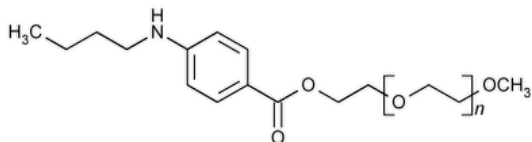


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-4A0837F7-52F4-4C3D-81FC-D31F1CD42D8A_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M8250_04_01
 DOI Ref: 7z8dm

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Benzonatate



$C_{30}H_{53}NO_{11}$ (av.) 603.74 (average)

Benzoic acid, 4-(butylamino)-, 2,5,8,11,14,17,20,23,26-nonaoxaocacos-28-yl ester.

2,5,8,11,14,17,20,23,26-Nonaoxaocacosan-28-yl *p*-(butylamino)benzoate CAS RN®: 104-31-4; UNII: 5P4DHS6ENR.

» Benzonatate contains not less than 95.0 percent and not more than 105.0 percent of $C_{30}H_{53}NO_{11}$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11)—

[USP Benzonatate RS](#)

Identification—

Change to read:

A: [▲Spectroscopic Identification Tests \(197\), Infrared Spectroscopy: 197F](#)▲ (CN 1-May-2020) ·

Change to read:

B: [▲Spectroscopic Identification Tests \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-May-2020) —

Solution: 15 µg per mL.

Medium: water.

REFRACTIVE INDEX (831): between 1.509 and 1.511 at 20°.

WATER DETERMINATION, Method I (921): not more than 0.3%.

RESIDUE ON IGNITION (281): not more than 0.1%.

CHLORIDE (221)—Mix 20 mL of a solution (1 in 10) with 20 mL of water and 1 mL of nitric acid, shake for 1 hour, and allow to stand for 1 hour. Pass through a filter having a porosity of 0.2 µm, and to the filtrate add 1 mL of silver nitrate TS. Dilute with water to 50 mL, mix, and allow to stand protected from light for 10 minutes: the turbidity does not exceed that produced by 0.10 mL of 0.020 N hydrochloric acid (0.0035%).

SULFATE (221)—Mix 5 mL of a solution (1 in 20) with 5 mL of water and 1 mL of 3 N hydrochloric acid, shake for 1 hour, and allow to stand for 1 hour. Pass through a filter having a porosity of 0.2 µm, and to the filtrate add 1 mL of barium chloride TS. Mix, and allow to stand for 10 minutes: the turbidity does not exceed that produced by 0.10 mL of 0.020 N sulfuric acid (0.04%).

Assay—Weigh accurately about 5 g of Benzonatate, and reflux with 25.0 mL of 0.5 N sodium hydroxide VS for 1 hour. Cool, add 25 mL of water and 10 drops of bromothymol blue TS, and titrate the excess alkali with 0.5 N hydrochloric acid VS. Perform a blank determination (see

[Residual Titrations](#) under [Titrimetry \(541\)](#)). Each mL of 0.5 N sodium hydroxide is equivalent to 301.5 mg of $C_{30}H_{53}NO_{11}$.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 44(1)

Current DocID: GUID-4A0837F7-52F4-4C3D-81FC-D31F1CD42D8A_4_en-US

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