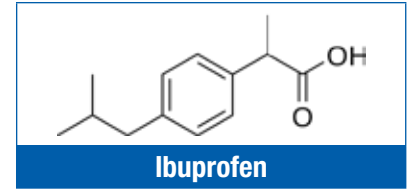


# APPLICATION

## 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

|                            |                                                                                                            |
|----------------------------|------------------------------------------------------------------------------------------------------------|
| <b>Resolution Solution</b> | Prepare a solution in acetonitrile containing in each mL about 5 mg of Ibuprofen and 5 mg of Valerophenone |
| <b>Test Preparation</b>    | Prepare a solution of Ibuprofen in acetonitrile containing about 5 mg per mL                               |

### Column

|                         |                                                                                                                                                      |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Size</b>             | 150 x 4.0 mm                                                                                                                                         |
| <b>Stationary Phase</b> | 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 |
| <b>Temperature</b>      | 30°C ± 0.5°C                                                                                                                                         |
| <b>Mobile Phase</b>     | Prepare a suitable filtered mixture of water, previously adjusted with phosphoric acid to pH 2.5 and acetonitrile (1340:680).                        |
| <b>Flow Rate</b>        | 2.0 mL/min                                                                                                                                           |
| <b>Detection</b>        | Spectrophotometer @ 214 nm                                                                                                                           |
| <b>Injection</b>        | 5 µL                                                                                                                                                 |

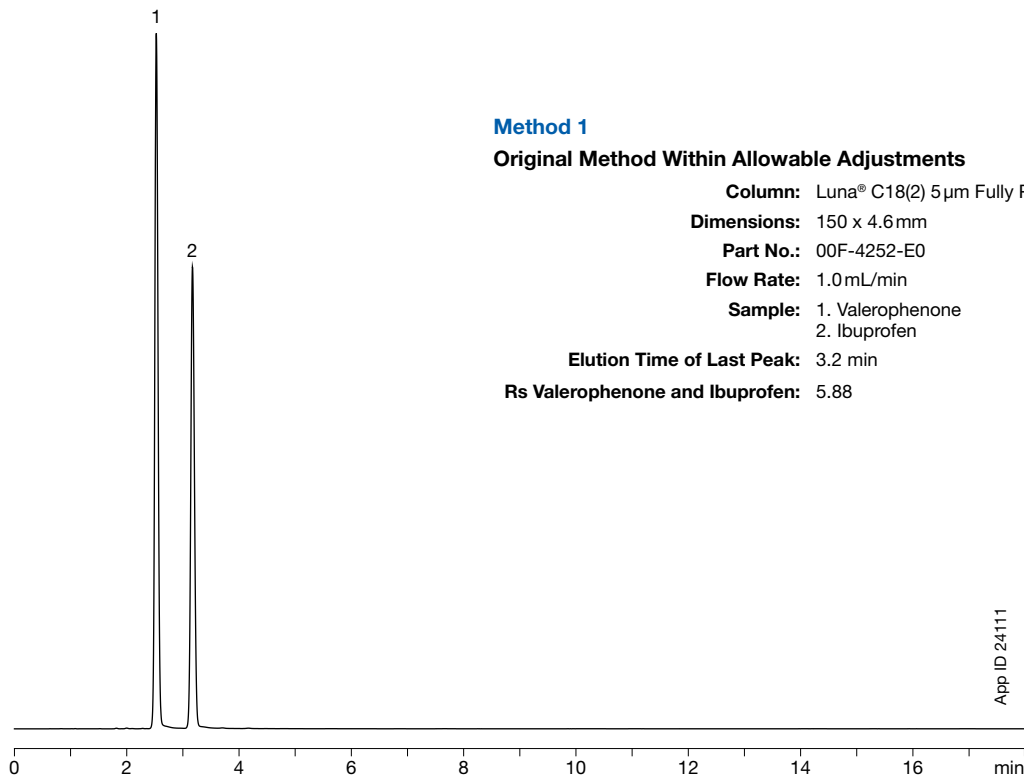
### Relative Retention with Reference to Ibuprofen\*

