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

Mercaptopurine Oral Suspension

General Notices

NOTE: *This monograph has been developed to cover unlicensed formulations.*

Action and use

Thiopurine cytotoxic.

DEFINITION

Mercaptopurine Oral Suspension is a suspension of Mercaptopurine Monohydrate in a suitable flavoured vehicle.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral suspension also complies with the requirements stated under Unlicensed Medicines.

Content of mercaptopurine monohydrate, $C_5H_4N_4S,H_2O$

90.0 to 110.0% of the stated amount.

Shake the oral suspension vigorously before carrying out the following tests.

IDENTIFICATION

A. Shake a quantity of the oral suspension containing 50 mg of Mercaptopurine Monohydrate with a mixture of 20 mL of *water* and 0.5 mL of 5M *sodium hydroxide* for not more than 5 minutes, add sufficient *water* to produce 100 mL, mix and filter. Dilute a portion of the filtrate with sufficient *0.1M hydrochloric acid* to give a final concentration of 0.0005% w/v of Mercaptopurine Monohydrate. The *light absorption* of the resulting solution, Appendix II B, exhibits a maximum at 325 nm.
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).

TESTS

Acidity

pH, 4.0 to 6.0, Appendix V L.

Dissolution

Complies with the requirements stated under Unlicensed Medicines, Oral Suspensions, using 900 mL of 0.1M *hydrochloric acid* as the dissolution medium and rotating the paddle at 50 revolutions per minute. Use a volume of the oral suspension containing one dose.

ASSAY

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

(1) Add 10 mL of a mixture of equal volumes of *methanol* and *water* to a weighed quantity of the oral suspension containing 15 mg of Mercaptopurine Monohydrate, mix with the aid of ultrasound for 15 minutes, shake for 1 hour and add sufficient of the mixture of equal volumes of *methanol* and *water* to produce 100 mL.
(2) 0.015% w/v of *mercaptopurine BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped base-deactivated octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil BDS 5 µm is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 328 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

10 volumes of *methanol* and 90 volumes of *water* containing 0.1% w/v of *sodium heptanesulfonate monohydrate* and 0.3% w/v of *sulfuric acid*.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_5H_4N_4S,H_2O$, weight in volume, using the declared content of $C_5H_4N_4S,H_2O$ in *mercaptopurine BPCRS*.

STORAGE

Mercaptopurine Oral Suspension should be protected from light.