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

Paracetamol Oral Suspension

General Notices

Action and use

Analgesic; antipyretic.

DEFINITION

Paracetamol Oral Suspension is a suspension of Paracetamol in a suitable flavoured vehicle.

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

Content of paracetamol, $C_8H_9NO_2$

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 the preparation being examined with *methanol* to produce a solution containing 0.24% w/v of Paracetamol and filter if necessary.
(2) 0.24% w/v of *paracetamol BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF_{254}*.
(b) Use the mobile phase described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry it in a current of warm air, examine under *ultraviolet light (254 nm)* and also reveal the spots using *Method 1*.

MOBILE PHASE

0.5 volume of *glacial acetic acid*, 10 volumes of *toluene*, 25 volumes of *acetone* and 65 volumes of *chloroform*.

CONFIRMATION

By each method of visualisation 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 peak due to paracetamol in the chromatogram obtained with solution (2).

4-Aminophenol

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

(1) Shake 5 mL of the preparation being examined with 15 mL of the mobile phase, dilute with the mobile phase to contain 0.48% w/v of Paracetamol and filter if necessary.
(2) 0.0024% w/v of *4-aminophenol* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm x 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Nucleosil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2.0 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 272 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

0.01M *sodium butanesulfonate* in a mixture of 0.4 volumes of *formic acid*, 15 volumes of *methanol* and 85 volumes of *water*.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to 4-aminophenol is not greater than the area of the peak in the chromatogram obtained with solution (2) (0.5%).

Peaks with a long retention time may occur due to preservatives in the preparation.

ASSAY

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

(1) Mix a weighed quantity of the preparation being examined containing 24 mg of Paracetamol with 100 mL of the mobile phase, dilute to 200 mL with the mobile phase and filter if necessary.
(2) 0.012% w/v of *paracetamol BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure may be carried out as described under the test for 4-Aminophenol using a detection wavelength of 243 nm.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the preparation, Appendix V G, and calculate the percentage content of $C_8H_9NO_2$, weight in volume, using the declared content of $C_8H_9NO_2$ in *paracetamol BPCRS*.

STORAGE

Paracetamol Oral Suspension should be protected from light.

When paediatric paracetamol oral suspension or paediatric paracetamol mixture is prescribed or demanded, Paracetamol Oral Suspension containing 2.4% w/v of Paracetamol shall be dispensed or supplied unless otherwise stated by the prescriber.