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Minoxidil Scalp Application

[General Notices](#)

Minoxidil Scalp Cutaneous Solution

Action and use

Vasodilator; treatment of hypertension; male pattern baldness.

DEFINITION

Minoxidil Scalp Application is a *cutaneous solution* of Minoxidil in a suitable ethanolic solvent.

The scalp application complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

Content of minoxidil, C₉H₁₅N₅O

95.0 to 110.0% of the stated amount.

IDENTIFICATION

Evaporate a volume of the scalp application containing about 50 mg of Minoxidil to dryness at a temperature of about 50° under a stream of nitrogen. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of minoxidil ([RS 376](#)).

Related substances

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

- (1) Dilute a suitable volume of the scalp application with the mobile phase to produce a solution containing 0.025% w/v of Minoxidil.
- (2) Dilute 1 volume of solution (1) to 100 volumes with the mobile phase.
- (3) Dilute 1 volume of solution (2) to 5 volumes with the mobile phase.
- (4) Dissolve 5 mg of [minoxidil for system suitability EPCRS](#) (containing impurities A, B and E) in the mobile phase and dilute to 20.0 mL with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (10 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (2.6 µm) (Kinetex XB-C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 0.8 mL per minute.
- (d) Use a column temperature of 40°.
- (e) Use a detection wavelength of 230 nm.
- (f) Inject 10 µL of each solution.

MOBILE PHASE

0.1% v/v of [trifluoroacetic acid](#) and 0.01M of [sodium heptanesulfonate](#) in a mixture of 45 volumes of [methanol](#) and 55 volumes of [water](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the [resolution](#) between the peaks due to impurity A and impurity B is at least 1.5 and the [resolution](#) between the peaks due to minoxidil and impurity E is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

identify any peak corresponding to impurity B using solution (4) and the chromatogram supplied with [minoxidil for system suitability EPCRS](#) and multiply the area of this peak by a correction factor of 1.6.

the area of any [secondary peak](#) is not greater than the area of the principal peak obtained with solution (3) (0.2%);

the sum of the areas of any [secondary peaks](#) is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%).

Disregard any peak with an area less than 0.5 times that of the principal peak in the chromatogram obtained with solution (3) (0.1%).

ASSAY

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

- (1) 0.025% w/v of Minoxidil, prepared by serial dilution of the scalp application with the mobile phase.
- (2) 0.025% w/v of [minoxidil BPCRS](#) in the mobile phase.
- (3) Dissolve 5 mg of [minoxidil for system suitability EPCRS](#) (containing impurities A, B and E) in the mobile phase and dilute to 20.0 mL with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

Use the chromatographic conditions described under Related substances but with a detection wavelength of 254 nm.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to impurity A and impurity B is at least 1.5 and the [resolution](#) between minoxidil and impurity E is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_9H_{15}N_5O$ in the scalp application using the declared content of $C_9H_{15}N_5O$ in [minoxidil BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Minoxidil.

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