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

Sodium Picosulfate Oral Drops

General Notices

Action and use

Stimulant laxative.

DEFINITION

Sodium Picosulfate Oral Drops are a solution of Sodium Picosulfate in a suitable vehicle in a suitable device fitted with an appropriate measuring system.

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

Content of sodium picosulfate, $C_{18}H_{13}NNa_2O_8S_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for thin-layer chromatography, Appendix III A, using the following solutions.
(1) Dilute, if necessary, a volume of the oral drops with sufficient *methanol* to produce a solution containing 0.1% w/v of Sodium Picosulfate.
(2) 0.1% w/v of *sodium picosulfate BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}* (Merck HPTLC plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 8 cm.
(e) After removal of the plate, dry in air and examine immediately under *ultraviolet light (254 nm)*. Spray with a 20% w/v solution of *hydrochloric acid* in *methanol* and heat at 110° for 10 minutes. Spray the hot plate with a freshly prepared solution containing 5% w/v of *iron(III) chloride* and 0.1% w/v of *potassium hexacyanoferrate(III)* and examine the wet plate in daylight.

MOBILE PHASE

2.5 volumes of *anhydrous formic acid*, 12.5 volumes of *water*, 25 volumes of *methanol* and 60 volumes of *ethyl acetate*.

CONFIRMATION

Under ultraviolet light (254 nm) The principal spot in the chromatogram obtained with solution (1) is similar in position and size to that in the chromatogram obtained with solution (2).

After spraying The principal spot in the chromatogram obtained with solution (1) is similar in position, size and colour to that in the chromatogram obtained with solution (2).

B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Impurity A

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

(1) Dilute, if necessary, a volume of the oral drops with sufficient *water* to produce a solution containing 0.005% w/v of Sodium Picosulfate.
(2) 0.0001% w/v of *sodium picosulfate BPCRS* in *water*.
(3) Dissolve 10 mg of *sodium picosulfate BPCRS* in 2 mL of 0.1M *hydrochloric acid*, bring rapidly to the boil and heat for 1 minute. Cool in ice-water, add 2 mL of 0.1M *sodium hydroxide* and dilute to 10 mL with the mobile phase. Dilute 1 volume to 25 volumes with the mobile phase (generation of impurity A).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *base-deactivated end-capped octylsilyl silica gel for chromatography* (5 µm) (YMC Basic 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 263 nm.
(f) Inject 50 µL of each solution.

MOBILE PHASE

380 volumes of *acetonitrile* and 620 volumes of a buffer solution containing 3.0 g *disodium hydrogen orthophosphate* and 0.5 g *cetyltrimethylammonium bromide* in 1000 mL of *water*, adjusting the final pH to 5.0 with orthophosphic acid.

When the chromatograms are recorded under the prescribed conditions the retention time relative to sodium picosulfate (retention time about 26 minutes) is impurity A, about 0.2.

SYSTEM SUITABILITY

The test is not valid unless, the chromatogram obtained with solution (3), closely resembles the appropriate reference chromatogram supplied with *sodium picosulfate BPCRS*.

LIMITS

In the chromatogram obtained with solution (1) the area of any peak due to impurity A is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (2.0%).

ASSAY

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

(1) Dilute, if necessary, a volume of the oral drops with sufficient *water* to produce a solution containing 0.005% w/v of Sodium Picosulfate.
(2) 0.005% w/v of *sodium picosulfate BPCRS* in *water*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under the test for Impurity A may be used.

DETERMINATION OF CONTENT

Calculate the content of sodium picosulfate, $C_{18}H_{13}NNa_2O_8S_2$, in the oral drops from the chromatograms obtained and using the declared content of $C_{18}H_{13}NNa_2O_8S_2$ in *sodium picosulfate BPCRS*.

STORAGE

Sodium Picosulfate Oral Drops should be kept in an airtight container and protected from light.

IMPURITIES

The impurity limited by the requirements of this monograph is:

A. 4-[(*RS*)-(4-Hydroxyphenyl)(pyridin-2-yl)methyl]phenyl sodium sulfate.