

Separation of Miconazole Nitrate and its Organic Impurities per USP Monograph using Kinetex™ 2.6 μm Phenyl-Hexyl Column

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Overview

Miconazole Nitrate belongs to the imidazole group of antifungal agents. The development of a quick and efficient analysis of Miconazole Nitrate and its related organic impurities is of interest for drug manufacturers. In this application note, we report the separation of Miconazole Nitrate and its related organic impurities using the Kinetex 2.6 μm Phenyl-Hexyl column specified by the USP monograph for Miconazole Nitrate.

System suitability per USP Monograph for the Miconazole Nitrate Assay is a resolution no less than (NLT) 1.5 between Miconazole Nitrate and Miconazole Related Compound F, a symmetry factor no more than (NMT) 2.0 for Miconazole Nitrate, and a percent relative standard deviation (%RSD) of NMT 0.73 % for Miconazole Nitrate. All system suitability requirements for Miconazole Nitrate Assay were met using the Kinetex Phenyl-Hexyl column (Figure 1 and 2).

System suitability per USP Monograph for the Miconazole Nitrate Organic Impurities is a resolution NLT 1.5 between Miconazole Related Compound C and Miconazole Related Compound I, a resolution NLT 1.5 between Miconazole Related Compound I and Econazole Nitrate, a resolution NLT 1.5 between Miconazole Related Compound F and Miconazole Nitrate, as well as a %RSD NMT 3.0 % for Miconazole Nitrate. The separation of Miconazole Nitrate and its organic impurities was achieved with all requirements for System Suitability for Organic Impurities met using the Kinetex Phenyl-Hexyl column (Figure 3).

All solutions were prepared as indicated in the USP Monograph for Miconazole Nitrate. USP Miconazole Nitrate RS (Catalog No. 1443500), USP Econazole Nitrate RS (Catalog No. 1231808), USP Miconazole Related Compound C RS (Catalog No. 1443431), USP Miconazole Related Compound F RS (Catalog No. 1443464), and USP Miconazole Related Compound I RS (Catalog No. 1443497) were purchased from USP.

LC-UV Conditions

Column: Kinetex 2.6 μm Phenyl-Hexyl

Dimension: 100 x 4.6 mm

Part No.: [00D-4495-EO](#)

Mobile Phase: A: Methanol/Water/1 M Triethylammonium Acetate (30:70:1, v/v/v)

B: Acetonitrile/Methanol/1 M Triethylammonium Acetate (25:75:0.2, v/v/v)

Gradient:	Time (min)	%B
	0	30
	5	30
	10	56
	27	56
	30	75
	35	75
	36	30
	40	30

Flow Rate: 0.8 mL/min

Injection Volume: 10 μL

Temperature: 40 °C

Detector: UV @ 215

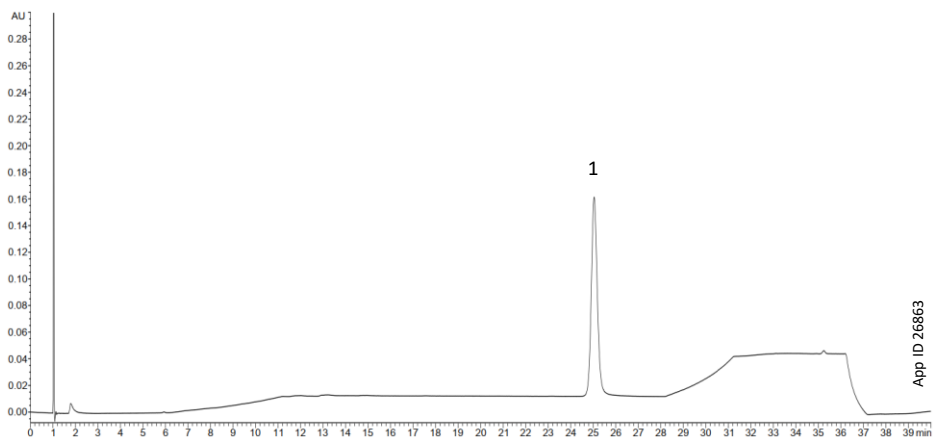
System: Waters® ACQUITY® I-Class UPLC

Table 1. Preparation of Solutions

Solution	Composition
Diluent – Assay	Methanol/Water (70:30, v/v)
Standard Solution – Assay	0.1 mg/mL USP Miconazole Nitrate RS in Diluent
System Suitability Solution – Assay	0.1 mg/mL of USP Miconazole Nitrate RS and 6 μg/mL of USP Miconazole Related Compound F RS in Diluent
Standard Solution – Organic Impurities	1.2 μg/mL each of USP Miconazole Nitrate RS, USP Econazole Nitrate RS, USP Miconazole Related Compound C RS, USP Miconazole Related Compound F RS, and USP Miconazole Related Compound I RS in Diluent

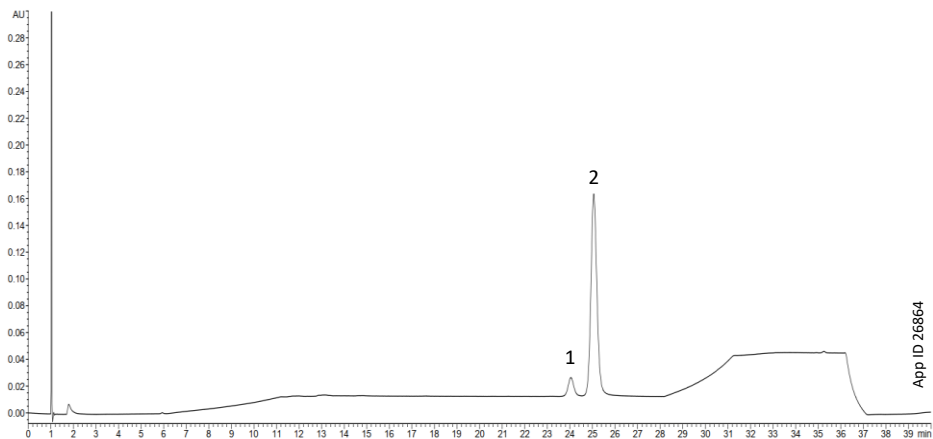


Figure 1. Standard Solution – Assay



Peak No.	Analyte	Symmetry Factor	Area %RSD
1	Miconazole Nitrate	1.11	0.421
N=6 Injections			

Figure 2. System Suitability Solution – Assay



Peak No.	Analyte	Resolution
1	Miconazole Related Compound F	2.1
2	Miconazole Nitrate	
N=6 Injections		



Figure 3. Standard Solution – Organic Impurities



Peak No.	Analyte	Resolution	Area %RSD
1	Miconazole Related Compound C	2.417	-
2	Miconazole Related Compound I		-
3	Econazole Nitrate	-	-
4	Miconazole Related Compound F	2.2	-
5	Miconazole Nitrate		2.592

N=6 Injections



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