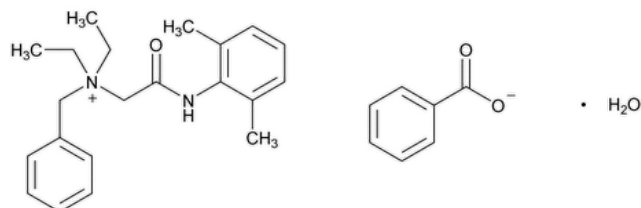


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Denatonium Benzoate



$C_{28}H_{34}N_2O_3 \cdot H_2O$ 464.60

$C_{28}H_{34}N_2O_3$ 446.59

Benzenemethanaminium, *N*-[2-[(2,6-dimethylphenyl)amino]-2-oxoethyl]-*N,N*-diethyl-, benzoate, monohydrate;

Benzyl-diethyl-[(2,6-xylilcarbonyl)methyl]ammonium benzoate monohydrate CAS RN®: 86398-53-0.

Anhydrous CAS RN®: 3734-33-6.

DEFINITION

Denatonium Benzoate, dried at 105° for 2 h, contains one molecule of water of hydration or is anhydrous. When dried at 105° for 2 h, it contains NLT 99.5% and NMT 101.0% of denatonium benzoate ($C_{28}H_{34}N_2O_3$).

IDENTIFICATION

Change to read:

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

Change to read:

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

Analytical wavelength: 263 nm

Sample solution: 100 µg/mL

Medium: Water

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

- C.

Sample: 150 mg

Analysis: Dissolve the *Sample* in 10 mL of water, and add 15 mL of trinitrophenol TS.

Acceptance criteria: A yellow precipitate is formed.

- D.

Sample: 100 mg

Analysis: Dissolve the *Sample* in 10 mL of water, and add 20 mL of 2 N sulfuric acid and 15 mL of ammonium reineckate TS. Mix, filter through a sintered-glass crucible using gentle suction, and wash thoroughly with water. Remove as much water as possible with suction, and then dry in an oven at 105° for 1 h.

Acceptance criteria: The denatonium reineckate so obtained melts at about 170° (see [Melting Range or Temperature \(741\)](#)).

ASSAY

• PROCEDURE

Sample: 900 mg, previously dried

Blank: 50 mL of glacial acetic acid

Titrimetric system

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

Mode: Direct titration**Titrant:** 0.1 N perchloric acid VS**Endpoint detection:** Visual

Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid, and add 1 drop of crystal violet TS. Titrate with *Titrant* to a green endpoint. Perform a blank determination, and make any necessary correction.

Calculate the percentage of denatonium benzoate ($C_{28}H_{34}N_2O_3$) in the portion of sample taken:

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

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

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

F = equivalency factor, 446.6 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 99.5%–101.0% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.1%

• **CHLORIDE AND SULFATE, Chloride** (221).

Standard solution: 0.10 mL of 0.020 N hydrochloric acid

Sample solution: Dissolve 350 mg in 9 mL of water, add 1 mL of nitric acid, and filter.

Analysis: Use 1.0 mL of the *Sample solution*, and proceed as directed in the chapter

Acceptance criteria: 0.2%; the *Sample solution* shows no more chloride than the *Standard solution*.

SPECIFIC TESTS

• **MELTING RANGE OR TEMPERATURE** (741): 163°–170°, on a dried specimen

• **pH** (791).

Sample solution: 30 mg/mL

Acceptance criteria: 6.5–7.5

• **LOSS ON DRYING** (731).

Analysis: Dry at 105° for 2 h.

Acceptance criteria

Monohydrate form: 3.5%–4.5%

Anhydrous form: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

• **LABELING:** Label it to indicate whether it is hydrous or anhydrous.

• **USP REFERENCE STANDARDS** (11).

[USP Denatonium Benzoate RS](#)

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

Topic/Question	Contact	Expert Committee
DENATONIUM BENZOATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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