Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-593E9240-40D9-4FDA-A6AA-4D338B610083_3_en-US
DOI: https://doi.org/10.31003/USPNF_M27920_03_01
DOI Ref: iz7mn

Docusate Sodium

$C_{20}H_{37}NaO_7S$ 444.56

Butanedioic acid, sulfo-, 1,4-bis(2-ethylhexyl) ester, sodium salt;

Sodium 1,4-bis(2-ethylhexyl) sulfosuccinate CAS RN®: 577-11-7.

DEFINITION

Docusate Sodium contains NLT 99.0% and NMT 100.5% of $C_{20}H_{37}NaO_7S$, calculated on the anhydrous basis.

IDENTIFICATION

• **Procedure**

Sample: Place a small piece of Docusate Sodium on a salt plate, add one drop of acetone, and promptly cover with another salt plate. Rub the plates together to dissolve the specimen, slide the plates apart, and allow the acetone to evaporate.

Acceptance criteria: The IR absorption spectrum of the film exhibits maxima only at the same wavelengths as that of a similar preparation of USP Docusate Sodium RS.

ASSAY

• **Procedure**

Solution A: 2.5 g/L of tetra-*n*-butylammonium iodide in water

Solution B: A mixture of 100 g/L of anhydrous sodium sulfate and 10 g/L of sodium carbonate in water

Sample: 50 mg

Analysis: Dissolve the *Sample* in 50 mL of chloroform in a glass-stoppered, 250-mL conical flask. Add 50 mL of *Solution B* and 500 µL of bromophenol blue TS. Titrate with *Solution A* until 1 mL from the endpoint, and shake the stoppered flask vigorously for 2 min. Continue the titration in two-drop increments, shaking vigorously for 10 s after each addition, and then allow the flask to stand 10 s. Continue the titration until the chloroform layer just assumes a blue color. Each mL of *Solution A* is equivalent to 3.009 mg of $C_{20}H_{37}NaO_7S$.

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩:** Between 15.5% and 16.5%, calculated on the anhydrous basis

Procedure: Transfer about 1 g, accurately weighed, to a tared crucible, ignite until thoroughly charred, and cool. Moisten the ash with 1 mL of sulfuric acid, and complete the ignition by heating at 800 ± 25° for 15-min periods to constant weight.

Organic Impurities

• **Procedure: Limit of Bis(2-Ethylhexyl) Maleate**

Mobile phase: Alcohol and water (78:22), filtered and degassed

Standard solution: 80 µg/mL of USP Bis(2-ethylhexyl) Maleate RS in alcohol

Sample solution: 20 mg/mL of Docusate Sodium in alcohol. [Note—If necessary, warm the mixture using the steam bath to achieve a complete dissolution.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 3-cm; 3.5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection size: 3 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bis(2-ethylhexyl) maleate in the portion of Docusate Sodium taken:

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

r_U = peak response of bis(2-ethylhexyl) maleate from the *Sample solution*

r_S = peak response of bis(2-ethylhexyl) maleate from the *Standard solution*

C_S = concentration of USP Bis(2-ethylhexyl) Maleate RS in the *Standard solution* (mg/mL)

C_U = concentration of Docusate Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.4%

SPECIFIC TESTS

- **Water Determination, *Method I* ⟨921⟩:** NMT 2.0%
- **Clarity of Solution**

Sample solution: 25 g in 100 mL of alcohol

Acceptance criteria: The *Sample solution* does not develop a haze within 24 h.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards ⟨11⟩**

USP Bis(2-ethylhexyl) Maleate RS	$C_{20}H_{36}O_4$	340.51
USP Docusate Sodium RS		

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

Topic/Question	Contact	Expert Committee
DOCUSATE SODIUM	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(5)

Current DocID: GUID-593E9240-40D9-4FDA-A6AA-4D338B610083_3_en-US
Previous DocID: GUID-593E9240-40D9-4FDA-A6AA-4D338B610083_1_en-US
DOI: https://doi.org/10.31003/USPNF_M27920_03_01
DOI ref: iz7mn