

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

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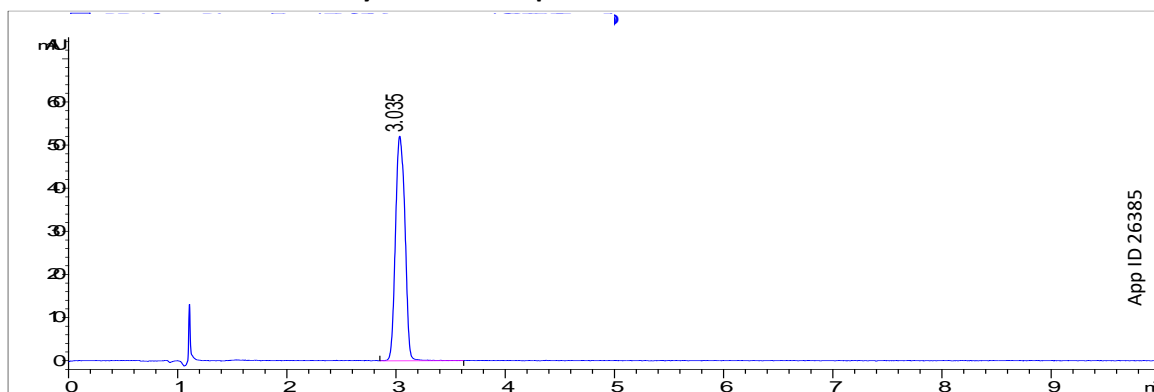
Overview

Alosetron hydrochloride, a potent and selective antagonist of the serotonin 5-HT₃ receptor, is the active pharmaceutical ingredient in Lotronex® tablets (Sebela Pharmaceuticals), and there are several generic versions of Alosetron tablets available on the market. This application note for the LC-UV assay and organic impurities for Alosetron tablets is based on the official 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 tablets, 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: 15 µL
System: Agilent® 1260 (binary)
Diluent: 1 mL H₃PO₄ in 1 Liter of Water
Sample: Alosetron (0.0115 mg/mL)

Standard Solution for Assay on Gemini 3 µm C18



Standard Solution
(0.0115 mg/mL of USP
Alosetron Hydrochloride RS in
diluent)

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

Analyte	Retention Time, min	Symmetry Factor (NMT 2.0)	% RSD (n = 6) (NMT 2 %)
Alosetron Hydrochloride	3.035	1.13	0.25



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

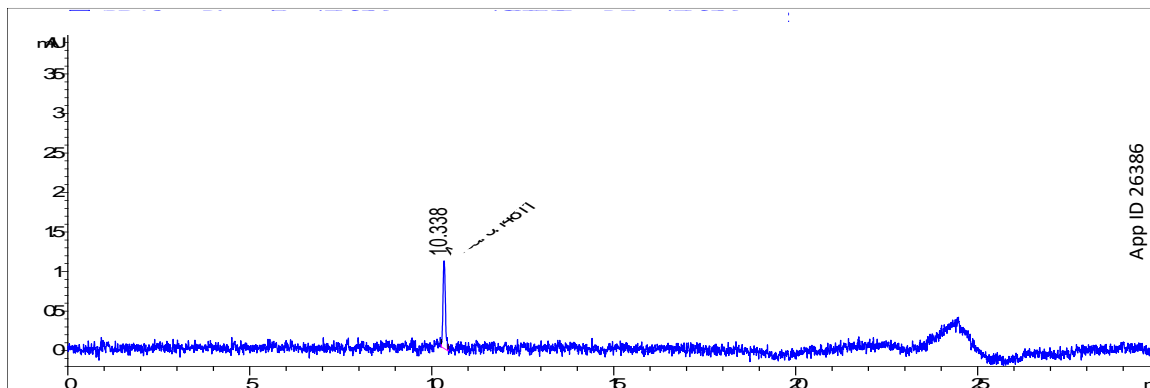
Detector: UV @ 220 nm

Injection: 5 μ L

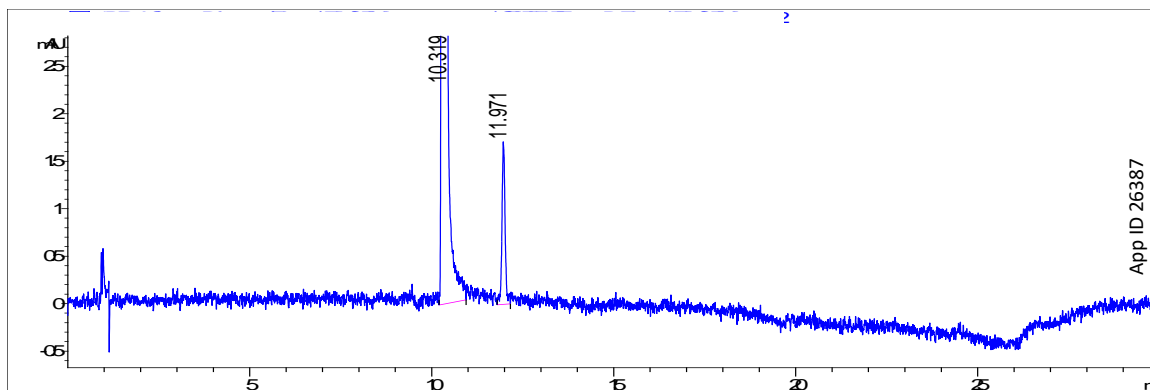
System: Agilent® 1260 (binary)

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
(0.46 μ g/mL of Alosetron Hydrochloride RS in diluent)

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

System Suitability Solution
(200 μ g/mL of USP Alosetron Hydrochloride RS and 0.5 μ g/mL of USP Alosetron Related Compound A RS in diluent)



Table 2. Summary of Results, Organic Impurities

Analyte	Retention Time, min	Resolution (NLT 7) (System Suitability solution)	% RSD (n = 6) (NMT 5.0 %) (Standard Solution)
Alosetrol Hydrochloride	10.319	--	0.27
Alosetrol Related compound A	11.971	12.3	3.95

Order Information

Gemini 3 μ m Analytical Columns (mm)

Phases 75 x 4.6

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

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