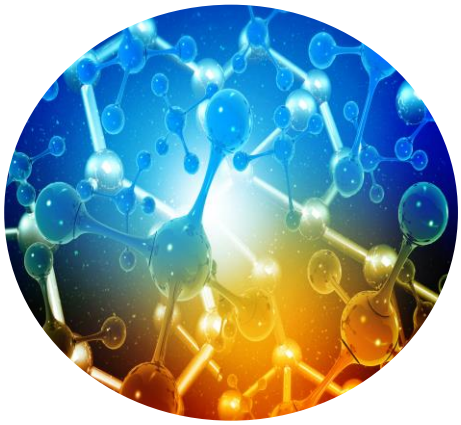

Purity of Trihexyphenidyl Hydrochloride Tablets per USP Monograph using Kinetex® 2.6 µm XB-C18 Column

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Overview

Trihexyphenidyl Hydrochloride is an anticholinergic drug used to inhibit the action of acetylcholine. The development of a quick and efficient analysis of Trihexyphenidyl Hydrochloride and its related organic impurities poses significant interest. In this application note, we report the separation of Trihexyphenidyl Hydrochloride using the Kinetex XB-C18 column according to the USP monograph for Trihexyphenidyl Hydrochloride tablets.

System suitability per USP Monograph for the Trihexyphenidyl Hydrochloride Assay is a tailing factor no more than (NMT) 3.0 and a percent relative standard deviation (%RSD) of NMT 1.0 %. The separation of Trihexyphenidyl Hydrochloride was achieved with a tailing factor of 2.52 and a %RSD of 0.67 (**Figure 1**). This met both system suitability requirements for the Assay.

System suitability per USP Monograph for the Trihexyphenidyl Hydrochloride Organic Impurities is a resolution no less than (NLT) 2 between Trihexyphenidyl Hydrochloride and Related Compound A, as well as a %RSD NMT 2.0 and a signal to noise ratio (S/N) of NLT 50. The separation of Trihexyphenidyl Hydrochloride and Related Compound A was achieved with a resolution of 29.85 (**Figure 2**). The %RSD for Trihexyphenidyl Hydrochloride Organic Impurities was 1.08 and a S/N ratio of 51.70 (**Figure 3**). All requirements for System Suitability for Organic Impurities were met.

All solutions were prepared as indicated in the USP Monograph for Trihexyphenidyl Hydrochloride Tablets. USP Trihexyphenidyl Hydrochloride RS (Catalog No. 1687006) and USP Trihexyphenidyl Hydrochloride Related Compound A RS (Catalog No. 1687017) were purchased from USP.

LC-UV Conditions

Column: Kinetex 2.6 µm XB-C18
Dimension: 100 X 2.1 mm
Part No.: 00D-4496-AN
Mobile Phase: A: 1.4 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 4.0. Pass the solution through a suitable filter of 0.22 µm pore size.
B: 0.5 mL of phosphoric acid in 1 L of acetonitrile.

Gradient:

Time (min)	%B
0	5
20	40
22	40
22.1	5
24	5

Flow Rate: 0.3 mL/min
Injection Volume: 3 µL
Temperature: 30 °C
Detector: UV @ 210 nm
System: Waters® ACQUITY® UPLC I-Class

Table 1. Preparation of Solutions

Solution	Composition
Diluent	Methanol/water (80:20, v/v)
Standard Solution – Assay	0.1 mg/mL of USP Trihexyphenidyl Hydrochloride RS in Diluent.
System Suitability Solution – Organic Impurities	0.1 mg/mL of USP Trihexyphenidyl Hydrochloride RS and 0.1 mg/mL of USP Trihexyphenidyl Related Compound A RS in Diluent.
Standard Solution – Organic Impurities	0.001 mg/mL of USP Trihexyphenidyl Hydrochloride RS in Diluent.

