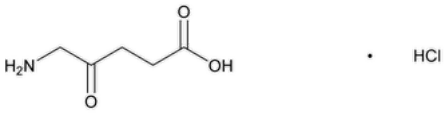
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-56619137-5947-4386-961B-232DEBAB580A_2_en-US
DOI: https://doi.org/10.31003/USPNF_M3032_02_01
DOI Ref: dwk4y

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*

C_S = concentration of USP Aminolevulinic Acid Related Compound A RS in the *Standard solution* (mg/mL)

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

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

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminolevulinic acid	1.0	—
Aminolevulinic acid related compound A	7.8	0.15
Aminolevulinic acid related compound B	12.0	0.15
Any individual unspecified impurity	—	0.10
Total impurities	—	0.5

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: 10 mg/mL in carbon dioxide–free water

  Acceptance criteria: 2.5–2.9

- **Loss on Drying** ⟨731⟩

  Sample: 1 g

  Analysis: Dry the *Sample* over phosphorous pentoxide under vacuum at 100°–105° for 5 h.

  Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store at room temperature.
- **USP Reference Standards** ⟨11⟩

USP Aminolevulinic Acid Hydrochloride RS

USP Aminolevulinic Acid Related Compound A RS

3,3′-(Pyrazine-2,5-diyl)dipropionic acid.

$C_{10}H_{12}N_2O_4$ 224.22

USP Aminolevulinic Acid Related Compound B RS

Methyl 5-(1,3-dioxoisoindolin-2-yl)-4-oxopentanoate.

$C_{14}H_{13}NO_5$ 275.26

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

Topic/Question	Contact	Expert Committee
AMINOLEVULINIC ACID HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(2)

Current DocID: GUID-56619137-5947-4386-961B-232DEBAB580A_2_en-US

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