

Separation of Desvenlafaxine Succinate and its Organic Impurities per USP Monograph

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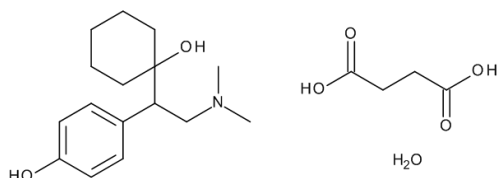
Overview

Desvenlafaxine Succinate is a serotonin-norepinephrine reuptake inhibitor (SNRI). It increases serotonin and norepinephrine activity in the brain, which helps regulate mood. The development of a quick and efficient analysis of Desvenlafaxine Succinate and its organic impurities is of interest for generic drug manufacturers. In this application note, we report the separation of Desvenlafaxine Succinate and its related organic impurities using a Luna™ Omega 3 µm C18 column according to the USP monograph for Desvenlafaxine Succinate.

System suitability per USP Monograph for the Desvenlafaxine Succinate Organic Impurities is a resolution no less than (NLT) 1.5 between Desvenlafaxine Related Compound B and Desvenlafaxine Succinate, a percent relative standard deviation (%RSD) no more than 5 % for Desvenlafaxine Succinate, and a signal-to-noise (S/N) ratio of NLT 10 for Desvenlafaxine Succinate. The area %RSD was 0.612 % for Desvenlafaxine Succinate using the Luna Omega 3 µm C18 column (**Figure 2**). The resolution between Desvenlafaxine Related Compound B and Desvenlafaxine Succinate was 3.05 (**Figure 3**) and the S/N ratio was 77.3 for Desvenlafaxine Succinate using the Luna Omega 3 µm C18 column (**Figure 4**). All requirements for System Suitability for Desvenlafaxine Succinate Organic Impurities were met by the Luna 3 µm C18 column.

All solutions were prepared as indicated in the USP Monograph for Desvenlafaxine Succinate. USP Desvenlafaxine Succinate RS (Catalog No. 1175773) and Desvenlafaxine Related Compound B (Catalog No. 1175795) were purchased from USP.

Figure 1. Desvenlafaxine Succinate



LC-UV Conditions

Column: Luna Omega 3 µm C18

Dimension: 250 x 4.6 mm

Part No.: [00G-4784-E0](#)

Mobile Phase: A: Acetonitrile/Buffer (10:90, v/v)
B: Acetonitrile/Buffer (60:40, v/v)

Buffer: 7.1 g/L of Anhydrous Dibasic Sodium Phosphate in water, adjusted to pH 3.0 with Phosphoric Acid

Gradient:	Time (min)	%B
	0	0
	5	0
	30	50
	35	65
	37	0

Flow Rate: 1.5 mL/min

Injection Volume: 20 µL

Temperature: 50 °C

Detector: UV @ 225 nm

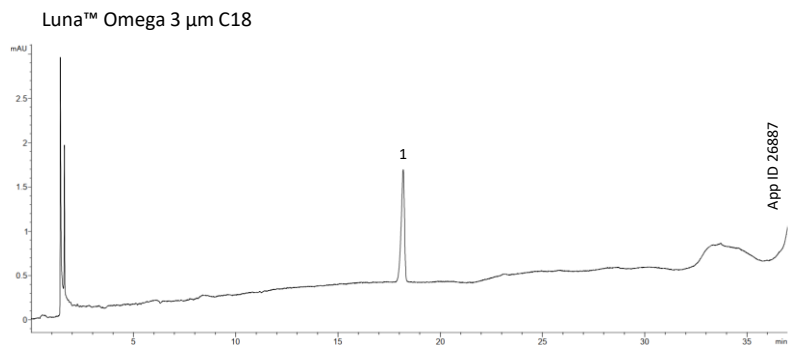
System: Agilent® 1260 Binary UHPLC

Table 1. Preparation of Solutions

Solution	Composition
Diluent	Mobile Phase A
Standard Solution	0.001 mg/mL of USP Desvenlafaxine Succinate RS in Diluent. Sonication may be used to promote dissolution.
System Suitability Solution	1 mg/mL of USP Desvenlafaxine Succinate RS and 0.0015 mg/mL of USP Desvenlafaxine Related Compound B RS in Diluent. Sonication may be used to promote dissolution.
Sensitivity Solution	0.5 µg/mL solution made by diluting Standard Solution by a factor of 2 in Diluent.



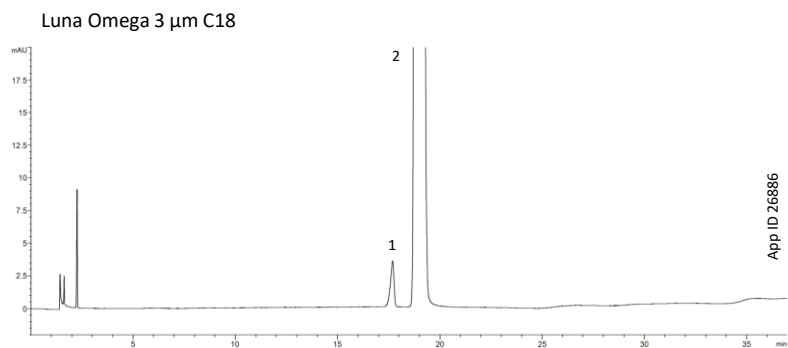
Figure 2. Standard Solution



Peak No.	Analyte	Retention Time (min)	Area %RSD
1	Desvenlafaxine Succinate	18.19	0.612

N = 6 Injections

Figure 3. System Suitability Solution

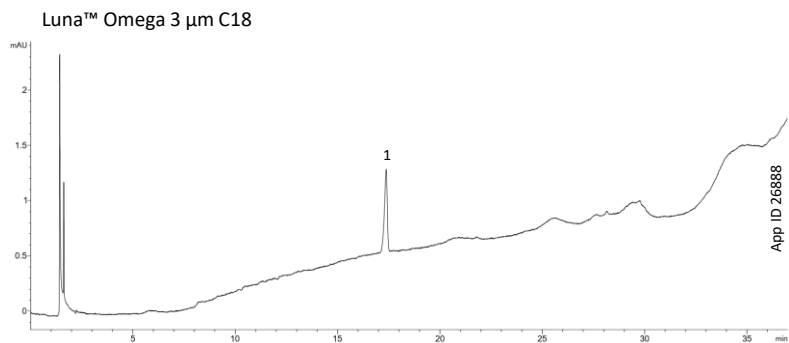


Peak No.	Analyte	Retention Time (min)	Resolution
1	Desvenlafaxine Related Compound B	17.69	3.05
2	Desvenlafaxine Succinate	18.88	

N = 6 Injections



Figure 4. Sensitivity Solution



Peak No.	Analyte	Retention Time (min)	S/N Ratio
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1	Desvenlafaxine Succinate	17.37	77.3
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N = 3 Injections



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