

USP Alosetron Hydrochloride Assay and Organic Impurities on Gemini® 3 µm C18

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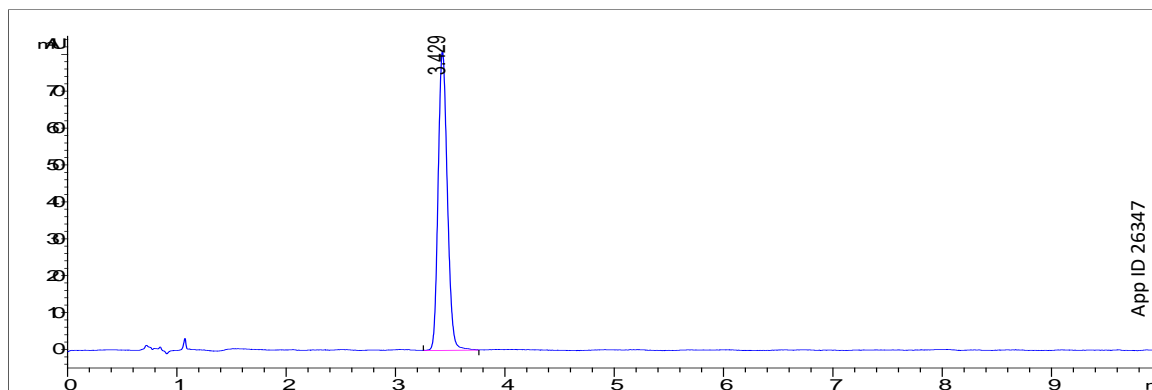
Overview

Alosetron hydrochloride is a potent and selective antagonist of the serotonin 5-HT₃ receptor. This application note for the LC-UV assay and organic impurities for Alosetron hydrochloride is based on the USP monograph. USP reference standards were used to prepare the standard solutions and system suitability solution, and mobile phase was prepared per the USP monograph for Alosetron hydrochloride, which was validated using the Gemini 3 µm C18 column for both the assay (isocratic) and organic impurities (gradient).

LC-UV Conditions (Assay)

Column: Gemini 3 µm C18 ([00C-4439-E0](#))
Dimension: 75 x 4.6 mm
Mobile Phase: A:B (80:20)
 A = 0.02 M monobasic sodium phosphate, adjusted with phosphoric acid to a pH of 3.0.
 B = Acetonitrile
Flow Rate: 1.0 mL/min
Temperature: 22 °C
Detector: UV @ 220 nm
Injection: 5 µL
System: Agilent® 1260 (binary)
Sample: 1. Alosetron (0.05 mg/mL)

Standard Solution for Assay on Gemini 3 µm C18



Standard Solution
(0.05 mg/mL of USP Alosetron Hydrochloride RS in mobile phase)

Table 1. Summary of Results, Assay (Standard Solution)

Analyte	Retention Time, min	Symmetry Factor (NMT 2.0)	% RSD (n = 6) (NMT 0.73 %)
Alosetron Hydrochloride	3.429	1.14	0.71



LC-UV Conditions (Organic Impurities)

Column: Gemini 3 μ m C18 ([00C-4439-E0](#))
Dimension: 75 x 4.6 mm
Mobile Phase: A = 0.02 M monobasic sodium phosphate, adjusted with phosphoric acid to a pH of 3.0.
 B = Acetonitrile

Gradient: Time (min)	% B
0	10
5	10
20	50
25	50
25.1	10
35	10

Flow Rate: 1.0 mL/min

Temperature: 22 °C

Detector: UV @ 220 nm

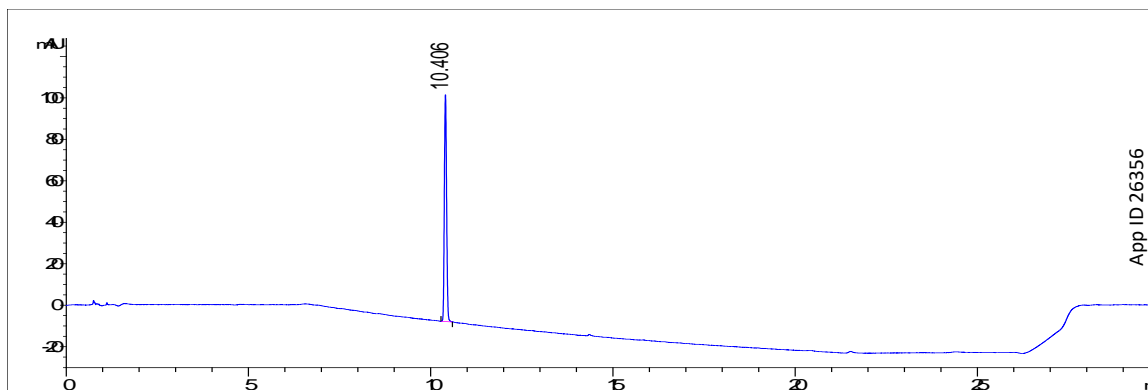
Injection: 5 μ L

System: Agilent® 1260 (binary)

Diluent: Buffer (mobile phase A) and Acetonitrile (90:10)

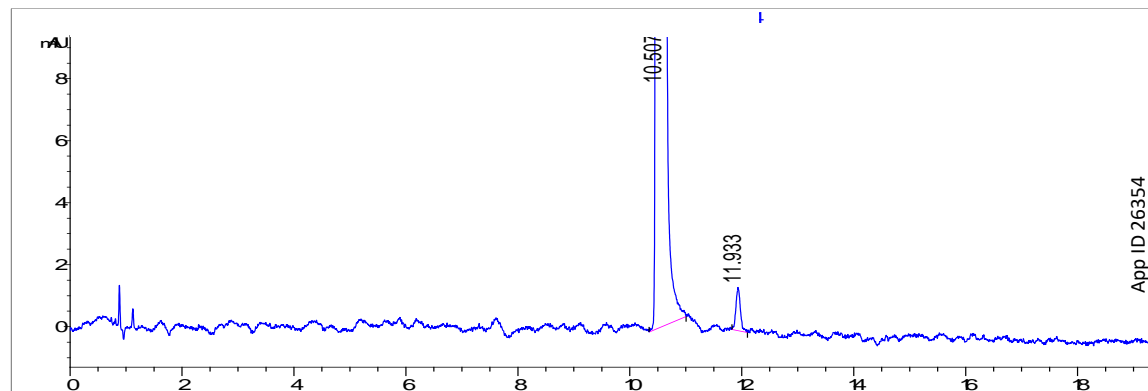
Sample: As indicated in chromatograms

Standard Solution for Organic Impurities on Gemini 3 μ m C18



Standard Solution
 (0.5 μ g/mL of Alosetron Hydrochloride RS in buffer and acetonitrile, 90:10)

System Suitability Solution for Organic Impurities on Gemini 3 μ m C18



System Suitability Solution
 (0.05 mg/mL of USP Alosetron Hydrochloride RS and 0.5 μ g/mL of USP Alosetron Related Compound A RS in buffer and acetonitrile, 90:10)



Table 2. Summary of Results, Organic Impurities

Analyte	Retention Time, min	Resolution (NLT 3) (System Suitability solution)	% RSD (n = 6) (NMT 5.0 %) (Standard Solution)	Signal-to-Noise (NLT 10) (Sensitivity Solution)
Alosetrol Hydrochloride	10.507	--	1.3	24.7
Alosetrol Related compound A	11.933	9.8	1.7	N/A

Order Information

Gemini 3 μ m Analytical Columns (mm)

Phases 75 x 4.6

C18 [00C-4439-E0](#)

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