Have questions or want more details on implementing this method? We would love to help!
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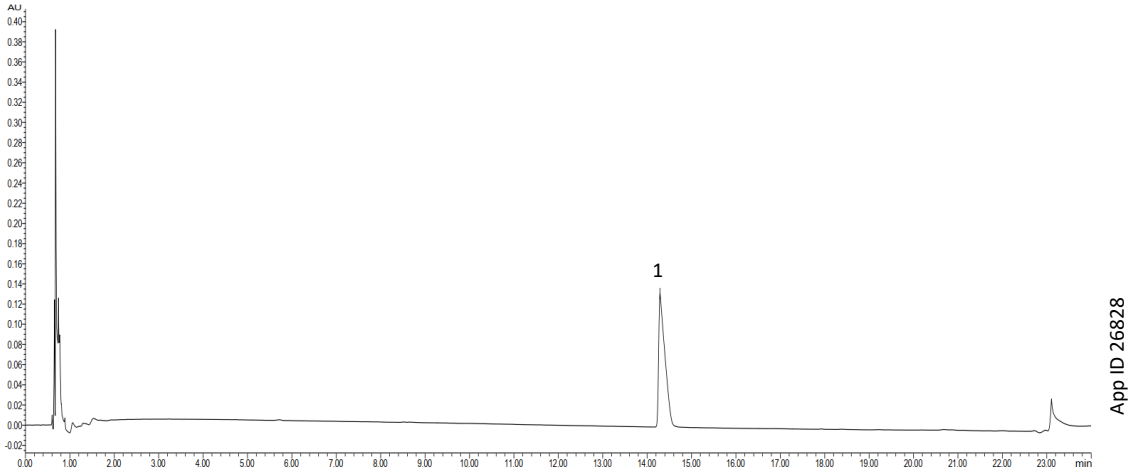
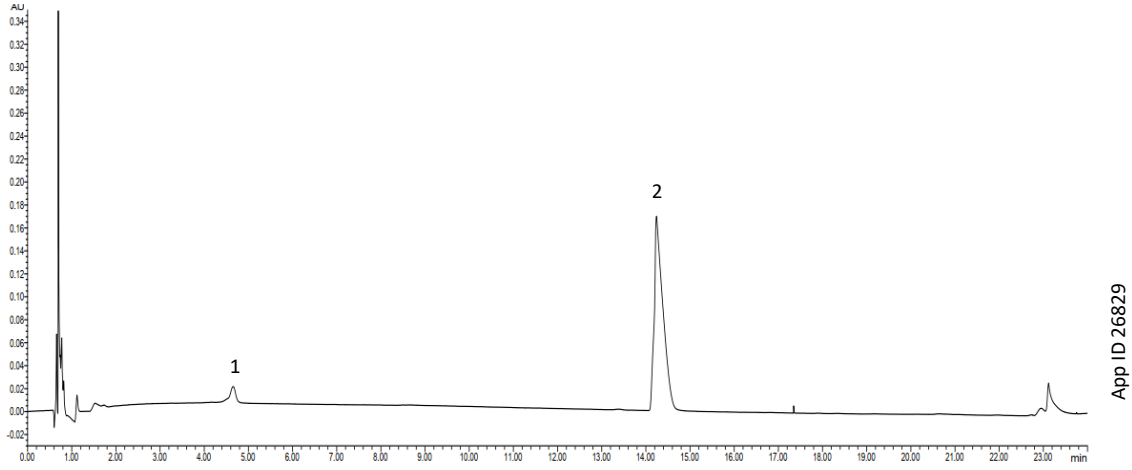
Figure 1. Standard Solution - Assay



Peak	Analyte	Area %RSD	Tailing Factor
1	Trihexyphenidyl Hydrochloride	0.67	2.52
Number of injections = 6			

Figure 2. System Suitability Solution – Organic Impurities



Peak	Analyte	Resolution
1	Trihexyphenidyl Hydrochloride Related Compound A	-
2	Trihexyphenidyl Hydrochloride	29.85

Number of injections = 6

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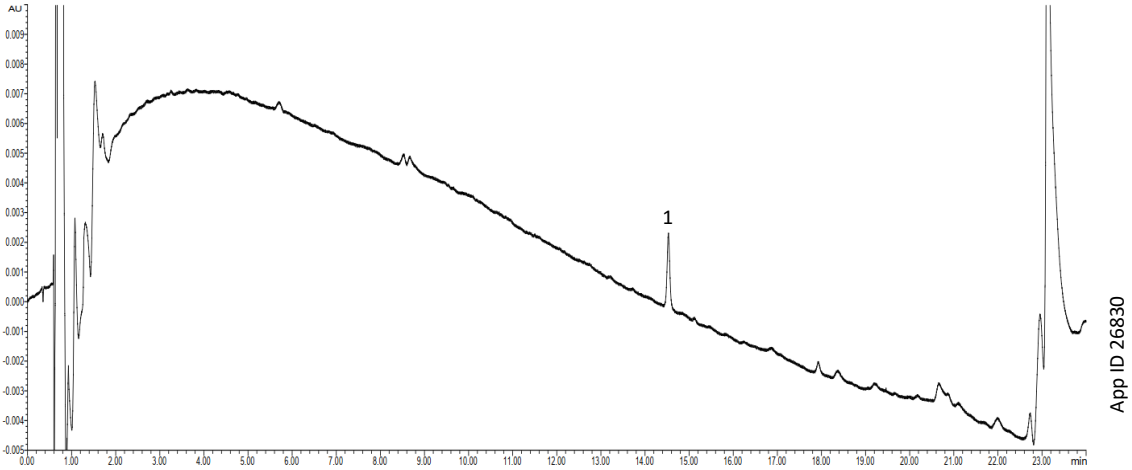
Figure 3. Standard Solution – Organic Impurities



Peak	Analyte	Area %RSD	Signal-to-Noise Ratio
1	Trihexyphenidyl Hydrochloride	1.08	51.70
Number of injections = 6			

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