

## Liquid Chromatography

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## HPLC Analysis of Olopatadine Hydrochloride Using a Quasar C8 Column in Accordance with the United States Pharmacopeia

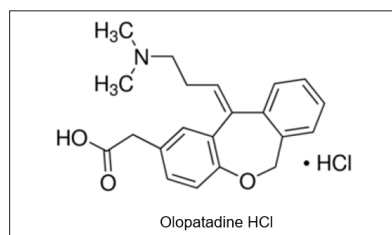


Figure 1. Structure of Olopatadine.

### Introduction

Olopatadine hydrochloride is an antihistamine used to treat itching and redness in the eyes due to allergies. It is commonly available over the counter in several forms

such as eye drops and as a nasal spray. Olopatadine was used in 1996 and 2002 to treat allergic conjunctivitis.<sup>1</sup> In 2017, it was the 290<sup>th</sup> most prescribed medication in the United States, with more than one million prescriptions.<sup>2</sup>

This application brief describes the use of a PerkinElmer Quasar™ C8 (150 x 4.6 mm, 5 μm) column in accordance with the official olopatadine hydrochloride USP monograph.<sup>3</sup>

## Experimental Conditions

### Method Parameters

All HPLC method parameters are shown in Table 1.

Table 1. HPLC method parameters.

<b>Instrument</b>	PerkinElmer Flexar™ with UV/Vis Detector			
<b>Quasar C8</b>	150 mm	4.6 mm	5 µm	N9308880
<b>Mobile Phase</b>	A: Buffer (Potassium phosphate monobasic, triethylamine, water, phosphoric acid, pH 3.0) B: Acetonitrile 72% A 28% B			
<b>Flow Rate</b>	1.0 mL/min			
<b>Wavelength</b>	299 nm			
<b>Injection Volume</b>	30 µL			
<b>Analyte</b>	Olopatadine Hydrochloride			

### Solvents and Samples

All solvents were HPLC grade and samples were filtered using a 0.45 µm nylon filter P/N: 02542903.

A standard solution of USP Olopatadine hydrochloride (0.1 mg/mL) was prepared using mobile phase as diluent.

The buffer solution was prepared by dissolving 13.6 g of potassium phosphate monobasic in 1000 mL of water. 1 mL of triethylamine was then added and the pH was adjusted to 3.0 using dilute phosphoric acid.

### Results and Discussion

The USP monograph specifies the use of an L7 column (150 x 4.6 mm, 5 µm). This is defined as octylsilane chemically bonded to totally porous or superficially porous silica particles, 1.5–10 µm in diameter, or a monolithic silica rod. The Quasar C8 column

complies with the USP monograph and is ideal for the separation of olopatadine hydrochloride as can be seen in the results, Table 2.

The analysis of olopatadine hydrochloride was carried out using a Quasar C8 (150 x 4.6 mm, 5 µm) column (P/N: N9308880) in under 20 minutes Figure 2. The USP monograph requires that the relative standard deviation (RSD) of five replicate injections be no more than 0.73 % and that the tailing factor be no more than 2.0. The Quasar C8 column met both requirements (Table 2) and gave an efficient separation (78,020 plates per meter (N/m) calculated using the tangential method). This is due to Quasar's ultra-high purity silica and its optimized ligand bonding technology.

Table 2. Results Summary.

Suitability Parameter	Quasar	USP Requirement
Peak Area RSD* (%)	0.37	< 0.73
Tailing Factor (5% Peak Height)	1.49	< 2.0

\*RSD calculated from five successive replicates

### Conclusions

- Analysis of olopatadine hydrochloride was completed in under 20 minutes using a Quasar C8 column.
- The Quasar C8 facilitates repeatable separations for olopatadine hydrochloride, meeting all suitability requirements in the USP monograph.
- An efficient separation of olopatadine was carried out with an efficiency of 78,020 N/m which is due to Quasar's optimized ligand bonding technology and ultra-high purity silica base.

