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# Minoxidil Tablets

## DEFINITION

Minoxidil Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of minoxidil ($C_9H_{15}N_5O$).

## IDENTIFICATION

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

• **B.** The UV absorption spectra of the minoxidil peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

## ASSAY

• **Procedure**

**Mobile phase:** Methanol, glacial acetic acid, and water (70:1:30). Add 3.0 g/L of docusate sodium, and adjust with perchloric acid to a pH of 3.0.

**Standard solution:** 0.25 mg/mL of USP Minoxidil RS in *Mobile phase*

**Sample solution:** Nominally 0.25 mg/mL of minoxidil in *Mobile phase* prepared as follows. Dissolve the equivalent to 5 mg of minoxidil, from a portion of powdered Tablets (NLT 10), in 20.0 mL of *Mobile phase*, and shake for 5 min.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

**Column:** 4-mm × 25-cm; 5-µm packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 10 µL

**Run time:** NLT 2 times the retention time of the minoxidil peak

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

**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 Tablets taken:

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

$r_U$ = peak response of minoxidil 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:** 90.0%–110.0%

## PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

**Medium:** pH 7.2 phosphate buffer (see *Reagents, Indicators, and Solutions—Solutions, Buffer Solutions*); 900 mL

**Apparatus 1:** 75 rpm

**Time:** 15 min

**Standard solution:** A known concentration of USP Minoxidil RS in *Medium*.

**Sample solution:** Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.

**Instrumental conditions**

**Mode:** UV

**Detector:** UV 231 nm for Tablets containing up to 10 mg of minoxidil; UV 287 nm for Tablets containing more than 10 mg of minoxidil

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of minoxidil ($C_9H_{15}N_5O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times (V/L) \times 100$$

$A_U$ = absorbance of the *Sample solution*

$A_S$ = absorbance of the *Standard solution*

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

$D$ = dilution factor for the *Sample solution*

$V$ = volume of the *Medium*, 900 mL

$L$ = label claim (mg/Tablet)

**Tolerances:** NLT 75% ($Q$) of the labeled amount of minoxidil ($C_9H_{15}N_5O$) is dissolved.

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

## IMPURITIES

***Change to read:***

- **Organic Impurities**

**Mobile phase:** Dissolve 2.0 g of sodium lauryl sulfate in a mixture of 600 mL of methanol, 10 mL of glacial acetic acid, and 400 mL of water. Adjust with perchloric acid to a pH of 3.0 ± 0.1, and pass through a suitable filter of 0.45-µm pore size.

**Diluent:** Methanol and water (50:50)

**Standard solution:** 0.005 mg/mL of USP Minoxidil RS in *Diluent*

**Sensitivity solution:** 0.25 µg/mL of USP Minoxidil RS in *Diluent* from *Standard solution*

**Sample solution:** Nominally 0.25 mg/mL of minoxidil in *Diluent* from NLT 20 powdered Tablets. Transfer a suitable amount of the powdered Tablets in an appropriate volumetric flask. Initially add *Diluent* to about 60% of the flask volume, shake on a mechanical shaker for 20 min, and then dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 280 nm

**Column:** 3.9-mm × 15-cm; 3- to 10-µm packing L1

**Flow rate:** 0.5 mL/min

**Run time:** NLT 3 times the retention time of the minoxidil peak

**Injection volume:** 40 µL

**System suitability**

**Samples:** *Standard solution* and *Sensitivity solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0, *Standard solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of any unspecified impurity in the portion of the Tablets taken:

$$\text{Result} = (r_U/r_S) \times ({}^{\blacktriangle}C_S/C_{U\blacktriangle\ (\text{ERR 1-Jun-2021})}) \times 100$$

$r_U$ = peak response of any 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 1*. The reporting threshold is 0.1%.

**Table 1**

| Name | Relative Retention Time | Acceptance Criteria, NMT (%) |
|---|---|---|
| Pyrimidine oxide analog[a] | 0.19 | —[b] |
| Pyrimidine analog[c] | 0.37 | —[b] |
| Minoxidil | 1.00 | — |
| Deoxyminoxidil[d] | 1.45 | —[b] |
| Any unspecified impurity | — | 0.2 |
| Total impurities[e] | — | 2.0 |

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

[b] Process-related impurities that are controlled in the drug substance.

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

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

[e] Total impurities is the sum of all the impurities, including process-related impurities.

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Minoxidil RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| MINOXIDIL TABLETS | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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