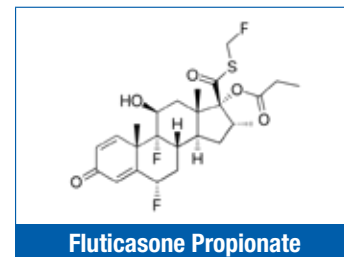


# APPLICATION

## Fluticasone Propionate and Related Substances USP

### Overview

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



### USP Monograph: Fluticasone Propionate Details

<b>System Suitability Solution</b>	Dissolve 2.0 mg of USP Fluticasone Propionate
<b>System Suitability Mixture</b>	RS in 5 mL of Solution A using sonication. Add 5 mL of Solution C.
<b>Sample Solution</b>	Dissolve 2.0 mg of Fluticasone Propionate in 5 mL of Solution A using sonication. Add 5 mL of Solution C.

### Column

<b>Size</b>	250 x 4.6 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>Mobile Phase</b>	<b>A:</b> 0.5 mL of phosphoric acid in 1000 mL of acetonitrile <b>B:</b> 0.5 mL of phosphoric acid in 1000 mL of methanol <b>C:</b> 0.5 mL of phosphoric acid in 1000 mL of water
<b>Gradient</b>	<b>Time (min):</b> <b>% (A/B/C)</b> 0                      42/3/55 40                     53/3/44 60                     87/3/10 70                     87/3/10 75                     42/3/55
<b>Flow Rate</b>	1.0 mL/min
<b>Detection</b>	Spectrophotometer @ 239 nm
<b>Injection</b>	50 µL

### Relative Retention with Reference to Fluticasone Propionate\*

<b>Related Compound A</b>	about 0.5
<b>Related Compound B</b>	about 0.75
<b>Related Compound C</b>	about 0.8
<b>Related Compound D</b>	about 0.95
<b>Related Compound E</b>	about 1.3

### System Suitability

Minimum resolution of 0.6 between Related Compound B and Related Compound C.  
Minimum resolution of 1.5 between Related Compound D and Fluticasone Propionate.

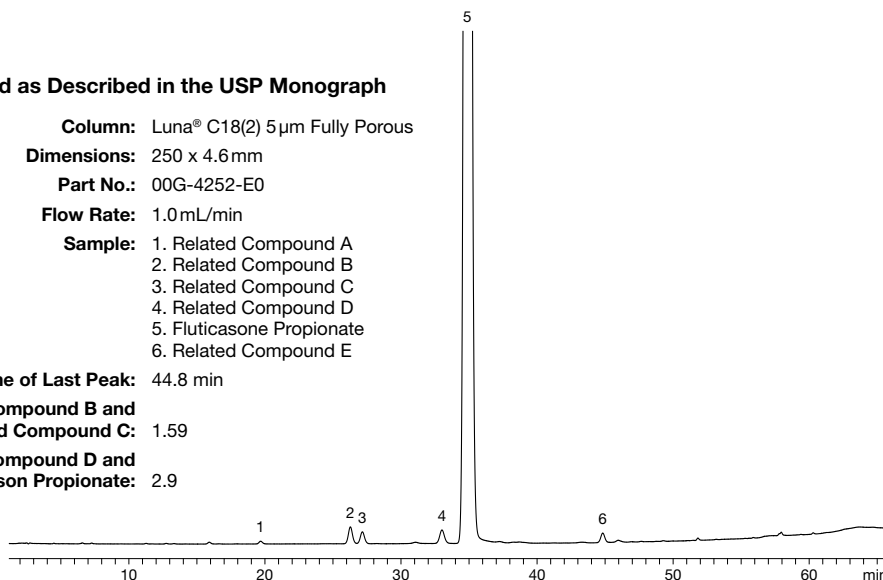
\* Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.

