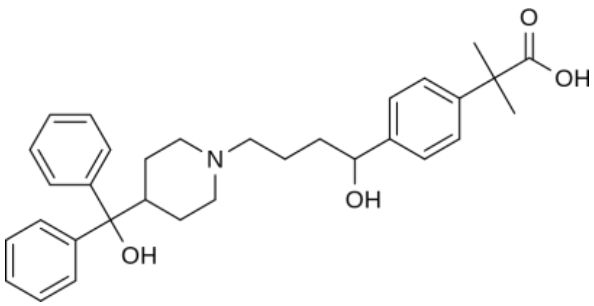
Fexofenadine Hydrochloride (USP)
– Tablets



Fexofenadine is an antihistamine pharmaceutical drug used in the treatment of allergy symptoms, such as hay fever, nasal congestion, and urticaria.

Common trade names are: Allegra, Fexidine, Telfast, Fastofen, Tilfur, Vifas, Telfexo, Allerfexo.

The current USP monograph method for dissolution testing of Fexofenadine tablets specifies the use of a 100x4.6 mm column with L1 (C18) packing as stationary phase. No particle size is mentioned wherefore the ratio must be calculated using the largest particle size consigned in the USP definition of the column, alternatively to comply with the system suitability criteria and provide adequate efficiency and resolution.

We have transferred this method to a monolithic column and the following pages illustrate that the acceptance criteras are being met for Fexofenadine dissolution Test 1 by following the experimental conditions in the USP37-NF32 monograph.

The new method is faster, having improved chromatographic resolution, and with lower column backpressure compared with a particle packed column.

Fexofenadine Hydrochloride (USP)
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Dissolution <711> HPLC

Test 1
Medium: 0.001 N hydrochloric acid; 900 mL, deaerated
Apparatus 2: 50 rpm
Time: 10 and 30 min

Determine the percentages of the labeled amount of $C_{32}H_{39}NO_4 \cdot HCl$ dissolved by using the following method.

Solution A: 1.0 g of monobasic sodium phosphate, 0.5 g of sodium perchlorate, and 0.3 mL of concentrated phosphoric acid in 300 mL of water.
Mobile phase: Acetonitrile and Solution A (7:3)
Standard solution: USP Fexofenadine Hydrochloride RS in Medium to obtain a solution having a known concentration similar to that expected for the solution under test. *[NOTE—A small amount of methanol, not exceeding 0.5% of the total volume, can be used to dissolve fexofenadine hydrochloride.]*
System suitability solution: 0.44 mg/mL of USP Fexofenadine Related Compound A RS in water. Transfer 1.0 mL of this solution into a vial, and add 40 mL of the Standard solution.
[*NOTE—A small amount of acetic acid, not exceeding 5% of the total volume, can be used to dissolve fexofenadine related compound A.]*
Sample solution: Pass portions of the solution under test through 0.45-µm pore size glass fiber filter.

Chromatographic system (See Chromatography 621 , System Suitability.)
Detector: UV 220 nm
Column: 100x4.6 mm column; packing L1
Flow rate: 1 mL/min
Injection size: 2–3 µg column load of fexofenadine hydrochloride

System suitability
Samples: Standard solution and System suitability solution
Suitability requirements
Resolution: NLT 2.0 between fexofenadine and fexofenadine related compound A, System suitability solution. Relative standard deviation: NMT 2.0%, Standard solution

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of $C_{32}H_{39}NO_4 \cdot HCl$ dissolved in the portion of Tablets taken:

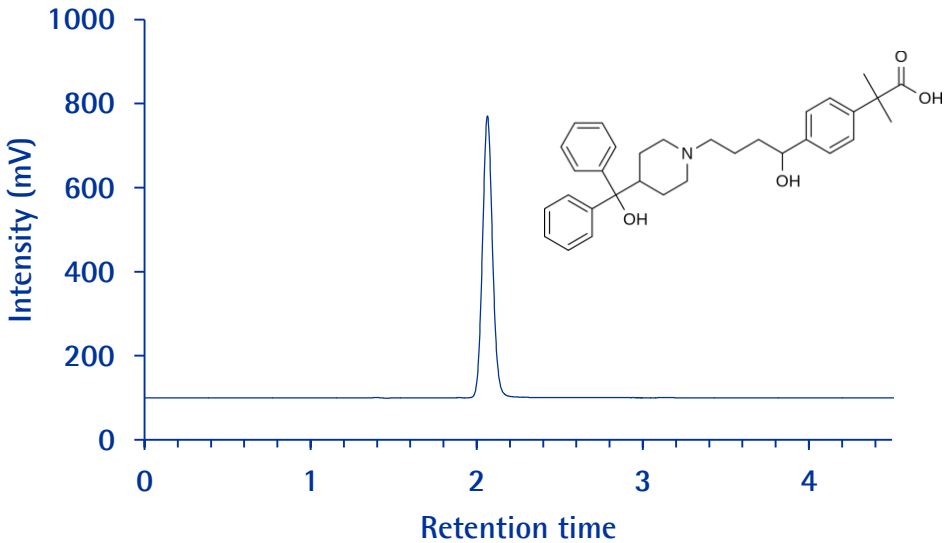
Result = (rU/rS) × (CS/L) × D × V × 100

Fexofenadine Tablet Dissolution (USP)

