Edition: BP 2025 (Ph. Eur. 11.6 update)

Docusate Oral Solution

General Notices

Action and use

Stimulant laxative; faecal softener.

DEFINITION

Docusate Oral Solution contains 1.0% w/v of Docusate Sodium in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements.

Content of docusate sodium, $C_{20}H_{37}NaO_7S$

0.95 to 1.05% w/v.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Pass a volume of the oral solution containing 10 mg of docusate sodium, with the aid of vacuum, through a solid phase extraction column of 1 mL capacity and containing 0.1 g of an octadecyl-bonded silica sorbent (a Sep-pak C18 column is suitable) which has been previously washed with 2 mL of *methanol*, followed by 5 mL of *water*. Wash the column with 2 mL of *water*, discarding the aqueous eluate and then elute the docusate sodium with 4 mL of *methanol*, retaining the methanol solution.
(2) 0.25% w/v of *docusate sodium BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel G* (Merck silica gel 60 plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air, expose to iodine vapour and examine in daylight.

MOBILE PHASE

2 volumes of 13.5M *ammonia*, 20 volumes of *ethanol (96%)*, 40 volumes of *water* and 50 volumes of *ethyl acetate*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Pass a weighed quantity of the oral solution containing 10 mg of docusate sodium, with the aid of vacuum, through a solid-phase extraction column of 1 mL capacity and containing 0.1 g of an octadecyl-bonded silica sorbent (a Sep-pak C18 column is suitable) previously washed with 2 mL of *methanol*, followed by 5 mL of *water*. Wash the column with 2 mL of *water*, discarding the aqueous eluate. Elute the docusate sodium with 4 mL of *methanol* and dilute to 20 mL with a mixture of 70 volumes of *acetonitrile* and 30 volumes of *water*.
(2) 0.05% w/v of *docusate sodium BPCRS* in a mixture of 70 volumes of *acetonitrile* and 30 volumes of *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with silica gel with a chemically bonded, strongly basic quaternary ammonium anion-exchange coating (10 µm) (Spherisorb SAX is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 214 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

1.6 volumes of *orthophosphoric acid*, 350 *v*olumes of *water* and 650 volumes of *acetonitrile*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2) the *symmetry factor* of the peak corresponding to docusate sodium is less than 1.5.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral solution, Appendix V G, and calculate the content of $C_{20}H_{37}NaO_7S$, weight in volume, using the declared content of $C_{20}H_{37}NaO_7S$ in *docusate sodium BPCRS*.