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Docusate Sodium Solution

DEFINITION

Docusate Sodium Solution contains 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 volume of Solution, equivalent to 100 mg of docusate sodium, to a 100-mL volumetric flask, 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 the 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 Solution 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%

SPECIFIC TESTS

- **pH (791):** 4.5–6.9

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS** (11).
[USP Docusate Sodium RS](#)

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

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Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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