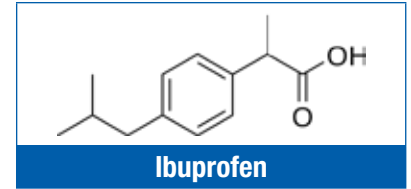


APPLICATION

Ibuprofen *USP*

Overview

The related substances test of the USP monograph outlines the separation of all relevant impurities from Ibuprofen. This method was studied and improvements were made to provide higher resolution (Rs) and a faster separation time within allowable adjustments.



USP Monograph: Ibuprofen Details

Resolution Solution	Prepare a solution in acetonitrile containing in each mL about 5 mg of Ibuprofen and 5 mg of Valerophenone
Test Preparation	Prepare a solution of Ibuprofen in acetonitrile containing about 5 mg per mL

Column

Size	150 x 4.0 mm
Stationary Phase	5 µm, L1: Octadecyl silane chemically bonded to porous or non-porous silica or ceramic microparticles, 1.5 to 10 µm in diameter, or a monolithic rod
Temperature	30°C ± 0.5°C
Mobile Phase	Prepare a suitable filtered mixture of water, previously adjusted with phosphoric acid to pH 2.5 and acetonitrile (1340:680).
Flow Rate	2.0 mL/min
Detection	Spectrophotometer @ 214 nm
Injection	5 µL

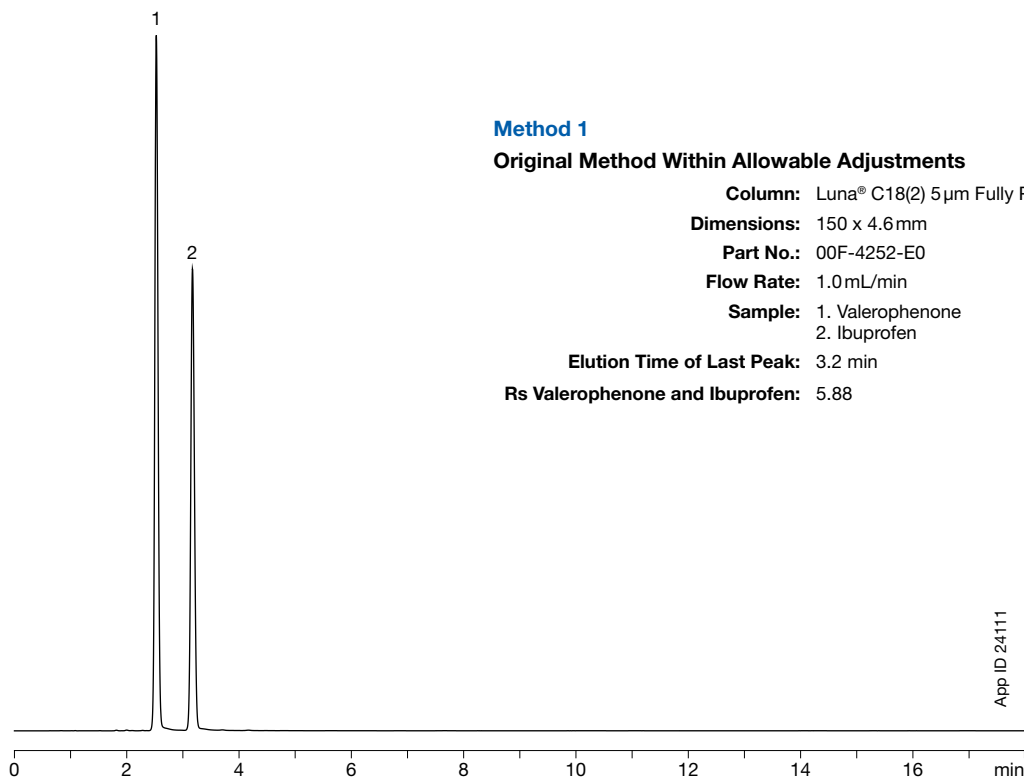
Relative Retention with Reference to Ibuprofen*

