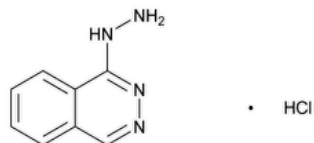


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Hydralazine Hydrochloride



$C_8H_8N_4 \cdot HCl$ 196.64

Phthalazine, 1-hydrazino-, monohydrochloride;

1-Hydrazinophthalazine monohydrochloride CAS RN®: 304-20-1; UNII: FD171B778Y.

DEFINITION

Hydralazine Hydrochloride contains NLT 98.0% and NMT 102.0% of hydralazine hydrochloride ($C_8H_8N_4 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)
Sample solution: 0.25 mg/mL of Hydralazine Hydrochloride in [water](#)
Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Mobile phase: Dissolve 1.44 g of [sodium dodecyl sulfate](#) and 0.75 g of [tetrabutylammonium bromide](#) in 770 mL of [water](#), and add 230 mL of [acetonitrile](#). Adjust with 0.1 N [sulfuric acid](#) to a pH of 3.0.

Diluent: 0.1 N [acetic acid](#)

System suitability stock solution: 0.25 mg/mL of [USP Hydralazine Hydrochloride RS](#) and 0.05 mg/mL of [USP Phthalazine RS](#) in *Diluent*

System suitability solution: 25 µg/mL of [USP Hydralazine Hydrochloride RS](#) and 5 µg/mL of [USP Phthalazine RS](#) in *Diluent* from the *System suitability stock solution*

Standard stock solution: 0.4 mg/mL of [USP Hydralazine Hydrochloride RS](#) in *Diluent*

Standard solution: 40 µg/mL of [USP Hydralazine Hydrochloride RS](#) in *Diluent* from the *Standard stock solution*

Sample stock solution: 0.4 mg/mL of Hydralazine Hydrochloride in *Diluent*

Sample solution: 40 µg/mL of Hydralazine Hydrochloride in *Diluent* prepared as follows. Transfer a suitable amount of the *Sample stock solution* to a suitable volumetric flask. Dilute with *Diluent* to volume and filter, discarding the first 10 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4.0-mm × 25-cm; 10-µm packing L10

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for phthalazine and hydralazine hydrochloride are 0.65 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between the phthalazine and hydralazine peaks, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydralazine hydrochloride ($C_8H_8N_4 \cdot HCl$) in the portion of Hydralazine Hydrochloride taken:

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

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

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

C_S = concentration of [USP Hydralazine Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Hydralazine Hydrochloride in the *Sample solution* (µg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Mobile phase, Diluent, and System suitability solution: Prepare as directed in the Assay.

Standard solution: 0.001 mg/mL of [USP Hydralazine Hydrochloride RS](#) in *Diluent*. Sonication may be necessary for complete dissolution.

Sample solution: 0.5 mg/mL of Hydralazine Hydrochloride in *Diluent* prepared as follows. Transfer a suitable amount of Hydralazine Hydrochloride to a suitable volumetric flask. Add *Diluent* to fill about 60% of the total volume, and sonicate to dissolve. Cool, and dilute with *Diluent* to volume.

Chromatographic system: Proceed as directed in the Assay, except for *Injection volume*.

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 4.0 between the phthalazine and hydralazine peaks, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Hydralazine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

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

C_S = concentration of [USP Hydralazine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
1-Phthalazinone	0.55	2.3	0.15
2-Formyl benzoic acid	0.60	1.1	0.15



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