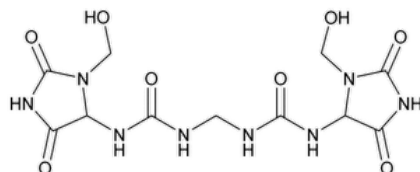


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: NF Monographs
 DocId: GUID-78401127-53B2-494C-8906-867ABD5CE907_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M40018_04_01
 DOI Ref: 97k7p

© 2025 USPC
 Do not distribute

Imidurea



$C_{11}H_{16}N_8O_8$ 388.29

N,N'-Methylenebis[*N'*-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]urea];

1,1'-Methylenebis[3-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]urea] CAS RN[®]: 39236-46-9.

DEFINITION

Imidurea contains NLT 26.0% and NMT 28.0% of nitrogen (N), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: **197K** ▲ (CN 1-MAY-2020)

OTHER COMPONENTS

• NITROGEN CONTENT

Sample: 150 mg

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Place the *Sample* in a 500-mL Kjeldahl flask, and add 8.0 g of anhydrous sodium sulfate, 0.5 g of anhydrous cupric sulfate, 0.1 g of yellow mercuric oxide, and 11 mL of sulfuric acid. Incline the flask at an angle of 45°, and gently heat the mixture, keeping the temperature below the boiling point until frothing has ceased. Increase the heat until the acid boils briskly, and continue the heating until the solution has become clear green in color or practically colorless for 30 min. Allow to cool, cautiously add 225 mL of water, mix the contents of the flask, and again cool. Add cautiously 1.0 g of zinc metal dust, 2.0 g of sodium thiosulfate, and 18.0 g of sodium hydroxide pellets, and without delay connect the flask to a Kjeldahl connecting bulb (trap), previously attached to a condenser, the delivery tube of which dips beneath the surface of 50 mL of boric acid solution (40 mg/mL) in a 300-mL conical flask. Mix the contents of the Kjeldahl flask by gentle rotation, and distill 125 mL into the receiver. Add NLT 3 drops of methyl red–methylene blue TS to the contents of the receiving vessel, and determine the ammonia by titration with *Titrant*. Perform a blank determination, and make any necessary correction.

Calculate the percentage of nitrogen in the portion of Imidurea taken. Each mL of 0.1 N hydrochloric acid is equivalent to 1.401 mg of nitrogen.

Acceptance criteria: 26.0%–28.0% of nitrogen (N) on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 3.0%

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: 6.0–7.5

- [Loss on Drying \(731\)](#).

Analysis: Dry under vacuum over phosphorus pentoxide for 48 h.

Acceptance criteria: NMT 3.0%

- **COLOR AND CLARITY OF SOLUTION**

Sample: 3.0 g

Analysis: Dissolve the *Sample* in 7.0 mL of water in a test tube.

Acceptance criteria: The solution is clear and colorless.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Imidurea RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
IMIDUREA	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: [GUID-78401127-53B2-494C-8906-867ABD5CE907_4_en-US](#)

DOI: https://doi.org/10.31003/USPNE_M40018_04_01

DOI ref: [97k7p](#)