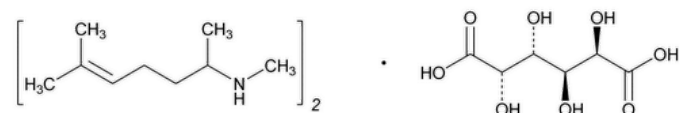


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Isometheptene Mucate



$(C_9H_{19}N)_2 \cdot C_6H_{10}O_8$ 492.65

Isometheptene, galactarate (2:1) (salt);

6-Methylamino-2-methylheptene, tetrahydroxyadipic acid (2:1) (salt) CAS RN®: 7492-31-1; UNII: 80120FDS6P.

DEFINITION

Isometheptene Mucate contains NLT 99.0% and NMT 103.0% of isometheptene mucate $[(C_9H_{19}N)_2 \cdot C_6H_{10}O_8]$, calculated on the dried basis.

IDENTIFICATION

Change to read:

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

ASSAY

• PROCEDURE

Sample: 500 mg of Isometheptene Mucate

Titrimetric system

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

Mode: Residual titration

Titrant: 0.1 N bromine VS

Back-titrant: 0.1 N sodium thiosulfate VS

Endpoint detection: Visual

Analysis:

Sample: *Sample*

Transfer the *Sample* to a 125-mL conical flask. Add 25 mL of water, and swirl to dissolve. Add 45.0 mL of *Titrant*. Attach a 30-mL separator to the conical flask, and evacuate the system. Stir with a magnetic stirrer for 1 h. Equilibrate the system to atmospheric pressure. Add 5 mL of hydrochloric acid to the separator, and allow 4 mL of it to enter the conical flask. Add 10 mL of potassium iodide TS to the separator, and allow the contents to pass into the conical flask.

Immediately titrate the liberated iodine with *Back-titrant*, adding 3 mL of starch TS as the endpoint is approached. Perform a blank titration. Each mL of 0.1 N sodium thiosulfate is equivalent to 12.32 mg of isometheptene mucate $[(C_9H_{19}N)_2 \cdot C_6H_{10}O_8]$.

Acceptance criteria: 99.0%–103.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

SPECIFIC TESTS

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

Sample solution: A solution of Isometheptene Mucate in water (1 in 20)

Acceptance criteria: 6.0–7.5

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 60° for 18 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

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

[USP Isometheptene Mucate RS](#)

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

Topic/Question	Contact	Expert Committee
ISOMETHEPTENE MUCATE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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