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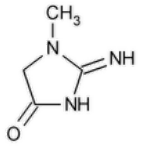
Creatinine



$C_4H_7N_3O$ 113.12

DEFINITION

Creatinine contains NLT 98.5% and NMT 102.0% of $C_4H_7N_3O$, as Creatinine, calculated on the dried basis.

IDENTIFICATION

Change to read:

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

ASSAY

• **Procedure**

Sample: 40 mg of Creatinine

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Indicator electrode: Glass

Reference electrode: Silver–silver chloride

Reference electrode solution: Saturated lithium perchlorate and silver chloride in glacial acetic acid

Analysis: Dissolve the *Sample* in 10 mL of glacial acetic acid. Titrate the *Sample* with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction.

Calculate the percentage of creatinine ($C_4H_7N_3O$) in the *Sample* taken:

$$\text{Result} = [(V - B) \times N \times F \times 100]/W$$

V = volume of the *Titrant* consumed by the *Sample* (mL)

B = volume of the *Titrant* consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 113.12 mg/mEq

W = weight of the *Sample* (mg)

Acceptance criteria: 98.5%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩:** Dry a sample at 105° for 3 h: it loses NMT 3.0% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**
USP Creatinine RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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