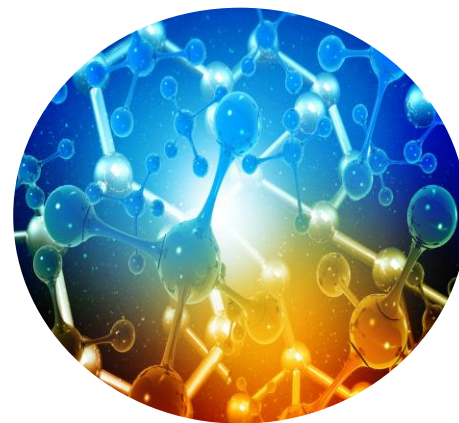




Separation of Gemifloxacin Mesylate and its Organic Impurities per USP Monograph using Luna™ Omega 5 µm C18 Column

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Overview

Gemifloxacin Mesylate is an antimicrobial drug used to inhibit the action of topoisomerase IV. The development of a quick and efficient analysis of Gemifloxacin Mesylate and its related organic impurities is of interest for drug manufacturers. In this application note, we report the separation of Gemifloxacin Mesylate and its related organic impurities using three batches of Luna Omega C18 media according to the USP monograph for Gemifloxacin Mesylate.

System suitability per USP Monograph for the Gemifloxacin Mesylate Assay is a resolution no less than 5.0 between Gemifloxacin Mesylate and Gemifloxacin Mesylate E-isomer, a tailing factor no more than (NMT) 1.5 for Gemifloxacin Mesylate and a percent relative standard deviation (%RSD) of NMT 1.0 % for Gemifloxacin Mesylate. All system suitability requirements for Gemifloxacin Mesylate Assay were met with all batches of Luna Omega C18 media (**Figure 1**).

System suitability per USP Monograph for the Gemifloxacin Mesylate Organic Impurities is a resolution no less than 5.0 between Gemifloxacin Mesylate and Gemifloxacin Mesylate E-isomer, as well as a %RSD NMT 10 %. The separation of Gemifloxacin Mesylate and E-isomer was achieved with all three batches of Luna Omega C18 media (**Figure 2**). The %RSD of each batch of Luna Omega C18 media for Gemifloxacin Mesylate were 8.067, 5.423, and 7.530. All requirements for System Suitability for Organic Impurities were met.

All solutions were prepared as indicated in the USP Monograph for Gemifloxacin Mesylate. USP Gemifloxacin Mesylate RS (Catalog No. 1288667) was purchased from USP.

LC-UV Conditions - Assay

Column: Luna Omega 5 µm C18
Dimension: 250 X 4.6 mm
Part No.: [00G-4785-E0](#)
Mobile Phase: Acetonitrile/Water/Trifluoroacetic acid (20:80:0.1, v/v/v)
Flow Rate: 1 mL/min
Injection Volume: 5 µL
Temperature: 40 °C
Detector: UV @ 272 nm
System: Agilent® 1260 Binary UHPLC

LC-UV Conditions - Organic Impurities

Column: Luna Omega 5 µm C18
Dimension: 250 x 4.6 mm
Part No.: [00G-4785-E0](#)
Mobile Phase: A: Acetonitrile/Water/Trifluoroacetic acid (20:80:0.1, v/v/v)
B: Acetonitrile/Water/Trifluoroacetic acid (80:20:0.1, v/v/v)
Gradient:

