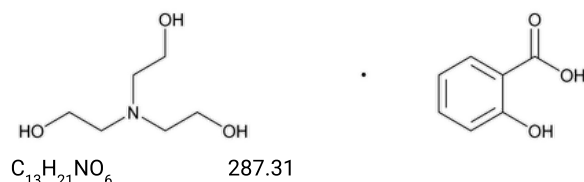


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Trolamine Salicylate



Triethanolamine salicylate CAS RN®: 2174-16-5; UNII: H8O4040BHD.

DEFINITION

Trolamine Salicylate is a compounded mixture of Trolamine and Salicylic Acid in propylene glycol. It contains NLT 95.0% and NMT 105.0% of the labeled amount of trolamine salicylate ($C_{13}H_{27}NO_3$).

IDENTIFICATION

Change to read:

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

Sample solution: 1 mg/mL. The *Sample solution* and the *Standard solution* contain the equivalent of 1 mg/mL of salicylic acid in *Medium*.

Medium: Methanol

Cell: 0.1 cm

Acceptance criteria: Absorptivities do not differ by more than 1.0%.

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and water (3:7)

Standard solution: 48 µg/mL of [USP Salicylic Acid RS](#) in methanol

Sample solution: Transfer an amount equivalent to 300 mg of salicylic acid from a portion of Trolamine Salicylate, into a 250-mL volumetric flask, and dilute with methanol to volume. Transfer 2 mL of this solution to a 50-mL volumetric flask, and dilute with methanol to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 308 nm

Column: 4.0-mm × 12.5-cm; packing L7

Flow rate: 1 mL/min

Column temperature: 30°

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 8000 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trolamine salicylate ($C_{13}H_{27}NO_3$) in the portion of Trolamine Salicylate taken:

$$\text{Result} = (r_U/r_S) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• LIMIT OF FREE SALICYLIC ACID

Standard solution 1: 0.2 mg/mL of [USP Salicylic Acid RS](#) in xylene

Standard solution 2: 0.1 mg/mL of [USP Salicylic Acid RS](#) from *Standard solution 1* in xylene

Sample solution: 0.96 mg/mL of Trolamine Salicylate in xylene

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 μ L

Developing solvent system: Toluene, acetone, and glacial acetic acid (17:8:0.2)

Analysis: Proceed as directed in the chapter. Develop in a chamber previously equilibrated with *Developing solvent system*. Examine the plate under long-wavelength UV light.

Acceptance criteria: NMT 0.02%; any secondary spot of the *Sample solution* is not greater in size or intensity than the spot of *Standard solution 1*.

• OTHER ORGANIC IMPURITIES

Mobile phase, Standard solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Sample solution: Use the *Sample solution* from the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Trolamine Salicylate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria: NMT 1.0% of any individual impurity and NMT 2.0% of total impurities are found.

SPECIFIC TESTS

• **SPECIFIC GRAVITY (841):** 1.190–1.220

• **REFRACTIVE INDEX (831):** 1.505–1.535 at 20°

• **pH (791).**

Solution: 50 mg/mL

Acceptance criteria: 6.5–7.5

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers in a cool place.

• **USP REFERENCE STANDARDS (11).**

[USP Salicylic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
TROLAMINE SALICYLATE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Most Recently Appeared In:

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