



Separation of Quinapril Hydrochloride and its Organic Impurities per USP Monograph

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Overview

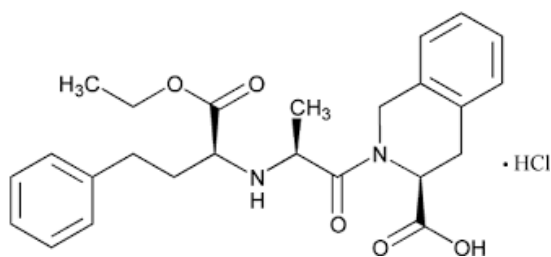
Quinapril Hydrochloride is a prodrug and non-sulphydryl angiotensin converting enzyme (ACE) inhibitor with antihypertensive activity. The development of a quick and efficient analysis of Quinapril Hydrochloride and its related organic impurities is of interest for drug manufacturers. In this application note, we report the separation of Quinapril Hydrochloride and its related organic impurities using a Luna 5 μm CN column according to the USP monograph for Quinapril Hydrochloride.

System suitability per USP Monograph for the Quinapril Hydrochloride Assay is resolution no less than (NLT) 1.75 between Quinapril Hydrochloride and Quinapril related compound A and resolution NLT 3.5 between Quinapril Hydrochloride and Quinapril related compound B, a tailing factor no more than (NMT) 2.0 for Quinapril Hydrochloride, and a percent relative standard deviation (%RSD) of NMT 0.55 % for Quinapril Hydrochloride. All system suitability requirements for Quinapril Hydrochloride Assay were met with the Luna 5 μm CN column.

System suitability per USP Monograph for the Quinapril Hydrochloride Organic Impurities is resolution no less than (NLT) 1.75 between Quinapril Hydrochloride and Quinapril related compound A and resolution NLT 3.5 between Quinapril Hydrochloride and Quinapril related compound B, a percent relative standard deviation (%RSD) of NMT 2.0 % for Quinapril Hydrochloride, and a Signal-to-Noise (S/N) NLT 10. These requirements for System Suitability for Organic Impurities were met using a Luna 5 μm CN column.

All solutions were prepared as indicated in the USP Monograph for Quinapril Hydrochloride. USP Quinapril Hydrochloride RS (Catalog No. 1593401), USP Quinapril Related Compound A RS (Catalog No. 1593412), and USP Quinapril Related Compound B RS (Catalog No. 1593423) were purchased from USP.

Figure 1. Quinapril Hydrochloride



LC-UV Conditions

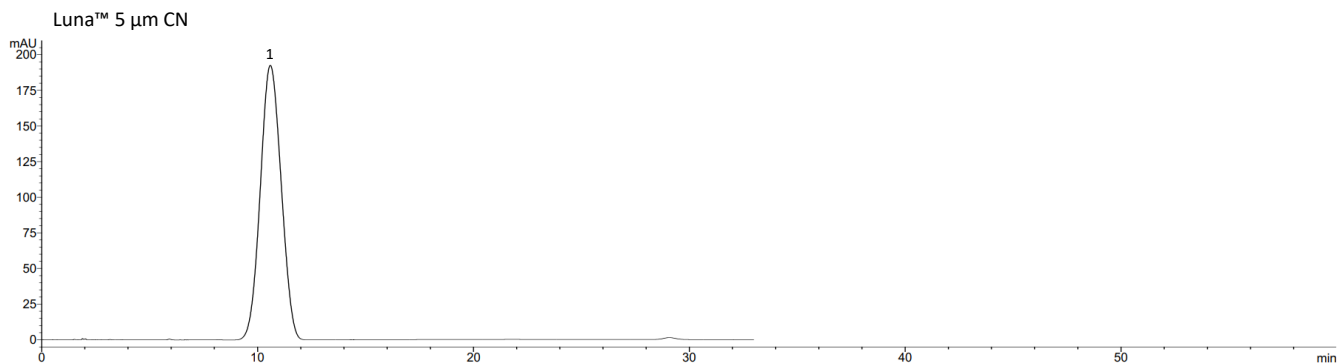
Column:	Luna™ 5 μm CN
Dimensions:	250 x 4.6 mm
Part No.:	00G-4255-E0
Guard Column:	Luna 5 μm CN
Guard Column Dimensions:	30 x 4.6 mm
Guard Column Part No.:	00A-4255-E0
Mobile Phase:	Acetonitrile / Methanesulfonic Acid / Water (28:0.1:72, v/v/v)
Flow Rate:	1.5 mL/min (Isocratic)
Injection Volume:	10 μL
Temperature:	Ambient
Detector:	UV @ 214 nm
System:	Agilent® 1200

