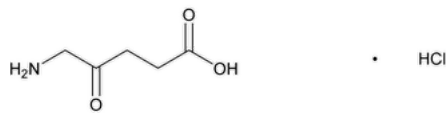


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Aminolevulinic Acid Hydrochloride



$C_5H_9NO_3 \cdot HCl$ 167.59
5-Aminolevulinic acid hydrochloride;
5-Amino-4-oxopentanoic acid hydrochloride CAS RN®: 5451-09-2.

DEFINITION

Aminolevulinic Acid Hydrochloride contains NLT 98.0% and NMT 102.0% of aminolevulinic acid hydrochloride ($C_5H_9NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197A or 197K ▲](#) (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, Chloride \(191\)](#): Meets the requirements

ASSAY

• **PROCEDURE**

Solution A: Water adjusted with 2 M sulfuric acid to a pH of 2.2

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Methanol (%)
0	95	5
2	95	5
6	60	40
8	60	40
9	95	5
23	95	5

Diluent: Methanol and *Solution A* (1:3)

Standard solution: 4 mg/mL of [USP Aminolevulinic Acid Hydrochloride RS](#) in *Diluent*

Sample solution: 4 mg/mL of Aminolevulinic Acid Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 2.1-mm × 10-cm; 1.7-μm packing L1

Flow rate: 0.4 mL/min

Injection volume: 5 μL

System suitability

Sample: *Standard solution*

Suitability requirements**Tailing factor:** NMT 1.6**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of aminolevulinic acid hydrochloride ($C_5H_9NO_3 \cdot HCl$) in the portion of Aminolevulinic Acid 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 Aminolevulinic Acid Hydrochloride RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Aminolevulinic Acid Hydrochloride in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%• **ORGANIC IMPURITIES****Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.**Standard solution:** 0.04 mg/mL each of [USP Aminolevulinic Acid Hydrochloride RS](#), [USP Aminolevulinic Acid Related Compound A RS](#), and [USP Aminolevulinic Acid Related Compound B RS](#) in *Diluent***Sample solution:** 40 mg/mL of Aminolevulinic Acid Hydrochloride in *Diluent***System suitability****Sample:** *Standard solution***Suitability requirements****Relative standard deviation:** NMT 10%**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of aminolevulinic acid related compound A or aminolevulinic acid related compound B in the portion of Aminolevulinic Acid Hydrochloride taken:

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

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of the corresponding USP Reference Standard from the *Standard solution* C_S = concentration of the corresponding USP Reference Standard in the *Standard solution* (mg/mL) C_U = concentration of Aminolevulinic Acid Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity eluting before aminolevulinic acid related compound A in the portion of Aminolevulinic Acid Hydrochloride taken:

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

 r_U = peak response of any unspecified impurity eluting before aminolevulinic acid related compound A from the *Sample solution* r_S = peak response of aminolevulinic acid from the *Standard solution* C_S = concentration of [USP Aminolevulinic Acid Hydrochloride RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Aminolevulinic Acid Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity eluting after aminolevulinic acid related compound A in the portion of Aminolevulinic Acid Hydrochloride taken:

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

 r_U = peak response of any unspecified impurity eluting after aminolevulinic acid related compound A from the *Sample solution* r_S = peak response of aminolevulinic acid related compound A from the *Standard solution*