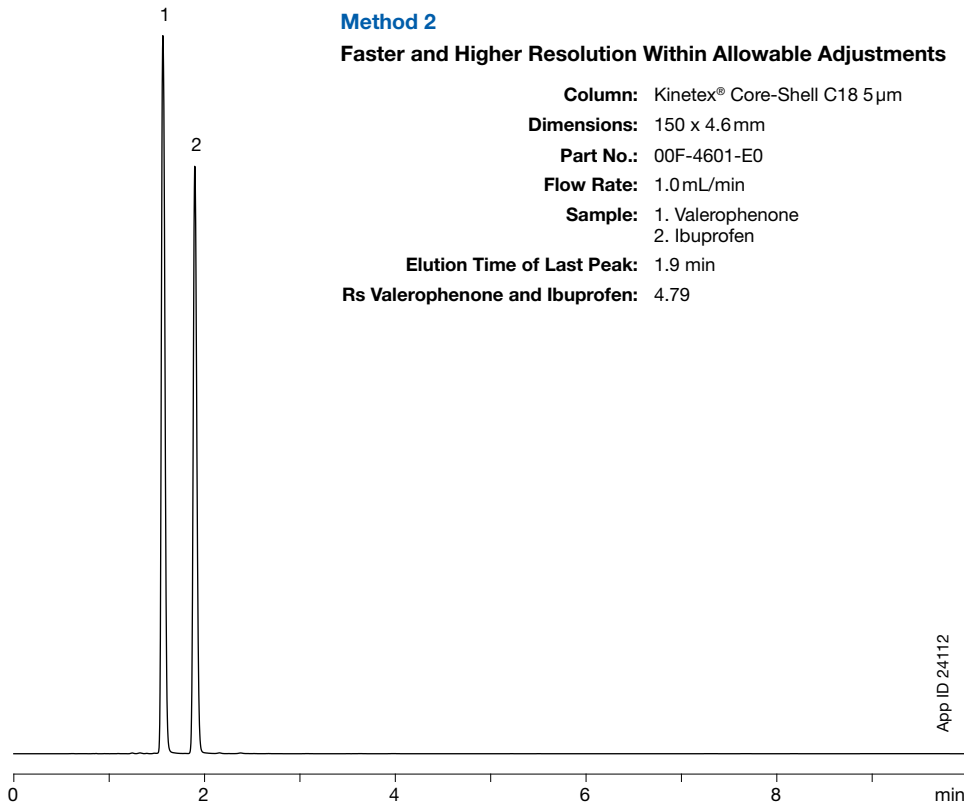
|                      |           |
|----------------------|-----------|
| <b>Valerophenone</b> | about 0.8 |
|----------------------|-----------|

### 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  $\mu$ m  
**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                  | $\pm 0.2$ units                                                                                             | As specified                            | As specified      |
| Concentration of Salts in Buffer | $\pm 10\%$                                                                                                  | As specified in Monograph Details Table | As specified      |
| Composition of the Mobile Phase  | $\pm 30\%$ Relative; cannot exceed $\pm 10\%$ 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 $\mu$ L (as specified)                | As specified      |
| Column Temperature               | $\pm 10^\circ\text{C}$                                                                                      | 30 $^\circ\text{C}$ (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 $\mu$ m (as specified)                | As specified      |
| Flow Rate                        | $\pm 50\%$ (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 <sup>†</sup> |
|----------------------------|-------------|-------------|-------------|-------------|----------------------------------------------|
| 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<br>for 2.1 mm ID                    |

| 5 µm MidBore™ Columns (mm) |             |             |             | SecurityGuard ULTRA Cartridges <sup>†</sup> |
|----------------------------|-------------|-------------|-------------|---------------------------------------------|
| Phases                     | 50 x 3.0    | 100 x 3.0   | 150 x 3.0   | 3/pk                                        |
| C18                        | 00B-4601-Y0 | 00D-4601-Y0 | 00F-4601-Y0 | AJO-8775<br>for 3.0 mm ID                   |

| 5 µm Analytical Columns (mm) |             |             |             |             | SecurityGuard ULTRA Cartridges <sup>†</sup> |
|------------------------------|-------------|-------------|-------------|-------------|---------------------------------------------|
| Phases                       | 50 x 4.6    | 100 x 4.6   | 150 x 4.6   | 250 x 4.6   | 3/pk                                        |
| C18                          | 00B-4601-E0 | 00D-4601-E0 | 00F-4601-E0 | 00G-4601-E0 | AJO-8768<br>for 4.6 mm ID                   |

| 5 µm Semi-Preparative Columns (mm) |             |             | SecurityGuard SemiPrep Cartridges <sup>***</sup> |
|------------------------------------|-------------|-------------|--------------------------------------------------|
| Phases                             | 150 x 10    | 250 x 10    | 3/pk                                             |
| C18                                | 00F-4601-N0 | 00G-4601-N0 | AJO-9278<br>for 9-16 mm ID                       |

