

APPLICATIONS

USP Assay (LC-UV) for Lopinavir and Ritonavir Tablets on Kinetex[®] 5 μ m C8 150 x 4.6 mm and Kinetex 2.6 μ m C8 100 x 4.6 mm LC Columns

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Overview

Ritonavir and Lopinavir are antiretroviral drugs which have been used successfully for the treatment and prevention of HIV/AIDS. They are currently being studied in combination with interferon beta-1b as a triple anti-viral therapy for treatment of COVID-19.

This application for the LC-UV assay of Lopinavir and Ritonavir tablets is based on the official USP method, utilizing a fully porous 5 μ m C8 150 x 4.6 mm column. Standard solution and system suitability solution were prepared in accordance with the USP monograph.

LC-UV Conditions

Column:Kinetex 5 μm C8Dimension:150 x 4.6 mmPart No:00F-4608-E0Mobile Phase:Acetonitrile/Methanol/
Tetrahydrofuran/Buffer
(175:100:100:625)
Buffer: 4.1 g/L of monobasic potassium
phosphate in waterFlow Rate:1.5 mL/minTemperature:40 °CDetector:UV @ 215 nmInjection:50 μLRun Time:90 minutesSample:1. Ritonavir
2. Lopinavir







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LC-UV Conditions

Column:	Kinetex [®] 2.6 μm C8			
Dimension:	100 x 4.6 mm			
Part No.:	<u>00D-4497-E0</u>			
Mobile Phase:	Acetonitrile/Methanol/			
	Tetrahydrofuran/Buffer			
	(175:100:100:625)			
	Buffer: 4.1 g/L of monobasic potass			
	phosphate in water			
Flow Rate:	1.5 mL/min			
Temperature:	40 °C			
Detector:	UV @ 215 nm			
Injection:	50 μL			
Run Time:	50 minutes			
Sample:	1. Ritonavir			
	2. Lopinavir			



System Suitability						
Compound	Resolution NLT 1.5	Tailing Factor 0.8 – 1.2 for Ritonavir	Theoretical Plates More than 5000 for Ritonavir	RSD (peak area, 5 replicates) NMT 2.0%		
Ritonavir		1.05	15,985	3.3		
Lopinavir	7.1	1.05	16,319	2.2		

LC-UV Conditions

Column:	Luna® 5 μm C8			
Dimension:	150 x 4.6 mm			
Part No.:	<u>00F-4249-E0</u>			
Mobile Phase:	Acetonitrile/Methanol/			
	Tetrahydrofuran/Buffer			
	(175:100:100:625)			
	Buffer: 4.1 g/L of monobasic potassium			
	phosphate in water			
Flow Rate:	1.5 mL/min			
Temperature:	40 °C			
Detector:	UV @ 215 nm			
Injection:	50 μL			
Run Time:	90 minutes			
Sample:	1. Ritonavir			
	2. Lopinavir			



System Suitability						
Compound	Resolution NLT 1.5	Tailing Factor 0.8 – 1.2 for Ritonavir	Theoretical Plates More than 5000 for Ritonavir	RSD (peak area, 5 replicates) NMT 2.0%		
Ritonavir		1.02	10,005	3.88		
Lopinavir	5.9	1.00	9804	1.36		



PLICATIONS

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