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## Docusate Potassium Capsules

### DEFINITION

Docusate Potassium Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of docusate potassium ( $C_{20}H_{37}KO_7S$ ).

### 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

**Diluent:** Transfer 180 mL of water to a 1000-mL volumetric flask, and dilute with methanol to volume.

**Tetrabutylammonium hydroxide solution:** 250 mg/mL of tetrabutylammonium hydroxide in methanol

**Mobile phase:** Mix 180 mL of water, 6.0 mL of glacial acetic acid, and 8.0 mL of *Tetrabutylammonium hydroxide solution* in a 1000-mL volumetric flask, and dilute with methanol to volume. The water concentration may be varied to meet *System suitability* requirements and to provide a suitable elution time (about 5 min) for docusate potassium.

**Standard solution:** 4 mg/mL of [USP Docusate Sodium RS](#), calculated on the anhydrous basis, in *Diluent*

#### Sample solution

**Solid-filled capsules:** Open and empty into a suitable container the contents of a counted number of Capsules, nominally equivalent to 1000 mg of docusate potassium. Place the Capsule shells in the container, and add 250.0 mL of *Diluent*. Shake by mechanical means for 20 min, and clarify a portion of the mixture by centrifuging. Pass a portion of the clear supernatant through a membrane filter of 0.5- $\mu$ m or finer pore size.

**Solution-filled capsules:** Cut open a counted number of Capsules, nominally equivalent to 2.5 g of docusate potassium, and place the shells and contents in a suitable container. Add 25 mL of methanol, agitate for NLT 2 min, and decant the liquid into a 200-mL volumetric flask. Repeat the addition of methanol, agitation, and decanting NLT four times. Dilute with methanol to volume. Pipet 8 mL of this solution into a 25-mL volumetric flask, add 4.5 mL of water, and dilute with methanol to volume.

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm  $\times$  25-cm; packing L1

**Flow rate:** 1.8 mL/min

**Injection volume:** 100  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Relative standard deviation:** NMT 3.0% for five replicate injections

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of docusate potassium ( $C_{20}H_{37}KO_7S$ ) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

$C_S$  = concentration of anhydrous [USP Docusate Sodium RS](#) in the *Standard solution* (mg/mL)

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

$M_{r1}$  = molecular weight of docusate potassium, 460.67

$M_{r2}$  = molecular weight of docusate sodium, 444.56

**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 of the 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 Potassium RS](#)

[USP Docusate Sodium RS](#)

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

Topic/Question	Contact	Expert Committee
DOCUSATE POTASSIUM CAPSULES	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

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