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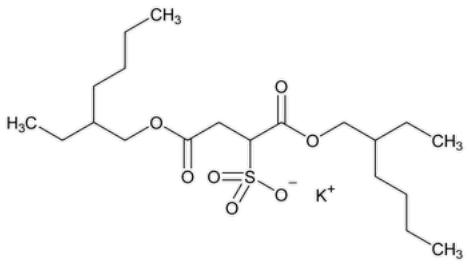
Docusate Potassium



$C_{20}H_{37}KO_7S$ 460.67

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

Potassium 1,4-bis(2-ethylhexyl) sulfosuccinate CAS RN®: 7491-09-0; UNII: CIK9F54ZHR.

DEFINITION

Docusate Potassium contains NLT 95.0% and NMT 100.5% of docusate potassium ($C_{20}H_{37}KO_7S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197F**▲ (CN 1-May-2020)

Sample: Place a small piece of Docusate Potassium on a salt plate, add 1 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: Meets the requirements

• **B.** The sample imparts a violet color to a nonluminous flame. Because the presence of small quantities of sodium masks the color, screen out the yellow color produced by sodium by viewing through a blue filter that blocks emission at 589 nm (sodium) but is transparent to emission at 404 nm (potassium). [Note—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

ASSAY

• **Procedure**

Solution A: 2.500 g/L of tetra-*n*-butylammonium iodide in water

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

Sample: 100 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 2-drop increments, shaking vigorously for 10 s after each addition, and then allow the flask to stand for 10 s. Continue the titration until the chloroform layer just assumes a blue color. Each mL of *Solution A* is equivalent to 3.118 mg of docusate potassium ($C_{20}H_{37}KO_7S$).

Acceptance criteria: 95.0%–100.5% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** 18.0%–20.0% on the dried basis

• **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 Potassium in alcohol. [Note—If necessary, warm the mixture by 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 volume: 3 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bis(2-ethylhexyl) maleate in the portion of Docusate Potassium 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 Potassium in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.4%

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry in a glass container at 105° for 4 h.

Acceptance criteria: NMT 3.0%

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 Potassium RS		

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

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

Chromatographic Database Information: Chromatographic Database

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