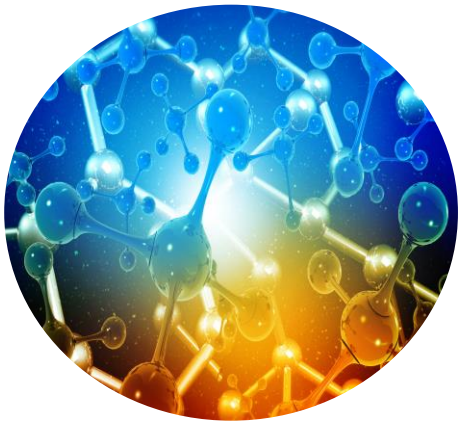

USP Albuterol Inhalation Solution: Assay on Kinetex® 2.6 µm C18 and Organic Impurities on Kinetex® 1.7 µm XB-C18

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Overview

Albuterol Inhalation Solution is an isotonic sterile solution of albuterol sulfate; albuterol (aka Salbutamol) is a bronchodilator used to treat or prevent bronchospasm in people with reversible obstructive airway disease. This application note for the LC-UV assay and organic impurities for Albuterol inhalation solution is based on the proposed USP monograph published in PF45(3). The mobile phase and standard solution for the assay was prepared in accordance with the proposed USP monograph, which is not yet official. The proposed monograph was validated using Kinetex 2.6 µm C18 for the assay, and validated using Kinetex 1.7 µm XB-C18 for the organic impurities.

USP reference standards were used to prepare the standard solutions and system suitability solution, and mobile phase was prepared per the USP draft monograph for Albuterol inhalation solution.

LC-UV Conditions (Assay)

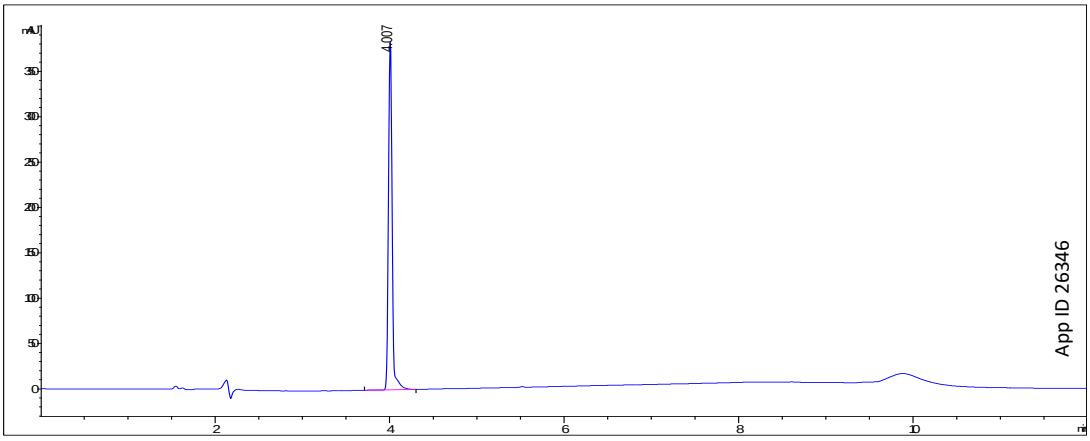
Column: Kinetex 2.6 µm C18 (00F-4462-E0)
Dimension: 150 x 4.6 mm
Mobile Phase: A = 3.4 g/L of monobasic potassium phosphate and 1.1 g of sodium 1-heptanesulfonate in water. Adjust with phosphoric acid to pH 2.1.
B = Acetonitrile

Gradient:

Time (min)	% B
0	15
6	40
7.5	40
7.6	15
11	15

Flow Rate: 0.75 mL/min
Temperature: 37 °C
Detector: UV @ 210 nm
Injection: 10 µL
System: Agilent® 1290 Infinity II (binary)
Sample: As indicated in chromatogram

Standard Solution for Assay on Kinetex 2.6 µm C18



Standard Solution
(0.1 mg/mL of USP Albuterol Sulfate RS (equivalent to 0.08 mg/mL of albuterol) in 0.01N HCl)

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

Analyte	Retention Time, min	Symmetry Factor (NMT 1.7)	% RSD (n = 6) (NMT 1.0 %)
Albuterol sulfate	4.007	1.08	0.16

LC-UV Conditions (Organic Impurities)

