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Docusate Sodium Syrup

DEFINITION
Docusate Sodium Syrup contains NLT 90.0% and NMT 110.0% of the labeled amount of docusate sodium ($C_{20}H_{37}NaO_7S$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: 2 mg/mL of USP Docusate Sodium RS in isopropyl alcohol

Sample solution: Dilute a volume of Syrup, equivalent to about 10 mg of docusate sodium, with isopropyl alcohol to obtain a preparation containing about 2 mg/mL, and mix. Use the upper layer of this preparation.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 50 µL. [Note—Apply with the aid of a stream of nitrogen.]

Developing solvent system: Ethyl acetate, alcohol, water, and ammonium hydroxide (25:10:20:1). [Note—This is a two-phase system.]

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the spots to dry, and develop the chromatogram in the *Developing solvent system*, until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Expose the plate to iodine vapors in a closed chamber for about 30 min, and locate the spots.

Acceptance criteria: The *Sample solution* produces a spot at the same R_F value and of approximately the same size as that obtained from the *Standard solution*.

ASSAY

• **Procedure**

Standard stock solution: 1.0 mg/mL of USP Docusate Sodium RS, first dissolved in alcohol using about 2.5% of the final volume, and then diluted with water to volume. This solution contains 1 mg/mL of USP Docusate Sodium RS.

Standard solution: 10 µg/mL in water from the *Standard stock solution*

Sample solution: Transfer an accurately measured volume of Syrup, equivalent to about 100 mg of docusate sodium, to a 1000-mL volumetric flask, allowing the pipet to drain for 15 min. Dilute with water to volume, and mix. Transfer 10.0 mL of the solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: Vis

Analytical wavelength: 650 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Transfer 20.0 mL each of the *Standard solution* and the *Sample solution* to two individual separators. Place 20 mL of water in a third separator (*Blank solution*). To each separator add 5 drops of hydrochloric acid, mix by swirling, add 1.0 mL of methylene blue solution (1 in 1000), and mix by swirling. To each separator add 20.0 mL of chloroform, and shake vigorously for 5 min. Wash each chloroform solution, in clean separators, with 20 mL of water, shaking vigorously for 60 s. Discard the washings, and filter each chloroform solution through a layer of 3 g of anhydrous granular sodium sulfate, supported on glass wool, into a 100-mL volumetric flask, washing each separator with two 10-mL portions of chloroform, and filtering the washings into each flask. Dilute each flask with chloroform to volume. Concomitantly determine the absorbances of the *Standard solution* and the *Sample solution*, using the *Blank solution* to set the instrument.

Calculate the percentage of the labeled amount of docusate sodium ($C_{20}H_{37}NaO_7S$) in the portion of Syrup taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Docusate Sodium RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of docusate sodium in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.5–6.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Docusate Sodium RS

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

Topic/Question	Contact	Expert Committee
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Chromatographic Database Information: Chromatographic Database

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