Separation of Fluvoxamine Maleate and its Organic Impurities per USP Monograph

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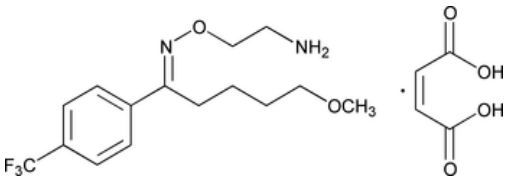
Overview

Fluvoxamine Maleate is a selective serotonin reuptake inhibitor (SSRI) in the brain. The development of a quick and efficient analysis of Fluvoxamine Maleate and its related organic impurities is of interest for generic drug manufacturers. In this application note, we report the separation of Fluvoxamine Maleate and its related organic impurities using a Luna 5 µm C8(2) column according to the USP monograph for Fluvoxamine Maleate.

System suitability per USP Monograph for the Fluvoxamine Maleate is a symmetry factor no more than (NMT) 2.0 and a percent relative standard deviation (%RSD) of NMT 2.0 % for Fluvoxamine Maleate. A resolution no less than (NLT) 3.0 between the Z-isomer and Fluvoxamine Maleate, and a resolution NLT 5.0 between Succinyl Fluvoxamine and the Z-isomer are also requirements of system suitability. All system suitability requirements for Fluvoxamine Maleate were met with the Luna C8(2) column.

All solutions were prepared as indicated in the USP Monograph for Fluvoxamine Maleate. USP Fluvoxamine Maleate RS (Catalog No. 1285909) was purchased from USP, and Maleic Acid was purchased from Sigma-Aldrich®.

Figure 1. Fluvoxamine Maleate



LC-UV Conditions

Column: Luna™ 5 µm C8(2) (00G-4249-E0)
Dimension: 250 x 4.6 mm
Mobile Phase: Acetonitrile/Solution A (38:62, v/v)

Solution A: 8 g/L of Sodium 1-Pentanesulfonate and 1.1 g/L of Monobasic Potassium Phosphate in water. Adjust with Phosphoric Acid to a pH of 3.00 ± 0.05.

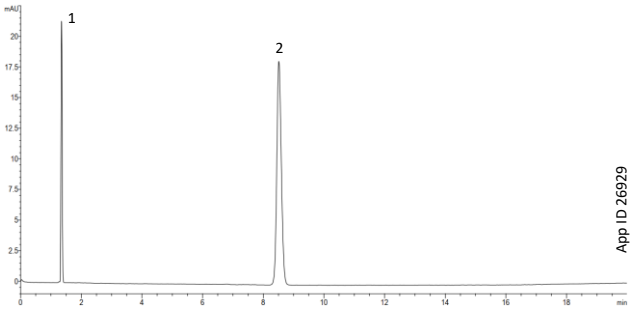
Flow Rate: 1.7 mL/min (Isocratic)
Injection Volume: 20 µL
Temperature: 40 °C
Detector: UV @ 234 nm
System: Agilent® 1260 Binary UHPLC

Table 1. Preparation of Solutions

Solution	Composition
Standard Solution	0.05 mg/mL of USP Fluvoxamine Maleate RS in mobile phase
System Suitability Solution	Transfer 6 mg of USP Fluvoxamine Maleate RS to a 50 mL volumetric flask. Heat the sample at 120 °C for 10 min. Cool to room temperature and add 3.0 mL of 0.1 N Hydrochloric Acid. Heat the solution in a water bath for 10 min. Cool to room temperature, add 50 mg of USP Fluvoxamine Maleate RS, and dissolve in 25 mL of mobile phase. Dilute with mobile phase to volume.
Identification Solution	0.35 mg/mL of Maleic Acid in mobile phase.

Figure 2. Standard Solution

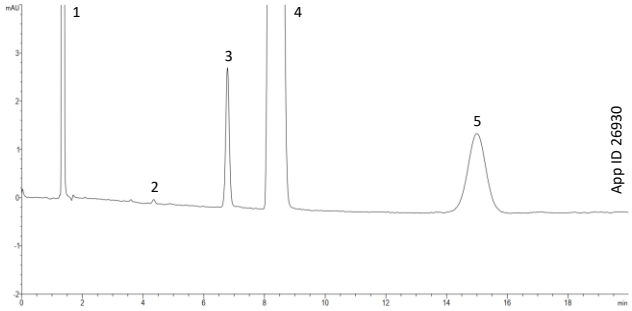
Luna™ 5 µm C8(2)



Peak No.	Analyte	Area %RSD	Symmetry Factor
1	Maleic Acid	-	-
2	Fluvoxamine Maleate	0.072	1.127
N = 6 Injections			

Figure 3. System Suitability Solution

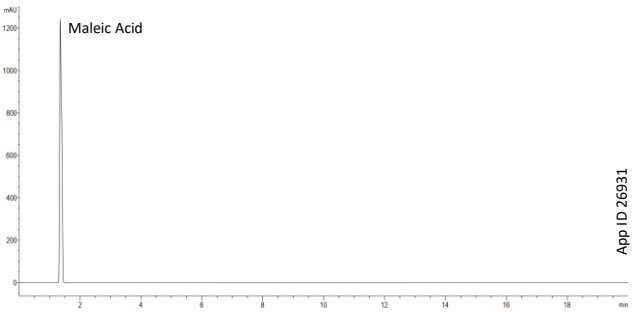
Luna 5 µm C8(2)



Peak No.	Analyte	Resolution	
1	Maleic Acid	-	-
2	Succinyl Fluvoxamine	-	12.55
3	Fluvoxamine Z-isomer	4.41	
4	Fluvoxamine Maleate		-
5	Dealkyl benzyl Fluvoxamine	-	-
N = 6 Injections			

Figure 4. Identification Solution

Luna 5 µm C8(2)



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