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Miconazole Nitrate Topical Powder

DEFINITION

Miconazole Nitrate Topical Powder contains NLT 90.0% and NMT 110.0% of the labeled amount of miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$).

IDENTIFICATION

- A.**
Sample: Transfer nominally 100 mg of miconazole nitrate from Topical Powder to a 50-mL beaker, disperse in 40 mL of [methanol](#), and mix for a minimum of 5 min. Allow to settle for 5–10 min and filter into a 100-mL beaker. Evaporate on a steam bath or by a rotary evaporator to dryness. Dry the residue at 105° for 10 min.
Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the residue obtained from the *Sample* exhibits maxima only at the same wavelengths as that of a similar preparation of [USP Miconazole Nitrate RS](#).
- 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**
Buffer: 4.6 g/L of [dibasic potassium phosphate trihydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 7.5.
Solution A: [Acetonitrile](#) and Buffer (65:35)
Solution B: [Acetonitrile](#)
Solution C: [Acetonitrile](#), [water](#), and [phosphoric acid](#) (50:50:0.05)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)	Flow rate (mL/min)
0	100	0	0	1.0
17.0	86	14	0	1.0
17.1	0	0	100	3.0
28.0	0	0	100	3.0
28.1	100	0	0	2.0
38.0	100	0	0	2.0
38.1	100	0	0	1.0
40	100	0	0	1.0

- Diluent:** [Acetonitrile](#) and [water](#) (50:50)
- Standard stock solution:** 2 mg/mL of [USP Miconazole Nitrate RS](#) in *Diluent*. Sonication may be needed to aid dissolution.
- Standard solution:** 0.2 mg/mL of [USP Miconazole Nitrate RS](#) in *Diluent* from the *Standard stock solution*
- Sample solution:** Nominally 0.2 mg/mL of miconazole nitrate in *Diluent* prepared as follows. Transfer an appropriate amount of miconazole nitrate from a portion of the Topical Powder to a suitable volumetric flask. Add *Diluent* equivalent to 50% of the flask volume, shake for 30 min, and sonicate for 10 min. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.
- Chromatographic system**
(See [Chromatography \(621\), System Suitability](#).)
- Mode:** LC
- Detector:** UV 220 nm
- Column:** 4.6-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 32°**Flow rate:** See [Table 1](#).**Injection volume:** 5 µL**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 miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$) in the portion of Topical Powder taken:

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

 r_U = peak response of miconazole from the *Sample solution* r_S = peak response of miconazole from the *Standard solution* C_S = concentration of [USP Miconazole Nitrate RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of miconazole nitrate in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**IMPURITIES**• **ORGANIC IMPURITIES****Buffer, Solution B, Solution C, Diluent, Standard stock solution, and Sample solution:** Prepare as directed in the Assay.**Solution A:** [Acetonitrile](#) and Buffer (35:65)**Mobile phase:** See [Table 2](#).**Table 2**

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)	Flow rate (mL/min)
0	100	0	0	1.0
55.0	30.8	69.2	0	1.0
55.1	0	0	100	3.0
68.0	0	0	100	3.0
68.1	100	0	0	2.0
83.0	100	0	0	2.0
83.1	100	0	0	1.0
85.0	100	0	0	1.0

System suitability solution: 0.2 mg/mL of [USP Miconazole Nitrate RS](#) from the *Standard stock solution* and 0.2 µg/mL of [USP Miconazole Related Compound C RS](#) in *Diluent***Standard solution:** 2 µg/mL of [USP Miconazole Nitrate RS](#) in *Diluent* from the *Standard stock solution***Sensitivity solution:** 0.1 µg/mL of [USP Miconazole Nitrate RS](#) in *Diluent* from the *Standard solution***Chromatographic system**(See [Chromatography \(621\)](#), *System Suitability*.)**Mode:** LC**Detector:** UV 220 nm**Column:** 4.6-mm × 25-cm; 5-µm packing [L7](#)**Column temperature:** 32°**Flow rate:** See [Table 2](#).**Injection volume:** 15 µL**System suitability****Samples:** *System suitability solution*, *Standard solution*, and *Sensitivity solution*