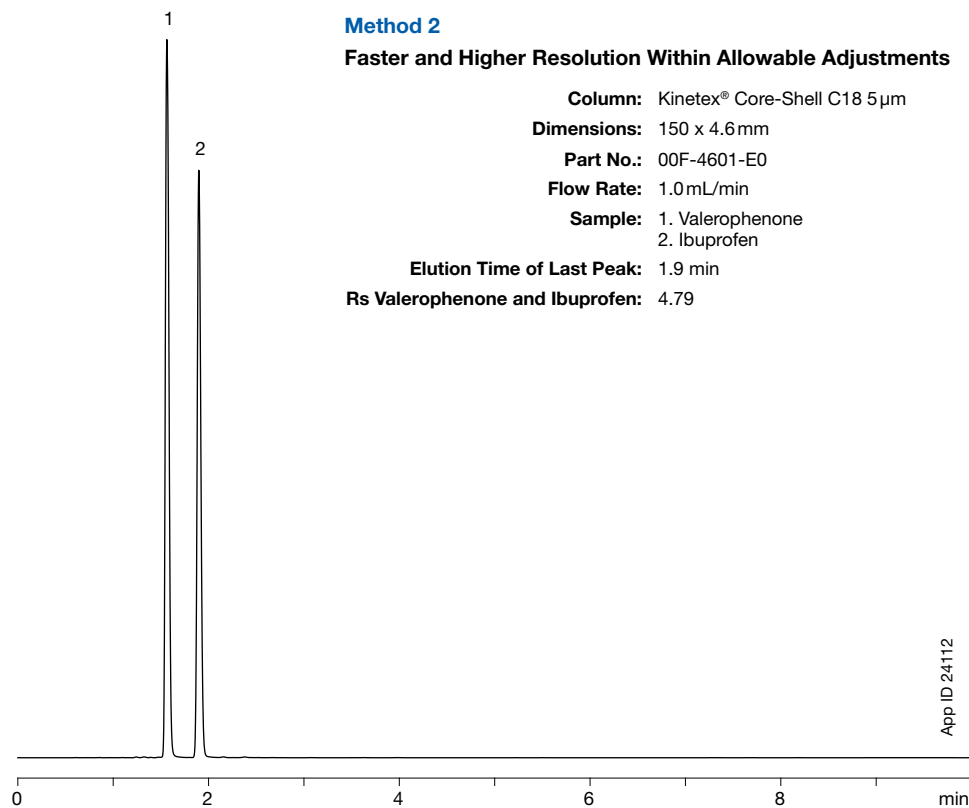
Valerophenone	about 0.8
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System Suitability

Minimum resolution of 2.0 between Valerophenone and Ibuprofen

* Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.





Method 2

Faster and Higher Resolution Within Allowable Adjustments

Column: Kinetex® Core-Shell C18 5 µm
Dimensions: 150 x 4.6 mm
Part No.: 00F-4601-E0
Flow Rate: 1.0 mL/min
Sample: 1. Valerophenone
 2. Ibuprofen

Elution Time of Last Peak: 1.9 min
Rs Valerophenone and Ibuprofen: 4.79

App ID 24112

Adjustments for Meeting System Suitability

Method Parameter	Allowed Adjustments (isocratic elution)	Method 1	Method 2
Mobile Phase pH	± 0.2 units	As specified	As specified
Concentration of Salts in Buffer	± 10 %	As specified in Monograph Details Table	As specified
Composition of the Mobile Phase	± 30 % Relative; cannot exceed ± 10 % Absolute change; cannot be reduced to zero	As specified in Monograph Details Table	As specified
Wavelength of Detector	No deviations permitted	214 nm (as specified)	As specified
Injection Volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements	5 µL (as specified)	As specified
Column Temperature	± 10 °C	30 °C (as specified)	As specified
Stationary Phase	No change of the identity of the substituent permitted (e.g. no replacement of C18 by C8)	L1 (as specified)	As specified
Column Length	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*	150 mm (as specified)	As specified
Column Internal Diameter	Can be adjusted so long as linear velocity is maintained	4.6 mm (+15 %)	4.6 mm (+15 %)
Particle Size	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*	5 µm (as specified)	As specified
Flow Rate	± 50 % (at given ID)	1.0 mL/min (-50 %)	1.0 mL/min (-50 %)