Table 1. Preparation of Solutions

Solution	Composition
Diluent	Acetonitrile / 0.025 M Monobasic Ammonium Phosphate solution, pH 6.5 (40:60, v/v)
Standard Solution – Assay and Organic Impurities	2 mg/mL of USP Quinapril Hydrochloride RS in Diluent
System Suitability Solution – Assay and Organic Impurities	2 mg/mL of USP Quinapril Hydrochloride RS and 0.005 mg/mL each of USP Quinapril Related Compound A RS and USP Quinapril Related Compound B RS in Diluent
Sensitivity Solution – Organic Impurities	2 mg/mL of USP Quinapril Hydrochloride RS in Diluent



Figure 2. Standard Solution – Assay

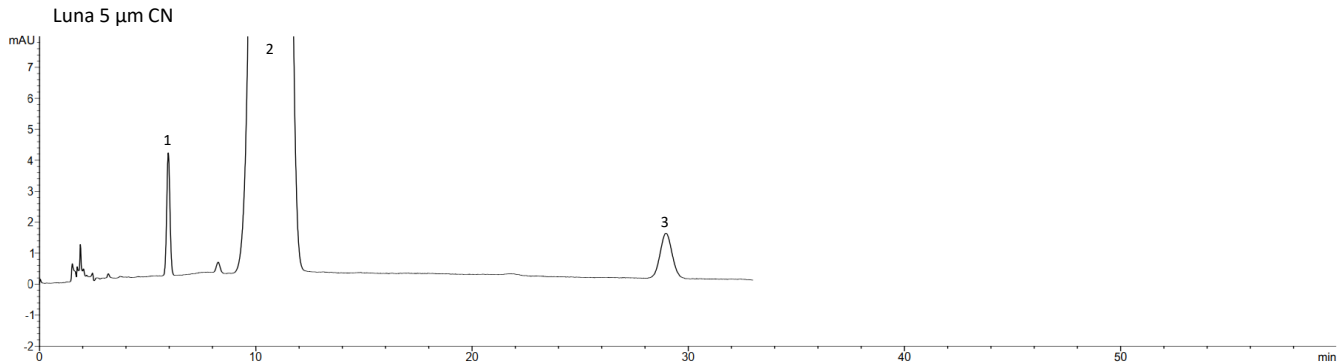


Peak No.	Analyte	Retention Time (min)	Height	Area	Area %RSD	Symmetry Factor
1	Quinapril Hydrochloride	10.538	196.68	12941.68	0.062	1.046

N = 5 Injections

App ID 27237

Figure 3. System Suitability Solution – Assay



Peak No.	Analyte	Retention Time (min)	Height	Area	Width	Resolution	
1	Quinapril Related Compound B	5.957	4	41.5	0.1621	4.52	-
2	Quinapril Hydrochloride	10.701	147	9863.8	1.0568		12.81
3	Quinapril Related Compound A	28.967	1.5	56.8	0.647	-	

