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

Tioconazole Nail Solution

General Notices

Tioconazole Cutaneous Solution

Action and use

Antifungal.

DEFINITION

Tioconazole Nail Solution is a *cutaneous solution*. It contains Tioconazole in a suitable vehicle.

The nail solution complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

Content of tioconazole, $C_{16}H_{13}Cl_3N_2OS$

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 a quantity of the nail solution containing 28 mg of Tioconazole to 10 mL with *methanol*.
(2) 0.28% w/v solution of *tioconazole BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel 60 F_{254}* (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

The upper layer obtained from a mixture of 40 volumes of *glacial acetic acid*, 40 volumes of *water* and 80 volumes *4-methylpentan-2-one*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

B. In the test for Related substances, the chromatogram obtained with solution (2) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (5).

TESTS

Related substances

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

(1) Dilute a quantity of the nail solution containing 20 mg of Tioconazole to 10 mL.
(2) Dilute 1 volume of solution (1) to 10 volumes.
(3) Dilute 1 volume of solution (2) to 20 volumes.
(4) 0.20% w/v of *tioconazole impurity standard BPCRS*.
(5) 0.02% w/v of *tioconazole BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 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 1.0 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 218 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

1 volume of 0.005M *tetrabutylammonium dihydrogen orthophosphate* adjusted to pH 7.4 with 2M *ammonia* and 4 volumes of *methanol*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (4) closely resembles the reference chromatogram supplied with *tioconazole impurity standard BPCRS*.

LIMITS

In the chromatogram obtained with solution (1):

the areas of any peaks corresponding to tioconazole impurities A, B and C are not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.5% of each).

ASSAY

Carry out Method I for *non-aqueous titration*, Appendix VIII A, using a quantity of the nail solution containing 0.28 g of Tioconazole. Each mL of *0.1M perchloric acid VS* is equivalent to 38.77 mg of $C_{16}H_{13}Cl_3N_2OS$. Determine the *weight per mL* of the nail solution, Appendix V G, and calculate the content of $C_{16}H_{13}Cl_3N_2OS$, weight in volume.