https://nhathuocngocanh.com/bp/

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

Paracetamol Dispersible Tablets

General Notices

Dispersible Paracetamol Tablets

Action and use

Analgesic; antipyretic.

DEFINITION

Paracetamol Dispersible Tablets contain Paracetamol in a suitable dispersible basis.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of paracetamol, $C_8H_9NO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the contents of the powdered tablets containing 0.5 g of Paracetamol with 20 mL of *acetone*, filter, evaporate the filtrate and dry at 105°. The *infrared absorption spectrum* of the dried residue, Appendix II A, is concordant with the *reference spectrum* of paracetamol (*RS 258*).

TESTS

Related substances

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

Solution A 15 volumes of *methanol* and 85 volumes of *water*.

(1) Disperse a quantity of powdered tablets containing 0.2 g of Paracetamol in 20 mL of solution A with the aid of ultrasound, add sufficient solution A to produce 25 mL, mix and filter (0.45 µm nylon filter is suitable). Prepare immediately before use.
(2) Dilute 1 volume of solution (1) to 20 volumes with solution A and dilute 1 volume of the resulting solution to 50 volumes with solution A.
(3) 0.00008% w/v of *4-aminophenol* (paracetamol impurity K) in solution A. Prepare immediately before use.
(4) 0.02% w/v solution of *4'-chloroacetanilide* (paracetamol impurity J) in *methanol*, diluted in solution A to produce a solution containing 0.000008% w/v of *4'-chloroacetanilide*.
(5) Mix equal volumes of solution (2) and solution (3).

CHROMATOGRAPHIC CONDITIONS

www.webofpharma.com

https://nhathuocngocanh.com/bp/

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *end-capped solid core octadecylsilyl silica gel for chromatography* (5 µm) (Halo C18 is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 30°.
(e) Use an autosampler at 5°.
(f) Use a detection wavelength of 254 nm.
(g) Inject 50 µL of each solution.

MOBILE PHASE

Mobile phase A Dissolve 1.7 g of *potassium dihydrogen phosphate* and 1.8 g of *dipotassium hydrogen phosphate* in *water* and dilute to 1000 mL with *water*.

Mobile phase B *Methanol*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-1.5	95	5	isocratic
1.5-14.5	95→90	5→10	linear gradient
14.5-29	90	10	isocratic
29-58	90→66	10→34	linear gradient
58-60	66	34	isocratic
60-65	66→95	34→5	linear gradient
65-70	95	5	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (5), the *resolution* between the peaks due to paracetamol impurity K and paracetamol is at least 5.0.

CALCULATION OF IMPURITIES

For impurity K, use the concentration in solution (3).

For impurity J, use the concentration in solution (4).

For any other impurity, use the concentration of paracetamol in solution (2).

For the reporting threshold, use the concentration of paracetamol in solution (2).

Paracetamol retention time: about 4 minutes.

Relative retention: impurity K, about 0.4; impurity J, about 10.0.

LIMITS

— impurity K: not more than 100 ppm;

— impurity J: not more than 10 ppm;

— unspecified impurities: for each impurity, not more than 0.10%;

— total impurities: not more than 0.5%;

— reporting threshold: 0.05%.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Protect the solutions from light.

www.webofpharma.com

https://nhathuocngocanh.com/bp/

(1) Disperse a quantity of the powdered tablets containing 0.5 g of Paracetamol in 80 mL of the mobile phase with the aid of ultrasound, add sufficient mobile phase to produce 100 mL, mix, filter (0.45 µm nylon filter is suitable) and dilute 1 volume of the resulting solution to 100 volumes with the mobile phase.
(2) 0.005% w/v of *paracetamol BPCRS* in the mobile phase.
(3) 0.002% w/v each of *4-aminophenol* and *paracetamol BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *base-deactivated octylsilyl silica gel for chromatography* (5 µm) (Zorbax Rx C8 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 a column temperature of 35°.
(e) Use a detection wavelength of 245 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

250 volumes of *methanol* containing 1.15 g of a 40% w/v solution of *tetrabutylammonium hydroxide*, 375 volumes of 0.05M *disodium hydrogen orthophosphate* and 375 volumes of 0.05M *sodium dihydrogen orthophosphate*.

SYSTEM SUITABILITY

The test is not valid unless in the chromatogram obtained with solution (3), the *resolution* between the two principal peaks is at least 4.0.

DETERMINATION OF CONTENT

Calculate the content of $C_8H_9NO_2$ in the tablets, using the declared content of $C_8H_9NO_2$ in *paracetamol BPCRS*.

STORAGE

Paracetamol Dispersible Tablets should be protected from light and moisture.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities J and K listed under Paracetamol.

www.webofpharma.com