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

Docusate Capsules

General Notices

Action and use

Stimulant laxative; faecal softener.

DEFINITION

Docusate Capsules contain a solution of Docusate Sodium in a suitable water miscible vehicle.

The capsules comply with the requirements stated under Capsules and with the following requirements.

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

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Dissolve, by heating on a water bath, a capsule in sufficient *water* to produce a solution containing 1% w/v of docusate sodium. Pass 1 mL of this solution 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 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 (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, dry in air and expose to iodine vapour.

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 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) Add 200 mL of *water* to a number of whole capsules containing 1 g of Docusate Sodium and warm on a water bath until the capsules have dissolved. Add 200 mL of *acetonitrile R1*, shake the mixture thoroughly and cool. Add sufficient of a mixture of equal volumes of *acetonitrile R1* and *water* to produce 1000 mL, mix well and filter to obtain a clear solution (Whatman No. 1 paper followed by a 0.4-µm filter is suitable).
(2) 0.1% w/v of *docusate sodium BPCRS* in a mixture of equal volumes of *acetonitrile R1* and *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Ultracarb ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 214 nm.
(f) Inject 25 µL of each solution.

MOBILE PHASE

30 volumes of 0.005M *tetrabutylammonium dihydrogen orthophosphate* and 70 volumes of *acetonitrile R1*.

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{37}NaO_7S$ in the capsules from the chromatograms obtained using the declared content of $C_{20}H_{37}NaO_7S$ in *docusate sodium BPCRS*.

STORAGE

Docusate Capsules should be kept in an airtight container.