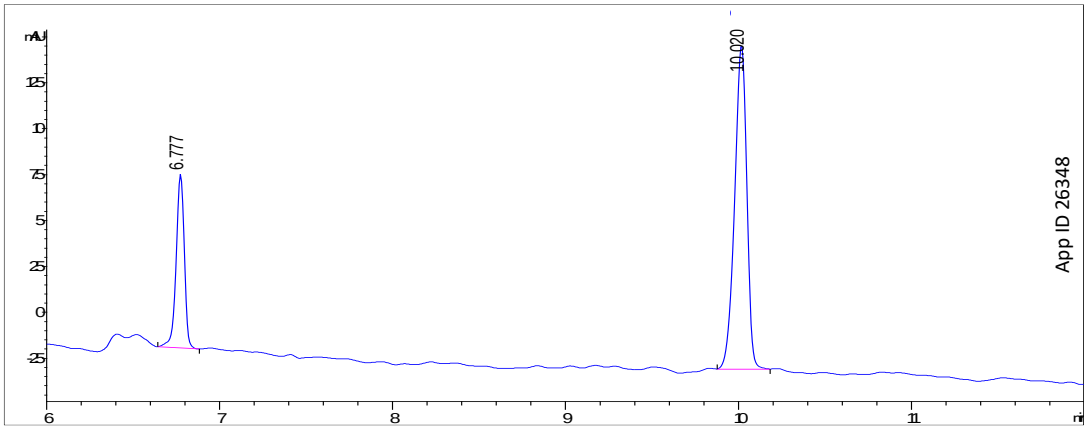
Column: Kinetex 1.7 µm XB-C18 (00F-4498-AN)
Dimension: 150 x 2.1 mm
Mobile Phase: A = 3.4 g/L of monobasic potassium phosphate and 1.1 g of sodium 1-heptanesulfonate in water. Adjust with phosphoric acid to pH 2.1.
B = Acetonitrile

Gradient:

Time (min)	% B
0	5
2.5	7.5
5	15
18	19.5
26	36
26.5	50
27.5	50
27.6	5
34	5

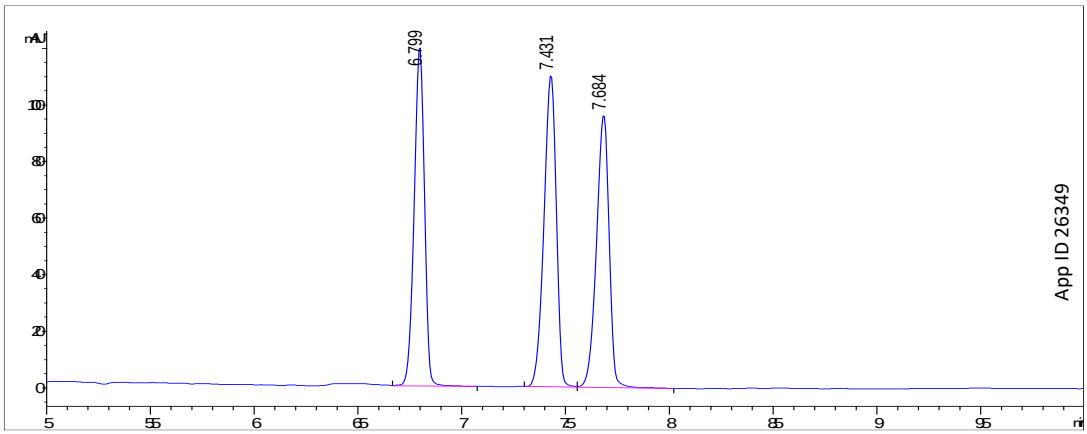
Flow Rate: 0.35 mL/min
Temperature: 37 °C
Detector: UV @ 210 nm
Injection: 10 µL
System: Agilent® 1290 Infinity II (binary)
Sample: As indicated in chromatograms

Standard Solution for Organic Impurities on Kinetex 1.7 µm XB-C18



Standard Solution
(1.25 µg/mL each of USP Albuterol Sulfate RS and USP Levalbuterol Related Compound D RS in 0.01N HCl)

System Suitability Solution for Organic Impurities on Kinetex 1.7 µm XB-C18



System Suitability Solution
(0.05 mg/mL each of USP Albuterol Sulfate RS, USP Albuterol Related Compound I RS, and USP Levalbuterol Related Compound H RS in 0.01N HCl)

Table 2. Summary of Results, Organic Impurities (Standard Solution)

Analyte	Retention Time, min	Symmetry Factor (NMT 2.0)	% RSD (n = 6) (NMT 5.0 %)	Signal-to-Noise (NLT 10)
Albuterol sulfate	6.777	1.03	1.3	15
Levalbuterol Related Compound D	10.020	0.96	1.7	50

Table 3. Summary of Results, Organic Impurities (System Suitability Solution)

Analyte	Retention Time, min	Resolution (NLT 2.0)
Albuterol sulfate	6.805	
Albuterol Related Compound I	7.434	5.9
Albuterol Related Compound H	7.687	2.2

Order Information

Kinetex 2.6 µm Analytical Columns (mm)	
Phases	**150 x 4.6**
C18	00F-4462-E0

Kinetex 1.7 µm Analytical Columns (mm)	
Phases	**150 x 2.1**
XB-C18	00F-4498-AN

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