https://trungtamthuoc.com/

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-C540FFE5-E894-4902-B5D4-7021C31E2106_2_en-US
DOI: https://doi.org/10.31003/USPNF_M54270_02_01
DOI Ref: sde7h

© 2025 USPC
Do not distribute

Minoxidil Topical Solution

DEFINITION
Minoxidil Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of minoxidil ($C_9H_{15}N_5O$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

Sample: Evaporate 1 mL of the Topical Solution under a stream of nitrogen while heating at 50°.

Acceptance criteria: Meets the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: Add 0.65 mL of heptafluorobutyric acid to a 1000-mL volumetric flask. Dilute with water to volume.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	100	0
10.0	60	40
10.1	100	0
15.0	100	0

Diluent: Methanol and water (50:50)

System suitability solution: 0.4 mg/mL of USP Minoxidil RS and 0.001 mg/mL of USP Minoxidil Related Compound E RS in *Diluent*

Standard solution: 0.05 mg/mL of USP Minoxidil RS in *Diluent*

Sample solution: Nominally 0.05 mg/mL of minoxidil in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing L1

Column temperature: 35°

Flow rate: 0.4 mL/min

Injection volume: 1 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between minoxidil and minoxidil related compound E, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of minoxidil ($C_9H_{15}N_5O$) in the portion of Topical Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

OFFICIAL

www.webofpharma.com

https://trungtamthuoc.com/

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Minoxidil RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of minoxidil in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.4 µg/mL of USP Minoxidil RS in *Diluent*

Sample solution: Nominally 0.4 mg/mL of minoxidil in *Diluent*. Pass through a suitable filter of 0.2-µm pore size.

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between minoxidil and minoxidil related compound E, *System suitability solution*

Relative standard deviation: NMT 2.8%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each unspecified impurity in the portion of Topical Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each unspecified impurity from the *Sample solution*

r_S = peak response of minoxidil from the *Standard solution*

C_S = concentration of USP Minoxidil RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of minoxidil in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*. Disregard any impurity peaks less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Minoxidil related compound A (pyrimidine oxide analog)[a,b]	0.36	—
Pyrimidine analog[b,c]	0.51	—
Minoxidil	1.00	—
Minoxidil related compound E (deoxyminoxidil)[b,d]	1.03	—
Individual unspecified impurity	—	0.2
Total impurities	—	2.0

[a] 2,6-Diamino-4-chloropyrimidine 1-oxide.

[b] Process impurity included in the table for identification only. Process impurities are controlled in the drug substance, and are not to be reported or included in the total impurities for the drug product.

[c] 6-Chloropyrimidine-2,4-diamine.

[d] 6-(Piperidin-1-yl)pyrimidine-2,4-diamine.

OFFICIAL
www.webofpharma.com

https://trungtamthuoc.com/

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

USP Minoxidil RS

USP Minoxidil Related Compound E RS

6-(Piperidin-1-yl)pyrimidine-2,4-diamine.

$C_9H_{15}N_5$ 193.25

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MINOXIDIL TOPICAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-C540FFE5-E894-4902-B5D4-7021C31E2106_2_en-US

DOI: https://doi.org/10.31003/USPNF_M54270_02_01

DOI ref: sde7h

OFFICIAL

www.webofpharma.com