

APPLICATIONS

USP Butamben Assay and Organic Impurities by LC-UV using the Kinetex® 5 µm XB-C18 Core-Shell HPLC Column

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Overview

Butamben is a local anesthetic and is the ester of 4-aminobenzoic acid and butanol. This application note for the LC-UV assay and organic impurities for Butamben is based on the official USP method, which was developed utilizing a Kinetex 5 µm XB-C18 100 x 2.1 mm core-shell LC column, as indicated in the USP Chromatographic Columns¹. The standard and system suitability solutions for the assay and organic impurities were prepared in accordance with the USP monograph.

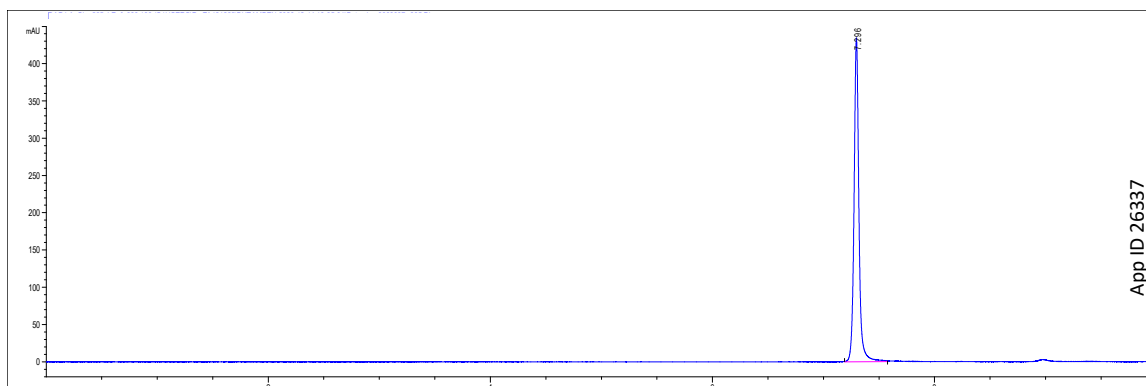
The system suitability requirements for the assay: peak symmetry NMT 2.0 for butamben, and RSD NMT 0.73 % for butamben were easily achieved. In order to meet the system suitability requirements for the organic impurities: resolution NLT 10 between the amino-benzoic acid and butamben peaks, and RSD NMT 5% for each peak corresponding to aminobenzoic acid and butamben, the injection volume was increased to 5 µL.

1. USP Chromatographic Columns
(<https://www.uspchromcolumns.com/chrom/display>).

LC-UV Conditions

Column:	Kinetex 5 µm XB-C18	
Dimension:	100 x 2.1 mm	
Part No.:	00D-4605-AN	
Mobile Phase:	A: 0.1% formic acid in Water B: 0.1% formic acid in Acetonitrile	
Gradient:	Time (min)	% B
	0	10
	1	10
	6	50
	8.5	50
	8.6	90
	10	90
Flow Rate:	0.4 mL/min	
Temperature:	30 °C	
Detector:	UV @ 285 nm	
Injection:	1 µL (assay); 5 µL (impurities)	
System:	Agilent® 1260 Infinity (binary)	
Sample:	As indicated in each chromatogram	

Figure 1: Standard Solution for Assay (0.2 mg/mL Butamben RS)

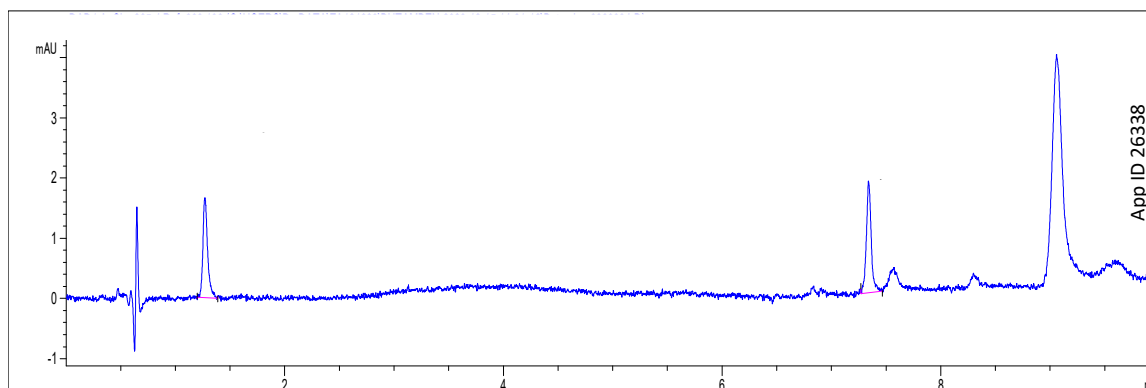


Sample: 1. Butamben

Results – Standard Solution (Assay)

Kinetex 5 μm XB-C18			
Analyte	Retention Time, min	Symmetry Factor, NMT 2.0	RSD, NLT 0.73% (n = 5)
Butamben	7.30	1.10	0.36%

Figure 2: Standard Solution for Organic Impurities (0.2 μg/mL each of Butamben RS and Aminobenzoic Acid RS)



Sample: 1. Aminobenzoic acid
2. Butamben

Results – Standard Solution (Organic Impurities)

Kinetex 5 μm XB-C18			
Analyte	Retention Time, min	Resolution, NLT 10	RSD, NMT 5% (n = 6)
Aminobenzoic acid	1.26		3.13
Butamben	7.34	83	2.96

APPLICATIONS

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