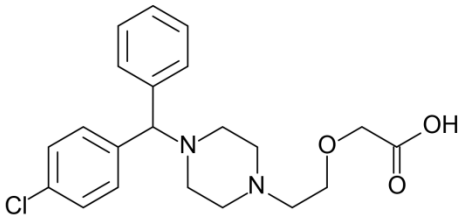
Cetirizine Hydrochloride (USP)

– Tablets



Cetirizine is a second-generation antihistamine.
Used in the treatment of hay fever, allergies, and angioedema
Cetirizine is a major metabolite of hydroxyzine, and a racemic selective H1 receptor antagonist.
Commercial brand names Zyrtec, Reactine...

Drug dissolution testing has been carried out following the experimental conditions in the USP37-NF32 monograph for Cetirizine Hydrochloride Tablets (using an isocratic HPLC method with RP-18 endcapped columns and thus scalable). A 250x4.6 mm column is prescribed with 5 µm L1 packing operating at 1.0 mL/min. To improve sample throughput we have transferred this method to a 100x4.6 mm long monolithic column.

The new method turned out to be faster, having improved chromatographic resolution, lower column backpressure, and still meeting all method performance criteria compared to the prescribed column.

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Dissolution <711>

HPLC

Test 1
Medium: Water; 900 mL, degassed
Apparatus 2: 50 rpm
Time: 30 min

Buffer: 2.9 mL/L of phosphoric acid in water
Mobile phase: Acetonitrile and Buffer (2:3)
Standard solution: 11 µg/mL of USP Cetirizine Hydrochloride RS in water.
(This solution can be stored for 48 h at room temperature.)
Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45 µm pore size.

Chromatographic system (see Chromatography 621, System Suitability.)
Detector: UV 230 nm
Column: 250x4.6 mm column; 5-µm packing L1
Flow rate: 1 mL/min
Injection volume: 50 µL
Run time: 1.3 times the retention time of cetirizine

System suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0%

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) dissolved:

Result = (rU/rS) × (CS/L) ×V× 100

rU = peak response from the Sample solution
rS = peak response from the Standard solution
CS = concentration of USP Cetirizine Hydrochloride RS in the Standard solution (mg/mL)
L = label claim (mg/Tablet)
V = volume of Medium, 900 mL

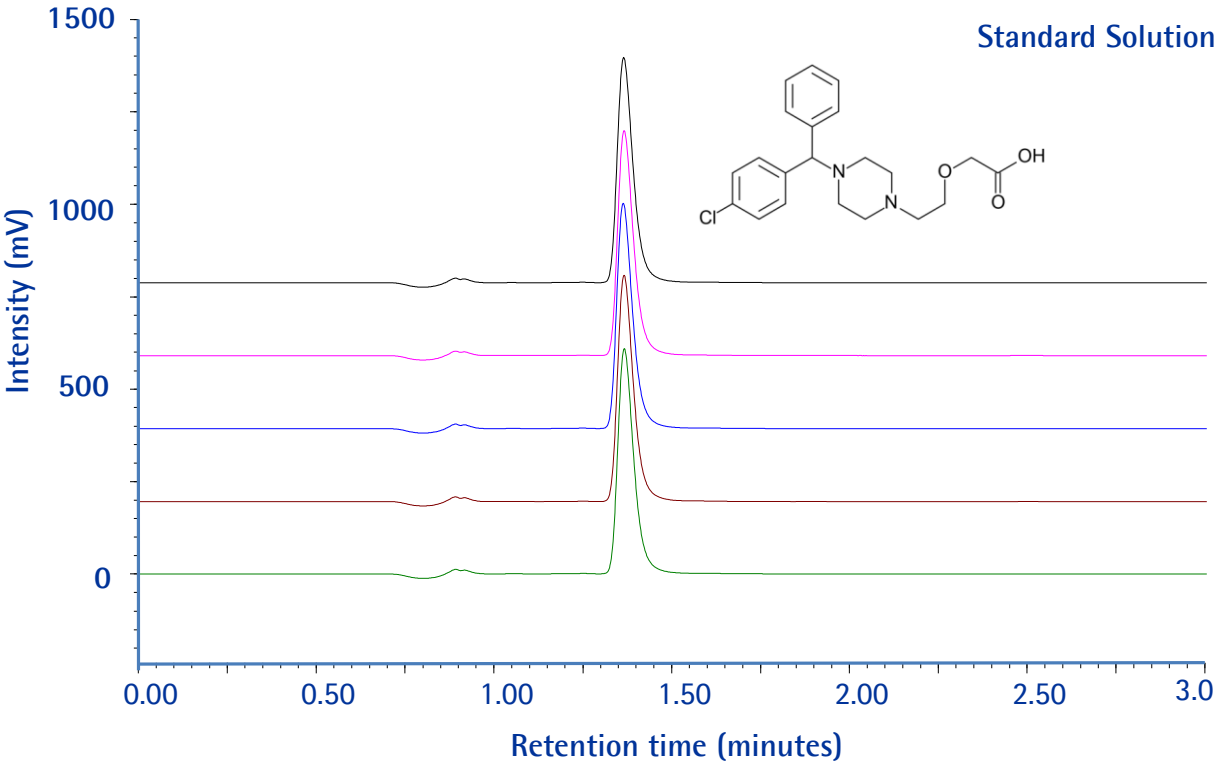
Tolerances: NLT 80% (Q) of the labeled amount of **cetirizine hydrochloride** ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