Chromolith® HighResolution RP-18 endcapped

Chromatographic Conditions

Column:	Chromolith® HighResolution RP-18 endcapped 100x4.6 mm	1.52022.0001
Injection:	20 µL	
Detection:	UV 220 nm	
Cell:	10 µL	
Flow Rate:	1.0 mL/min	
Medium:	0.001 N hydrochloric acid; 900 mL	
Apparatus	USP Apparatus 2 (Paddle)	
Time:	10 minutes and 30 minutes	
Buffer:	1.0 g of monobasic sodium phosphate, 0.5 g of sodium perchlorate, and 0.3 mL of concentrated phosphoric acid in 300 mL of water	
Mobile Phase :	Buffer: Acetonitrile (30:70) (v/v)	
Temperature:	Ambient	
Sample prep:	50 ppm (0.05 mg/mL) Fexofenadine in medium	
Pressure Drop:	43 Bar (1957 psi)	

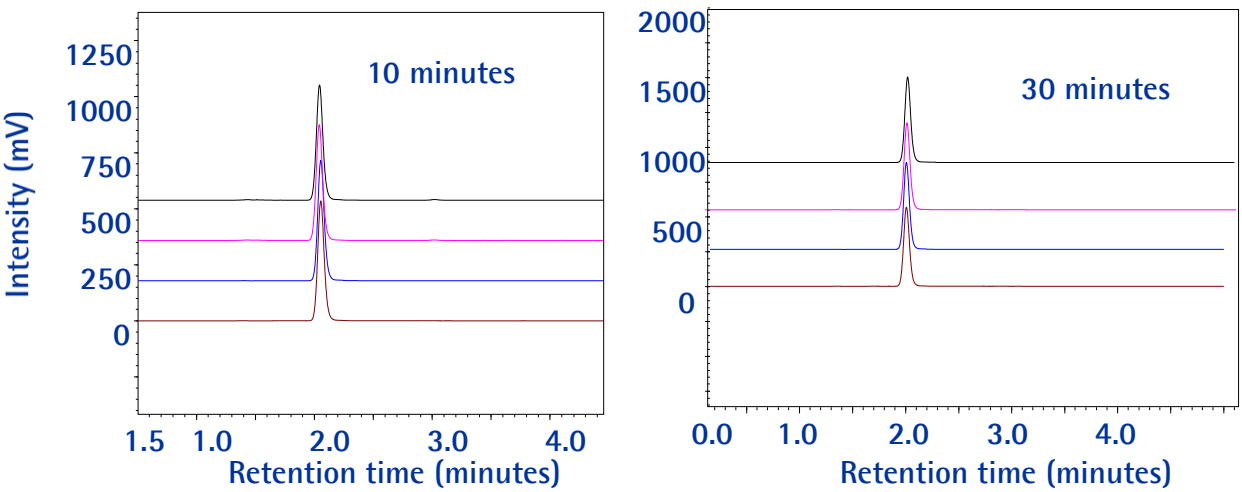


Chromatographic Data : Standard

No.	Compound	Retention Time (min)	Tailing factor	Theoretical plates
1	Fexofenadine	2.0	1.1	5592

Fexofenadine Tablet Dissolution (USP)

Chromolith® HighResolution RP-18 endcapped



Sample (area units)		Standard (area units)	[Standard] (mg/ml)	Label claim (mg/tablet)	Media (ml)	Dissolution (%)	
10 min	30 min					10 min	30 min
2108046	2439720	2804596	0.133	120	900	74.98	86.77
2101879	2444410					74.76	86.94
2069429	2438892					73.60	86.74
2073005	2436893					73.73	86.67
Average						**74.3**	**86.8**

Calculation of percentage Fexofenadine dissolved:

Result after 10 minutes = $(rU/rS) \times (CS/L) \times V \times 100$ = 74.3±0.6 % (n=4)

Result after 30 minutes = $(rU/rS) \times (CS/L) \times V \times 100$ = 86.8±0.1 % (n=4)

rU = peak response from the *Sample solution*
rS = peak response from the *Standard solution*
CS = concentration of the *Standard solution* (mg/mL)
L = label claim (mg/Capsule)
V = volume of *Medium*, 900 mL

Acceptance Criteria:

NLT 60% (Q) of the labeled amount of Fexofenadine is dissolved after 10 minutes;
NLT 80% (Q) of the labeled amount of Fexofenadine is dissolved after 30 minutes.