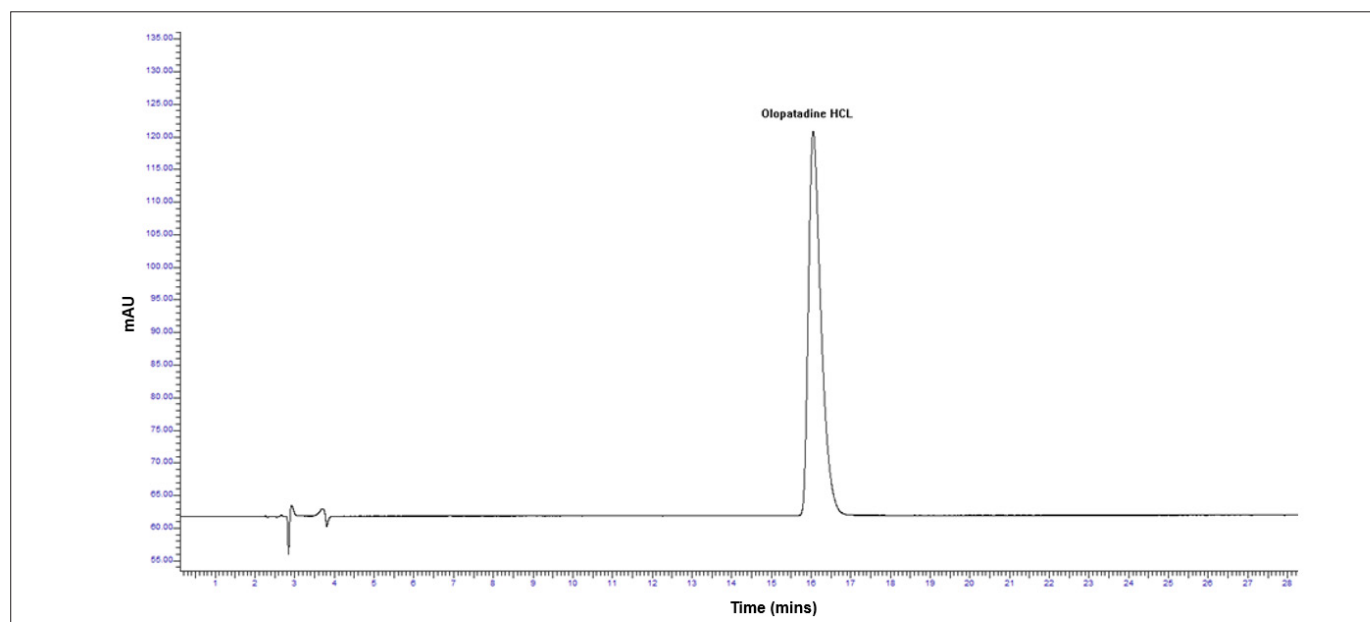


Figure 2. Analysis of Olopatadine hydrochloride on a Quasar C8 column.

## References

1. Drug bank database, <https://go.drugbank.com/drugs/DB00768>, (accessed 18/12/2020).
2. ClinCalc website, <https://clincalc.com/DrugStats/Drugs/Olopatadine>, (accessed 18/12/2020).
3. Olopatadine hydrochloride USP monograph, [https://online.uspnf.com/uspnf/document/1\\_GUID-7223EC10-ED8A-4D85-8568-F6389224087B\\_4\\_en-US?source=Search%20Results&highlight=olopatadine](https://online.uspnf.com/uspnf/document/1_GUID-7223EC10-ED8A-4D85-8568-F6389224087B_4_en-US?source=Search%20Results&highlight=olopatadine), (accessed 18/12/2020).

## Consumables Used

Component	Description	Part Number
Column	Quasar C8 (150 x 4.6 mm, 5 µm)	N9308880
HPLC Vials	2 mL Amber 9 mm Screw Top Vial with Write-on Patch and Fill Lines (100/pack)	N9307802
HPLC Vial Caps	9 mm Screw Top Blue (Polypropylene) Cap with PTFE/Silicone Pre-Slit Septa (100/pack)	N9306203
Syringes	Syringe 1 mL BD Luer-Lok Disposable (100/pack)	02542890
Syringe Filters	0.45 µm Nylon Filter, 13 mm Diameter	02542903
PEEK Fittings	Finger-tight for 1/16" OD PEEK Tubing	09920513