

Meeting System Suitability for USP Desvenlafaxine Succinate Assay Using Kinetex™ XB-C18 Columns

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Overview

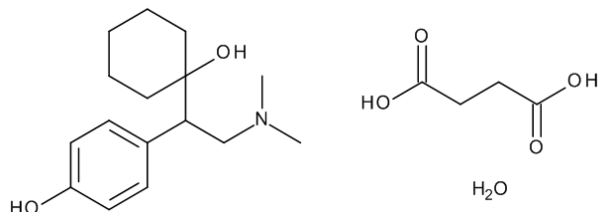
Desvenlafaxine Succinate is a serotonin-norepinephrine reuptake inhibitor (SNRI). It increases serotonin and norepinephrine activity in the brain, which helps regulate mood. The development of a quick and efficient analysis of Desvenlafaxine Succinate is of interest for generic drug manufacturers. In this application note, we report meeting system suitability requirements of the USP Monograph for Desvenlafaxine Succinate Assay using a Kinetex 2.6 μm XB-C18 column and a Kinetex 5 μm XB-C18 column.

The use of the 150 mm length Kinetex 2.6 μm XB-C18 column is an allowable adjustment per USP <621> since the L/dp ratio ($150/2.6 = 57,692$) is within the allowable range of -25 to +50 % of the L/dp ratio ($250/5 = 50,000$) for the original 250 mm length, 5 μm column used to elucidate the assay method.

System suitability per USP Monograph for the Desvenlafaxine Succinate Assay is a symmetry factor no more than (NMT) 1.5 and a percent relative standard deviation (%RSD) NMT 0.73 %. Both the Kinetex 2.6 μm XB-C18 column and the Kinetex 5 μm XB-C18 column met all system suitability requirements, with the shorter Kinetex 2.6 μm XB-C18 column providing a shorter run time and increased sensitivity (**Figure 2**).

All solutions were prepared as indicated in the USP Monograph for Desvenlafaxine Succinate. USP Desvenlafaxine Succinate RS (Catalog No. 1175773) was purchased from USP.

Figure 1. Desvenlafaxine Succinate



LC-UV Conditions

Column: Kinetex 2.6 μm XB-C18

Kinetex 5 μm XB-C18

Dimension: 150 x 4.6 mm

250 x 4.6 mm

Part No.: [00F-4496-E0](#)

[00G-4605-E0](#)

Mobile Phase: To each liter of mobile phase A, add 5.4 mL Triethylamine and adjust the pH to 4.0 with Phosphoric Acid

A: Acetonitrile/Buffer (18:82, v/v)

Buffer: 2.7 g/L of Monobasic Potassium Phosphate in Water

Flow Rate: 1.5 mL/min (Isocratic)

Injection Volume: 10 μL

Temperature: Ambient

Detector: UV @ 225 nm

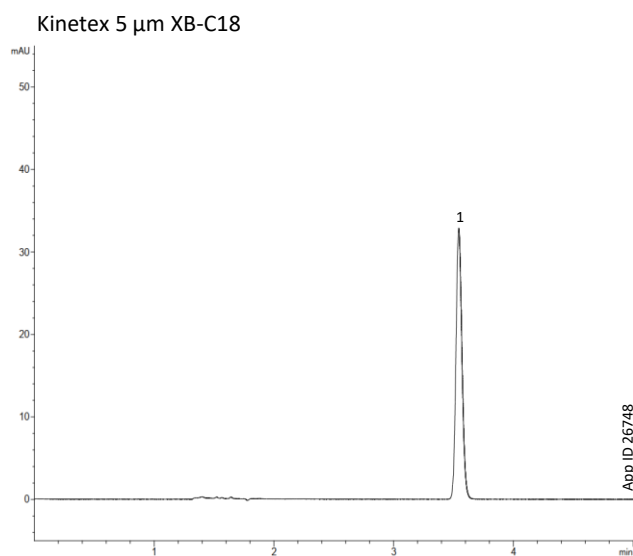
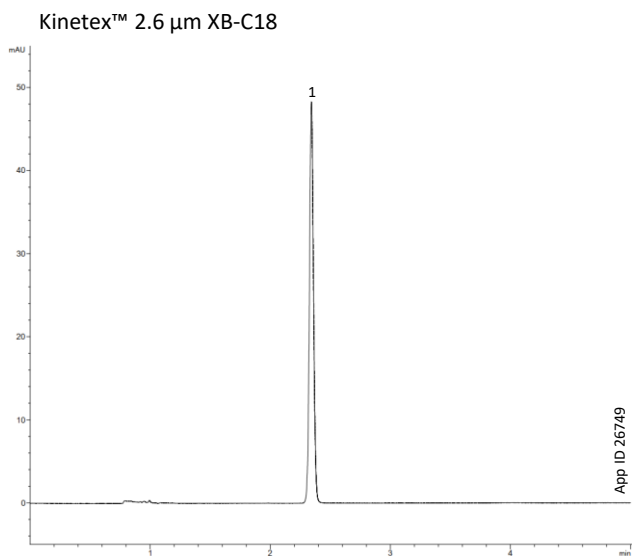
System: Agilent® 1260 Binary UHPLC

Table 1. Preparation of Solutions

Solution	Composition
Standard Solution	0.05 mg/mL of USP Desvenlafaxine Succinate RS in mobile phase. Sonication may be used to promote dissolution.



Figure 2. Standard Solution



Peak No.	Analyte	Kinetex 2.6 μm XB-C18			Kinetex 5 μm XB-C18		
		Retention Time (min)	Symmetry Factor	Area %RSD	Retention Time (min)	Symmetry Factor	Area %RSD
1	Desvenlafaxine Succinate	2.34	1.072	0.079	3.54	1.142	0.062

N = 5 Injections



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