App ID 27238



Figure 4. Standard Solution – Organic Impurities

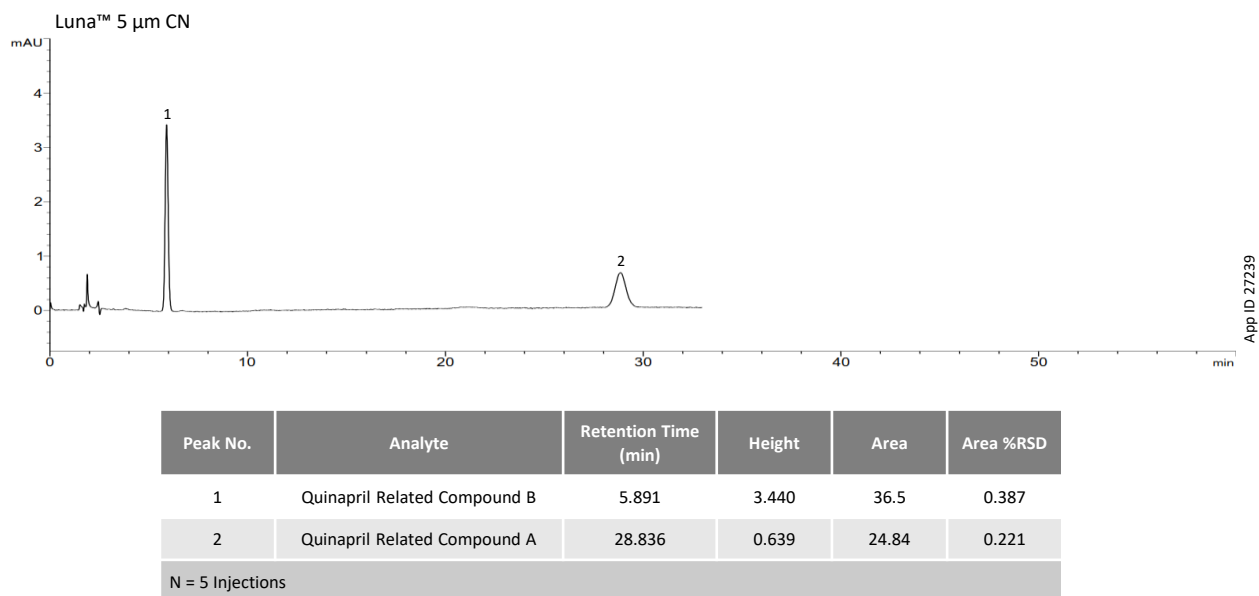


Figure 5. System Suitability Solution – Organic Impurities

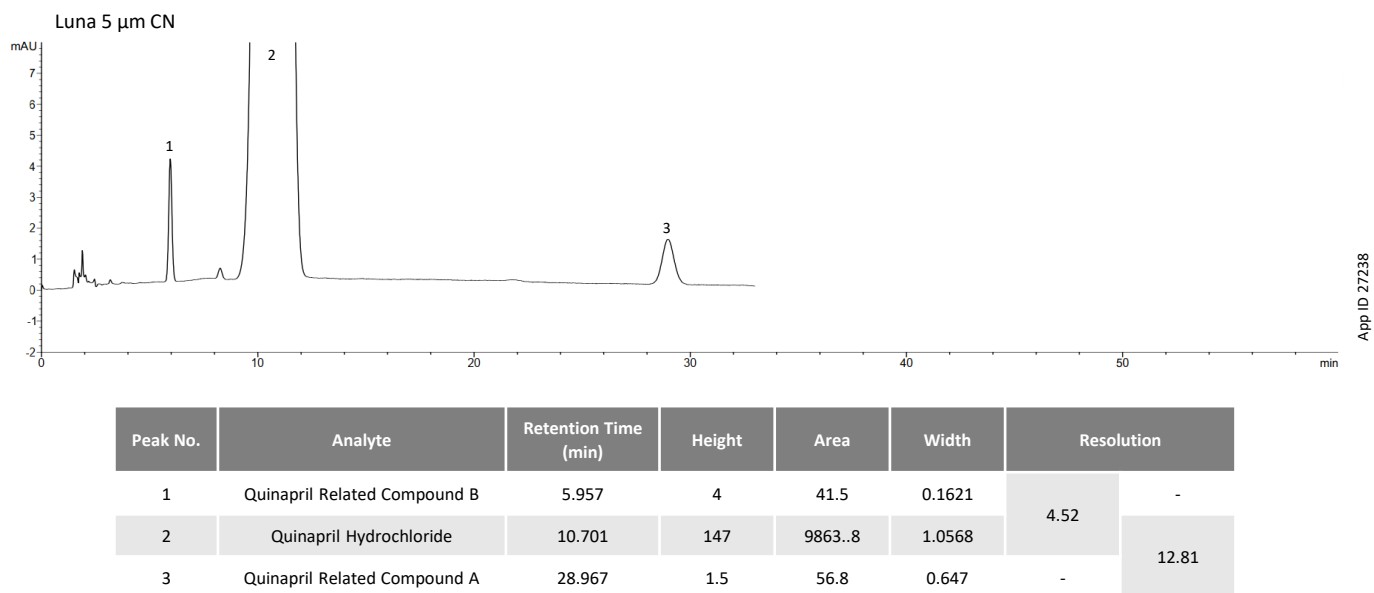
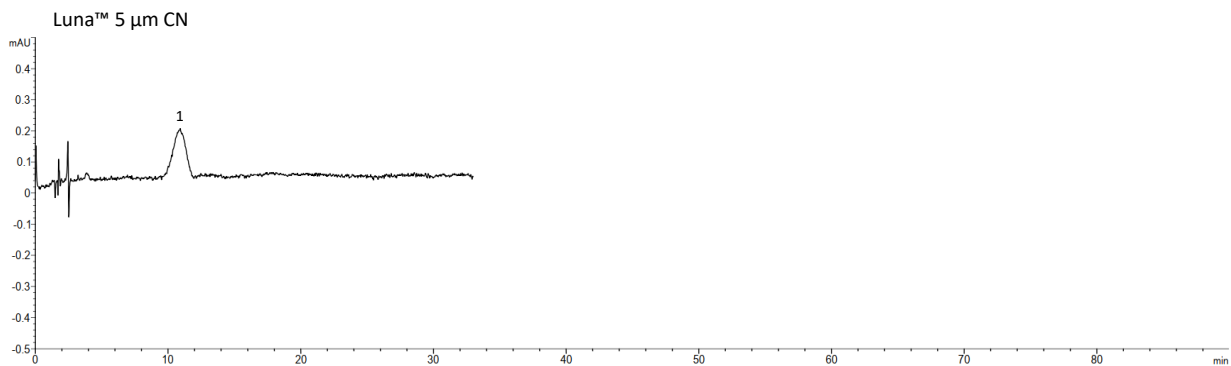


Figure 6. Sensitivity Solution – Organic Impurities



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Peak No.	Analyte	Retention Time (min)	Area	Height	S/N
1	Quinapril Hydrochloride	10.92	11	1.6e-1	29.68



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