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Docusate Sodium Tablets

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

IDENTIFICATION

Change to read:

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

Sample: Finely divide a suitable number of Tablets, extract with solvent hexane, filter, and evaporate the solvent hexane extract on a steam bath. Use the dry residue.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 7 mM ammonium acetate (1:1)

Standard solution: Dissolve the USP Docusate Sodium RS in alcohol, and dilute with water to obtain a solution containing 1.0 mg/mL of USP Docusate Sodium RS.

Methylparaben solution: 0.15 mg/mL of methylparaben in water

System suitability solution: Mix 0.1 mL of *Methylparaben solution* and 10 mL of *Standard solution*.

Sample solution: Transfer 10 Tablets to a 1-L volumetric flask, add 200 mL of alcohol and 300 mL of water, and shake by mechanical means for NLT 90 min to completely disintegrate the Tablets. Dilute with water to volume, and filter, discarding the first 3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 10-cm; packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 40 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[Note—The relative retention times for methylparaben and docusate are about 0.74 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methylparaben and docusate, *System suitability solution*

Tailing factor: NMT 2.5, *Standard solution*

Relative standard deviation: NMT 1.8%, *Standard solution*

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 Tablets 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 USP Docusate Sodium RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Medium: Proceed as directed in the chapter, except substitute simulated gastric fluid TS for water in the test for *Uncoated Tablets*.

Time: 1 h

Acceptance criteria: Meet the requirements

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed 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
DOCUSATE SODIUM TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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

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