



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

Econazole Cream

[General Notices](#)

Action and use

Antifungal.

DEFINITION

Econazole Cream contains Econazole Nitrate in a suitable basis.

The cream complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.

Content of econazole nitrate, $C_{18}H_{15}Cl_3N_2O, HNO_3$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

- A. Mix a quantity of the cream containing 40 mg of Econazole Nitrate with 20 mL of a mixture of 1 volume of 1M [sulfuric acid](#) and 4 volumes of [methanol](#) and shake with two 50-mL quantities of [carbon tetrachloride](#) discarding the organic layers. Make the aqueous phase alkaline with 2M [ammonia](#) and extract with two 40-mL quantities of [chloroform](#). Combine the [chloroform](#) extracts, shake with 5 g of [anhydrous sodium sulfate](#), filter and dilute the filtrate to 100 mL with [chloroform](#). Evaporate 50 mL to dryness and dissolve the residue in 50 mL of a mixture of 1 volume of [0.1M hydrochloric acid](#) and 9 volumes of [propan-2-ol](#). The [light absorption](#) of the resulting solution, [Appendix II B](#), in the range 240 to 350 nm exhibits maxima at 265, 271 and 280 nm. The ratio of the [absorbance](#) at the maximum at 271 nm to that at the maximum at 280 nm is 1.55 to 1.77. The test is not valid unless the ratio of the [absorbance](#) in the test for [resolution](#) is at least 2.
- B. In the Assay, the principal peak in the chromatogram obtained with solution (3) has the same retention time as the peak due to econazole in the chromatogram obtained with solution (4).

ASSAY

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

Buffer Solution

Dissolve 2.5 g of [potassium dihydrogen orthophosphate](#) and 2.5 g of [dipotassium hydrogen orthophosphate](#) in 1000 mL of [water](#).

- (1) 0.05% w/v solution of miconazole nitrate in [methanol](#) (internal standard solution).
- (2) Mix a quantity of the cream containing 10 mg of Econazole Nitrate with 20 mL of internal standard solution and 55 mL of [methanol](#), warm on a water-bath for 30 seconds, shake for 1 minute, repeat the process twice and add 25 mL of buffer solution. Cool in an ice bath for 15 minutes, centrifuge for 10 minutes and use the supernatant liquid, filtered if necessary.
- (3) Prepare in the same manner as solution (2) but using 20 mL of [methanol](#) in place of internal standard solution.
- (4) 10 mL of a 0.1% w/v solution of [econazole nitrate BPCRS](#) in [methanol](#) with 20 mL of internal standard solution, 45 mL of [methanol](#) and 25 mL of buffer solution.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (20 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Hypersil 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 232 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

1 volume of buffer solution and 3 volumes of [methanol](#).

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{15}Cl_3N_2O, HNO_3$ in the cream using the declared content of $C_{18}H_{15}Cl_3N_2O, HNO_3$ in [econazole nitrate BPCRS](#).

STORAGE

If Econazole Cream is kept in aluminium tubes, their inner surfaces should be coated with a suitable lacquer.