<sup>†</sup>SecurityGuard ULTRA Cartridges require holder, Part No.: AJO-9000

<sup>\*\*\*</sup>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-A0 | 00F-4252-A0 | 00G-4252-A0 | 00A-4252-B0 | 00B-4252-B0 | 00F-4252-B0 | 00G-4252-B0 | /10pk<br>AJO-4286<br>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-Y0 | 00B-4252-Y0 | 00F-4252-Y0 | 00G-4252-Y0 | 00A-4252-E0 | 00B-4252-E0 | 00C-4252-E0 | /10pk<br>AJO-4286<br>for ID: 2.0-3.0 mm | /10pk<br>AJO-4287<br>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 <sup>‡</sup>        |
| C18(2)                                     | 00D-4252-E0 | 00F-4252-E0 | 00G-4252-E0 | 00G-4252-N0 | /10pk<br>AJO-4287<br>for ID: 3.2-8.0 mm | /3pk<br>AJO-7221<br>9-16 mm |

<sup>\*</sup>SecurityGuard™ Analytical Cartridges require holder, Part No.: KJO-4282

<sup>‡</sup>SemiPrep SecurityGuard Cartridges require holder, Part No.: AJO-9281



If Phenomenex products in this technical note do not provide at least an equivalent separation as compared to a competing product of the same particle size, similar phase and dimensions, return the product with comparative data within 45 days for a FULL REFUND.



# APPLICATION

## **Australia**

t: +61 (0)2-9428-6444  
f: +61 (0)2-9428-6445  
auinfo@phenomenex.com

## **Austria**

t: +43 (0)1-319-1301  
f: +43 (0)1-319-1300  
anfrage@phenomenex.com

## **Belgium**

t: +32 (0)2 503 4015 (French)  
t: +32 (0)2 511 8666 (Dutch)  
f: +31 (0)30-2383749  
beinfo@phenomenex.com

## **Canada**

t: +1 (800) 543-3681  
f: +1 (310) 328-7768  
info@phenomenex.com

## **China**

t: +86 400-606-8099  
f: +86 (0)22 2532-1033  
phen@agela.com

## **Denmark**

t: +45 4824 8048  
f: +45 4810 6265  
nordicinfo@phenomenex.com

## **Finland**

t: +358 (0)9 4789 0063  
f: +45 4810 6265  
nordicinfo@phenomenex.com

## **France**

t: +33 (0)1 30 09 21 10  
f: +33 (0)1 30 09 21 11  
franceinfo@phenomenex.com

## **Germany**

t: +49 (0)6021-58830-0  
f: +49 (0)6021-58830-11  
anfrage@phenomenex.com

## **India**

t: +91 (0)40-3012 2400  
f: +91 (0)40-3012 2411  
indiainfo@phenomenex.com

## **Ireland**

t: +353 (0)1 247 5405  
f: +44 1625-501796  
eireinfo@phenomenex.com

## **Italy**

t: +39 051 6327511  
f: +39 051 6327555  
italiainfo@phenomenex.com

## **www.phenomenex.com**

Phenomenex products are available worldwide. For the distributor in your country, contact Phenomenex USA, International Department at [international@phenomenex.com](mailto:international@phenomenex.com)

## **Luxembourg**

t: +31 (0)30-2418700  
f: +31 (0)30-2383749  
nlinfo@phenomenex.com

## **Mexico**

t: 01-800-844-5226  
f: 001-310-328-7768  
tecnicomx@phenomenex.com

## **The Netherlands**

t: +31 (0)30-2418700  
f: +31 (0)30-2383749  
nlinfo@phenomenex.com

## **New Zealand**

t: +64 (0)9-4780951  
f: +64 (0)9-4780952  
nzinfo@phenomenex.com

## **Norway**

t: +47 810 02 005  
f: +45 4810 6265  
nordicinfo@phenomenex.com

## **Puerto Rico**

t: +1 (800) 541-HPLC  
f: +1 (310) 328-7768  
info@phenomenex.com

## **Spain**

t: +34 91-413-8613  
f: +34 91-413-2290  
espinfo@phenomenex.com

## **Sweden**

t: +46 (0)8 611 6950  
f: +45 4810 6265  
nordicinfo@phenomenex.com

## **United Kingdom**

t: +44 (0)1625-501367  
f: +44 (0)1625-501796  
ukinfo@phenomenex.com

## **USA**

t: +1 (310) 212-0555  
f: +1 (310) 328-7768  
info@phenomenex.com

## **All other countries Corporate Office USA**

t: +1 (310) 212-0555  
f: +1 (310) 328-7768  
info@phenomenex.com

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