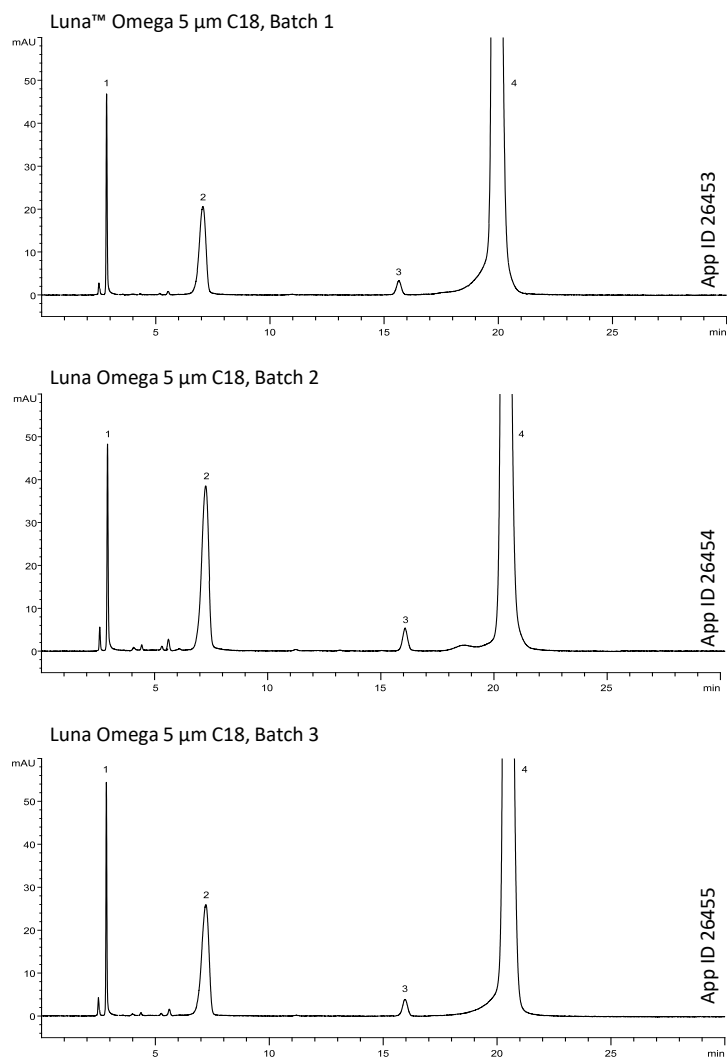
Time (min)	%B
0	0
15	0
35	100
37	0
45	0

Flow Rate: 1 mL/min
Injection Volume: 5 µL
Temperature: 40 °C
Detector: UV @ 207 nm (0-5 min), then 272 nm (5.1-37 min)
System: Agilent 1260 Binary UHPLC

Table 1. Preparation of Solutions

Solution	Composition
Standard Solution – Assay	0.5 mg/mL of USP Gemifloxacin Mesylate RS in water
Diluent – Organic Impurities	Acetonitrile/Water (20:80, v/v)
System Suitability Solution – Organic Impurities	0.5 mg/mL of USP Gemifloxacin Mesylate RS in Diluent
Standard Solution – Organic Impurities	0.0005 mg/mL of USP Gemifloxacin Mesylate RS in Diluent from System Suitability Solution

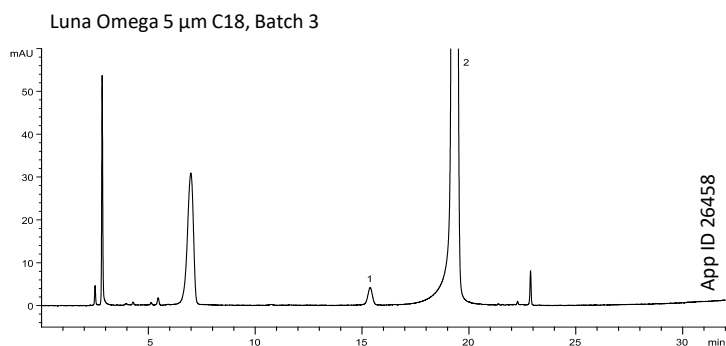
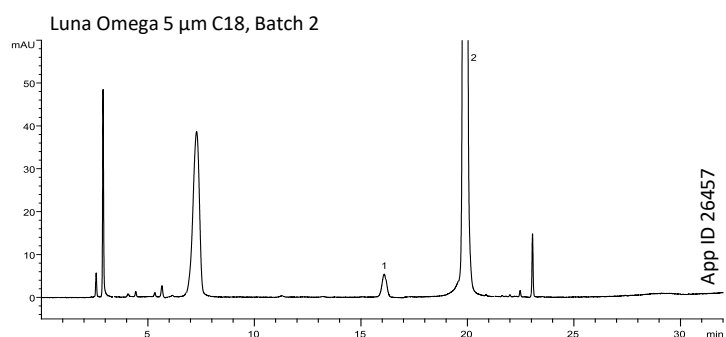
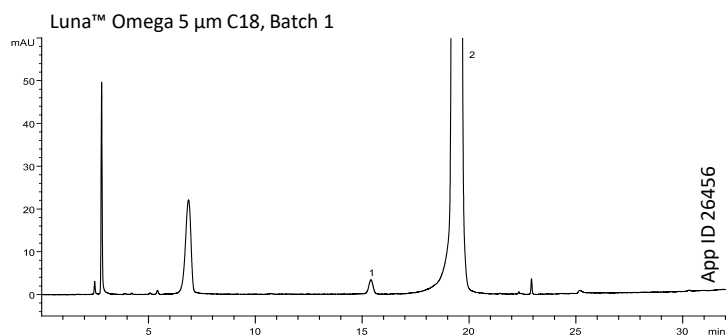


Figure 1. Standard Solution – Assay

Peak	Analyte
1	Gemifloxacin Mesylate Related Compound A
2	Gemifloxacin Mesylate Related Compound C
3	Gemifloxacin Mesylate E-isomer
4	Gemifloxacin Mesylate

	Batch 1			Batch 2			Batch 3		
Analyte	Area %RSD	Tailing Factor	Resolution	Area %RSD	Tailing Factor	Resolution	Area %RSD	Tailing Factor	Resolution
Gemifloxacin Mesylate E-isomer	-	-	9.22	-	-	9.13	-	-	9.51
Gemifloxacin Mesylate	0.87	1.41		0.55	1.38		0.32	1.35	
N = 6 Injections									



Figure 1. System Suitability Solution – Organic Impurities

Peak	Analyte
1	Gemifloxacin Mesylate E-isomer
2	Gemifloxacin Mesylate

	Batch 1	Batch 2	Batch 3
Analyte	Resolution	Resolution	Resolution
Gemifloxacin Mesylate E-isomer	9.22	9.13	9.51
Gemifloxacin Mesylate			
N = 6 Injections			



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