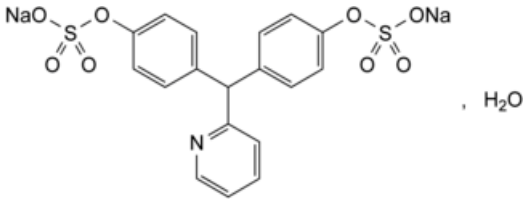
https://nhathuocngocanh.com/bp/

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

Sodium Picosulfate

General Notices

(Ph. Eur. monograph 1031)



$C_{18}H_{13}NNa_2O_8S_2,H_2O$ 499.4

Action and use

Stimulant laxative.

Preparations

Compound Sodium Picosulfate Powder for Oral Solution

Sodium Picosulfate Oral Solution Drops

Sodium Picosulfate Oral Solution

Ph Eur

DEFINITION

4,4′-[(Pyridin-2-yl)methylene]diphenyl bis(sodium sulfate) monohydrate.

Content

98.5 per cent to 100.5 per cent (anhydrous substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Freely soluble in water, slightly soluble in ethanol (96 per cent).

www.webofpharma.com

https://nhathuocngocanh.com/bp/

IDENTIFICATION

First identification: A, D.

Second identification: B, C, D.

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison *sodium picosulfate CRS*.

B. Thin-layer chromatography (*2.2.27*).

Test solution Dissolve 20 mg of the substance to be examined in *methanol R* and dilute to 5 mL with the same solvent.

Reference solution Dissolve 20 mg of *sodium picosulfate CRS* in *methanol R* and dilute to 5 mL with the same solvent.

Plate *TLC silica gel GF_{254} plate R*.

Mobile phase *anhydrous formic acid R*, *water R*, *methanol R*, *ethyl acetate R* (2.5:12.5:25:60 *V/V/V/V*).

Application 5 µL.

Development Over 1/2 of the plate.

Drying In a current of warm air for 15 min.

Detection Examine in ultraviolet light at 254 nm.

Results The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

C. To 5 mL of solution S (see Tests) add 1 mL of *dilute hydrochloric acid R* and heat to boiling. Add 1 mL of *barium chloride solution R1*. A white precipitate is formed.
D. Solution S gives reaction (a) of sodium (*2.3.1*).

TESTS

Solution S

Dissolve 2.5 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 50 mL with the same solvent.

Appearance of solution

Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution GY_7 (*2.2.2, Method II*).

Acidity or alkalinity

To 10 mL of solution S add 0.05 mL of *phenolphthalein solution R*. The solution is colourless. Not more than 0.25 mL of *0.01 M sodium hydroxide* is required to change the colour of the indicator to pink.

Related substances

Liquid chromatography (*2.2.29*).

Test solution Dissolve 50 mg of the substance to be examined in the mobile phase and dilute to 100.0 mL with the mobile phase.

Reference solution (a) Dilute 1.0 mL of the test solution to 100.0 mL with the mobile phase. Dilute 10.0 mL of this solution to 100.0 mL with the mobile phase.

Reference solution (b) Dissolve the contents of a vial of *picosulfate for system suitability CRS* (containing impurities A and B) in 1.0 mL of the mobile phase.

www.webofpharma.com

https://nhathuocngocanh.com/bp/

Column:

— *size*: *l* = 0.25 m, Ø = 4.0 mm;

— *stationary phase*: spherical *end-capped octadecylsilyl silica gel for chromatography R1* (5 µm);

— *temperature*: 40 °C.

Mobile phase Dissolve 2.3 g of *disodium hydrogen phosphate dihydrate R* in 800 mL of *water for chromatography R*, add 0.2 g of *cetyltrimethylammonium bromide R*, adjust to pH 7.5 with *phosphoric acid R* and dilute to 1000 mL with *water for chromatography R*; mix 550 mL of this solution and 450 mL of *acetonitrile R* (if necessary vary the buffer/acetonitrile proportion in 10 mL increments in order to fulfil the resolution requirement).

Flow rate 1.0 mL/min.

Detection Spectrophotometer at 263 nm.

Injection 40 µL.

Run time Twice the retention time of picosulfate.

Identification of impurities Use the chromatogram supplied with *picosulfate for system suitability CRS* and the chromatogram obtained with reference solution (b) to identify the peaks due to impurities A and B.

Relative retention With reference to picosulfate (retention time = about 7.4 min): impurity B = about 0.5; impurity A = about 0.7.

System suitability Reference solution (b):

— *resolution*: minimum 4.0 between the peaks due to impurities B and A.

Limits:

— *correction factors*: for the calculation of content, multiply the peak areas of the following impurities by the corresponding correction factor: impurity A = 0.7; impurity B = 0.5;

— *impurities A, B*: for each impurity, not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent);

— *unspecified impurities*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent);

— *total*: not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent);

— *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Chlorides (*2.4.4*)

Maximum 200 ppm.

Dilute 5 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*)

Maximum 400 ppm.

Dilute 7.5 mL of solution S to 15 mL with *distilled water R*.

Water (*2.5.12*)

3.0 per cent to 5.0 per cent, determined on 0.500 g.

ASSAY

www.webofpharma.com

https://nhathuocngocanh.com/bp/

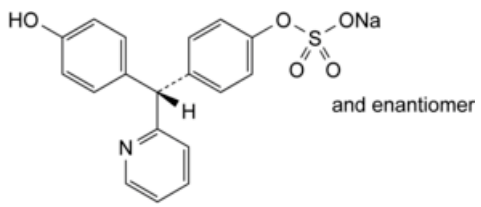
Dissolve 0.400 g in 80 mL of *methanol R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

1 mL of *0.1 M perchloric acid* is equivalent to 48.14 mg of $C_{18}H_{13}NNa_2O_8S_2$.

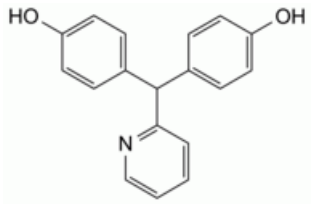
IMPURITIES

Specified impurities *A, B*.

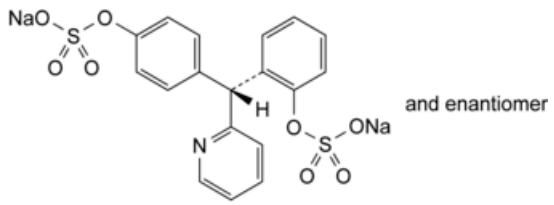
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use) *C*.



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



B. 4,4′-[(pyridin-2-yl)methylene]diphenol,



C. 2-[(*RS*)-(pyridin-2-yl)[4-(sulfonatooxy)phenyl]methyl]phenyl disodium sulfate.

www.webofpharma.com