Cetirizine Hydrochloride Tablets (USP)

– Chromolith® HighResolution RP-18 endcapped

Chromatographic Conditions

Column:	Chromolith® HighResolution RP-18e, 100x4.6 mm	1.52022.0001
Injection:	10 µl	
Detection:	UV 220 nm	
Cell:	10 µL	
Flow Rate:	1 mL/min	
Mobile Phase:	Buffer: 2.9 mL/L of phosphoric acid in water. Mix acetonitrile and buffer 2:3 (v/v)	
Temperature:	35 °C	
Diluent:	Water 900 ml , 50 rpm for 30 minutes	
Sample soltion:	Filter the solution through 0.45 µm Millex HV Filter (PVDF Filter)	
Pressure Drop:	92 Bar(1334psi)	



Chromatographic Data :

No.	Compound	Retention Time (min)	Tailing factor	Theoretical Plate
1	Cetrizine Hydrochloride	1.4	1.4	4610

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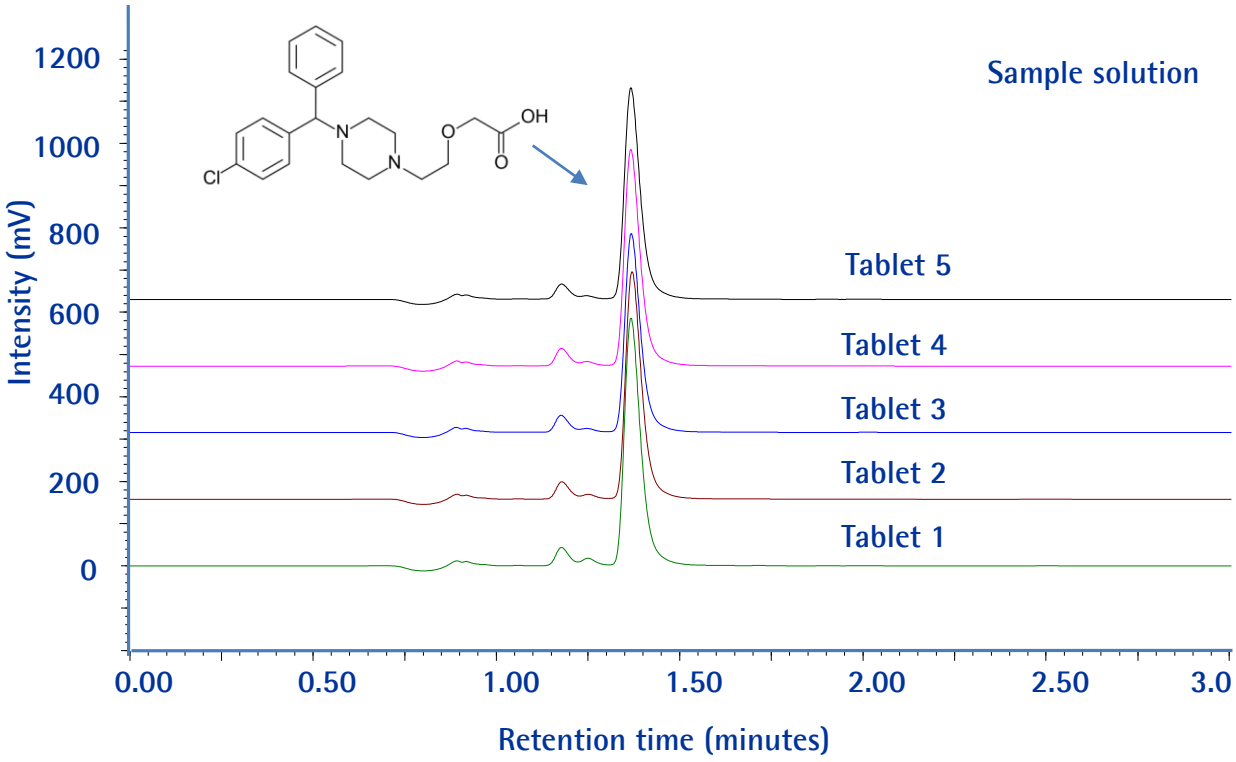
– Chromolith® HighResolution RP-18 endcapped



Result (%) = (rU/rS) ×CS× V × D × (100/L)

Peak Response		CS (Weight of Std)	V Media Volume	L* 100/Label claim	Dissolution
RU	RS	(mg/mL)	(mL)		(%)
1922106	1536929	0.012	900	8	108.0
1933635	1582924	0.012	900	8	105.5
1933035	1448987	0.012	900	8	115.3
1918776	1680700	0.012	900	8	98.6
1935359	1831921	0.012	900	8	91.3
Average					104±9

* Label claim of the Cetrizine HCl Tablet = 12.5 mg and D = 1 (Dilution Factor)