### Method 1

#### Original Method as Described in the USP Monograph

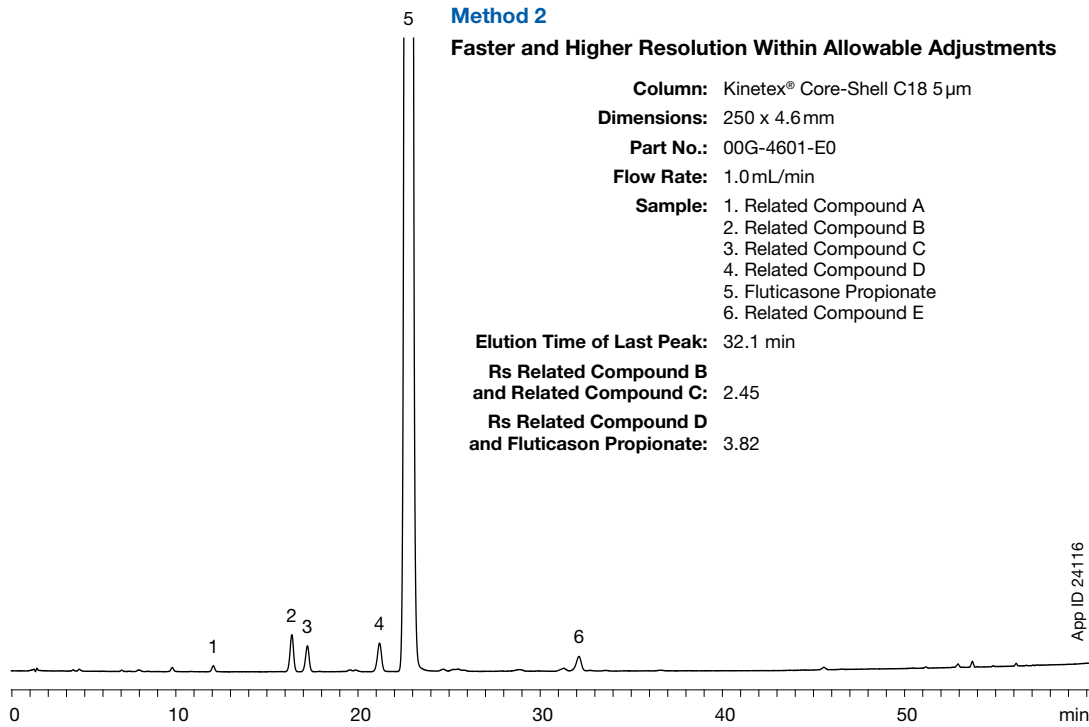
**Column:** Luna<sup>®</sup> C18(2) 5 µm Fully Porous  
**Dimensions:** 250 x 4.6 mm  
**Part No.:** 00G-4252-E0  
**Flow Rate:** 1.0 mL/min  
**Sample:** 1. Related Compound A  
2. Related Compound B  
3. Related Compound C  
4. Related Compound D  
5. Fluticasone Propionate  
6. Related Compound E

**Elution Time of Last Peak:** 44.8 min  
**Rs Related Compound B and Related Compound C:** 1.59  
**Rs Related Compound D and Fluticasone Propionate:** 2.9



App ID 24115





### Adjustments for Meeting System Suitability

Method Parameter	Allowed Adjustments (gradient 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	Changes to gradient composition are not recommended	As specified in Monograph Details Table	As specified
Wavelength of Detector	No deviations permitted	239 nm (as specified)	As specified
Injection Volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements	50 $\mu$ L (as specified)	As specified
Column Temperature	$\pm 10^\circ\text{C}$	40 $^\circ\text{C}$ (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	No deviations permitted	250 mm (as specified)	As specified
Column Internal Diameter	No deviations permitted	4.6 mm (as specified)	As specified
Particle Size	No deviations permitted	5 $\mu$ m (as specified)	As specified
Flow Rate	No deviations permitted	1.0 mL/min (as specified)	As specified

## 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 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-YO	00D-4601-YO	00F-4601-YO	AJO-8775 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 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 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 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-Y0	00B-4252-Y0	00F-4252-Y0	00G-4252-Y0	00A-4252-E0	00B-4252-E0	00C-4252-E0	/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 <sup>‡</sup>
C18(2)	00D-4252-E0	00F-4252-E0	00G-4252-E0	00G-4252-N0	/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

<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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