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Docusate Sodium Capsules

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

IDENTIFICATION
• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Mobile phase: Acetonitrile and 0.01 M tetrabutylammonium dihydrogen phosphate (66:34)

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.1 mg/mL of USP Docusate Sodium RS in *Diluent*. Filter the solution, discarding the first 6 mL of the filtrate.

Sample stock solution: Transfer a number of Capsules, equivalent to 250 mg of docusate sodium, to a 250-mL volumetric flask, and add 50 mL of water. Heat the mixture with occasional swirling until the Capsule shells have ruptured and dissolved. [Note—Take special care to ensure that all of the Capsules have ruptured.] Remove from heat, and add 50 mL of acetonitrile. Allow this solution to cool to room temperature, and dilute with *Diluent* to volume.

Sample solution: Transfer 5.0 mL of the *Sample stock solution* to a 50-mL volumetric flask, dilute with *Diluent* to volume, and filter, discarding the first 6 mL of filtrate.

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 15-cm; packing L1 that has been highly deactivated (carbon loading of 30%)

Flow rate: 1.5 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of anhydrous docusate sodium in the *Standard solution*, as determined from the concentration of USP Docusate Sodium RS corrected for moisture by a titrimetric water determination (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 15 min

Analysis: Place 1 Capsule in each vessel, and allow the Capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the Capsules, and record the time taken for each Capsule shell to rupture.

Tolerances: The requirements are met if all of the Capsules tested rupture in NMT 15 min. If 1 or 2 Capsules rupture in more than 15 min but NMT 30 min, repeat the test on 12 additional Capsules. NMT 2 of the total of 18 Capsules tested rupture in more than 15 min but NMT 30 min.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements for *Content Uniformity* for solid-filled capsules and meet the requirements for *Weight Variation* for solution-filled capsules

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.

• **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
DOCUSATE SODIUM CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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