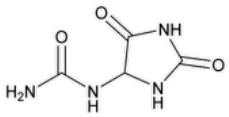
Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-D7232C12-2AB8-4E04-9999-D9F6026459C0_3_en-US
DOI: https://doi.org/10.31003/USPNF_M1400_03_01
DOI Ref: fq34a

Allantoin



$C_4H_6N_4O_3$ 158.12

Urea, (2,5-dioxo-4-imidazolidinyl)-;

Allantoin CAS RN®: 97-59-6; UNII: 344S277G0Z.

DEFINITION

Allantoin contains NLT 98.5% and NMT 101.0% of $C_4H_6N_4O_3$.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B. Thin-Layer Chromatographic Identification Test ⟨201⟩:** The R_F value of the principal spot from *Sample solution B* corresponds to that from *Standard solution A*, as described in the test for *Organic Impurities*.

ASSAY

• **Procedure**

Sample: 120 mg

Analysis: Transfer the *Sample* to a 100-mL beaker, dissolve by stirring in 40 mL of water, and titrate with 0.1 M sodium hydroxide. Use a suitable electrode system (see *Titrimetry ⟨541⟩*). Each mL of 0.1 M sodium hydroxide is equivalent to 15.81 mg of $C_4H_6N_4O_3$.

Acceptance criteria: 98.5%–101.0%

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Adsorbent: Cellulose

Diluent: Methanol and water (1:1)

Urea stock solution: 1 mg/mL of USP Urea RS in water

Standard solution A: 1 mg/mL of USP Allantoin RS in *Diluent*

Standard solution B: 0.1 mg/mL of USP Urea RS in methanol, from *Urea stock solution*

Standard solution C: *Standard solution A* and *Standard solution B* (1:1)

Sample solution A: Transfer 0.10 g of Allantoin to a 10-mL volumetric flask, add 5 mL of water, dissolve by heating, and allow to cool. Dilute with methanol to volume. [Note—Use immediately after preparation.]

Sample solution B: Transfer 1 mL of *Sample solution A* to a 10-mL volumetric flask, and dilute with *Diluent* to volume.

Spray reagent: 5 mg/mL of *p*-dimethylaminobenzaldehyde in a mixture of methanol and hydrochloric acid (3:1)

Application volume

Standard solution A: 5 µL

Standard solution B: 5 µL

Standard solution C: 5 µL

Sample solution A: 10 µL

Sample solution B: 5 µL

Developing solvent system: Butyl alcohol, glacial acetic acid, and water (60:15:25)

Analysis: Proceed as directed for *Chromatography ⟨621⟩, Thin-Layer Chromatography*. Develop the chromatogram until the solvent front has moved about 10 cm. Spray the plate with *Spray reagent*, dry in a current of hot air, and after 30 min examine under visible light.

Acceptance criteria: Any spot from *Sample solution A*, except for the principal spot, is not more intense than the spot from *Standard solution B* (NMT 0.5%). The test is not valid unless the principal spots from *Standard solution C* are clearly separated.

SPECIFIC TESTS

- **Acidity or Alkalinity**

  Sample solution: 5 mg/mL in carbon dioxide-free water

  Analysis: To 5 mL of the *Sample solution* add 5 mL of water, 0.1 mL of methyl red TS, and 0.2 mL of 0.01 M sodium hydroxide.

  Acceptance criteria: A yellow color is observed. The solution turns red upon the addition of 0.4 mL of 0.01 M hydrochloric acid.

- **Loss on Drying ⟨731⟩:** Dry a sample at 105° to constant weight: it loses NMT 0.1% of its weight.

- **Reducing Substances**

  Sample solution: 1.0 g of Allantoin in 10 mL of water. Shake for 2 min, and filter.

  Analysis: To the *Sample solution* add 1.5 mL of 0.02 M potassium permanganate.

  Acceptance criteria: The solution remains violet for at least 10 min.

ADDITIONAL REQUIREMENTS

- **USP Reference Standards ⟨11⟩**

  USP Allantoin RS

  USP Urea RS

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

Topic/Question	Contact	Expert Committee
ALLANTOIN	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-D7232C12-2AB8-4E04-9999-D9F6026459C0_3_en-US

DOI: https://doi.org/10.31003/USPNF_M1400_03_01

DOI ref: fq34a