratio: NLT 30 for the phenazopyridine peak, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 2,6-diaminopyridine in the portion of Phenazopyridine Hydrochloride taken:

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

r_U = peak response of 2,6-diaminopyridine from the *Sample solution*

r_S = peak response of 2,6-diaminopyridine from the *Standard solution*

C_S = concentration of 2,6-diaminopyridine in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Phenazopyridine Hydrochloride taken:

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

r_U = peak response of each individual unspecified impurity from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 2*. Disregard any impurity peaks less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
2,6-Diaminopyridine	0.37	0.2
Phenazopyridine	1.00	—
Individual unspecified impurity	—	0.10
Total impurities	—	2.0

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

USP Phenazopyridine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PHENAZOPYRIDINE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(2)

Current DocID: GUID-CF707DD1-7E1D-4DEE-8028-B0E7EF06E11A_4_en-US
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