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Phenazopyridine Hydrochloride Tablets

DEFINITION

Phenazopyridine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$).

IDENTIFICATION

• **A.** The UV spectrum of the phenazopyridine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

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

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
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 stock solution: Nominally 0.3 mg/mL of phenazopyridine hydrochloride from NLT 20 finely powdered Tablets in *Diluent*, prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add *Diluent* equivalent to 75% of the flask volume and sonicate for 15 min. Allow the solution to cool to room temperature, dilute with *Diluent* to volume, and centrifuge.

Sample solution: Nominally equivalent to 0.03 mg/mL of phenazopyridine hydrochloride in *Diluent* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification A*, use a diode array detector in the range of 200–600 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 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$) in the portion of Tablets 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 = nominal concentration of phenazopyridine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: USP Phenazopyridine Hydrochloride RS in *Medium*

Sample solution: Filter portions of the solution under test and suitably dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 422 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$) dissolved by using UV absorption from the *Sample solution* in comparison with the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of phenazopyridine hydrochloride ($C_{11}H_{11}N_5 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

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

Sensitivity solution: 0.25 µg/mL of USP Phenazopyridine Hydrochloride RS in *Diluent*

Standard solution: 0.001 mg/mL of USP Phenazopyridine Hydrochloride RS in *Diluent*

Sample solution: Nominally 0.5 mg/mL of phenazopyridine hydrochloride from NLT 20 finely powdered Tablets in *Diluent*, prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add *Diluent* equivalent to 60% of the flask volume and sonicate for 15 min. Allow the solution to cool to room temperature and dilute with *Diluent* to volume. Centrifuge the solution and dilute the supernatant with *Diluent* to obtain 0.5 mg/mL of phenazopyridine hydrochloride.

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*

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 any individual unspecified impurity in the portion of the Tablets 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 = nominal 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[a]	0.37	—
Phenazopyridine	1.00	—
Individual unspecified impurity	—	0.2
Total impurities	—	2.0

[a] For identification only. These are process impurities monitored in the drug substance and are not included in the total impurities.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.
- **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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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