*Alternatively (as for the application of particle size adjustment to superficially porous particles), other L/dp combinations can be used provided that the number of theoretical plates (N) is within -25 % to +50 %

Kinetex® Ordering Information

5 µm Minibore Columns (mm)					SecurityGuard™ ULTRA Cartridges [†]
Phases	30 x 2.1	50 x 2.1	100 x 2.1	150 x 2.1	3/pk
C18	00A-4601-AN	00B-4601-AN	00D-4601-AN	00F-4601-AN	AJO-8782 for 2.1 mm ID

5 µm MidBore™ Columns (mm)				SecurityGuard ULTRA Cartridges [†]
Phases	50 x 3.0	100 x 3.0	150 x 3.0	3/pk
C18	00B-4601-YO	00D-4601-YO	00F-4601-YO	AJO-8775 for 3.0 mm ID

5 µm Analytical Columns (mm)					SecurityGuard ULTRA Cartridges [†]
Phases	50 x 4.6	100 x 4.6	150 x 4.6	250 x 4.6	3/pk
C18	00B-4601-EO	00D-4601-EO	00F-4601-EO	00G-4601-EO	AJO-8768 for 4.6 mm ID

5 µm Semi-Preparative Columns (mm)			SecurityGuard SemiPrep Cartridges ^{***}
Phases	150 x 10	250 x 10	3/pk
C18	00F-4601-NO	00G-4601-NO	AJO-9278 for 9-16 mm ID

[†]SecurityGuard ULTRA Cartridges require holder, Part No.: AJO-9000

^{***}SemiPrep SecurityGuard Cartridges require holder, Part No.: AJO-9281

Luna® Ordering Information

5 µm Microbore and Minibore Columns (mm)								SecurityGuard™ Cartridges (mm)
Phases	50 x 1.0	150 x 1.0	250 x 1.0	30 x 2.0	50 x 2.0	150 x 2.0	250 x 2.0	4 x 2.0*
C18(2)	00B-4252-AO	00F-4252-AO	00G-4252-AO	00A-4252-BO	00B-4252-BO	00F-4252-BO	00G-4252-BO	/10pk AJO-4286 for ID: 2.0-3.0 mm

5 µm MidBore and Analytical Columns (mm)								SecurityGuard™ Cartridges (mm)	
Phases	30 x 3.0	50 x 3.0	150 x 3.0	250 x 3.0	30 x 4.6	50 x 4.6	75 x 4.6	4 x 2.0*	4 x 3.0*
C18(2)	00A-4252-YO	00B-4252-YO	00F-4252-YO	00G-4252-YO	00A-4252-EO	00B-4252-EO	00C-4252-EO	/10pk AJO-4286 for ID: 2.0-3.0 mm	/10pk AJO-4287 3.2-8.0 mm

5 µm Analytical and Semi-Prep Columns (mm)					SecurityGuard™ Cartridges (mm)	
Phases	100 x 4.6	150 x 4.6	250 x 4.6	250 x 10	4 x 3.0*	10 x 10 [‡]
C18(2)	00D-4252-EO	00F-4252-EO	00G-4252-EO	00G-4252-NO	/10pk AJO-4287 for ID: 3.2-8.0 mm	/3pk AJO-7221 9-16 mm

^{*}SecurityGuard™ Analytical Cartridges require holder, Part No.: KJO-4282

[‡]SemiPrep SecurityGuard Cartridges require holder, Part No.: AJO-9281



APPLICATION

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