

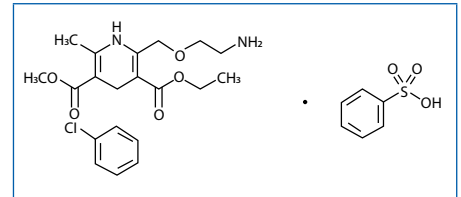
# APPLICATION

## Amlodipine Besylate

USP

### Overview

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



**Amlodipine Besylate**

### USP Monograph: Amlodipine Besylate Details

<b>pH 3.0 Buffer</b>	Dissolve 7.0 of triethylamine in 800mL of water. Adjust with phosphoric acid to a pH of 3.0± 0.1, and dilute with water to 1 L.
<b>System Suitability Solution</b>	Dissolve about 5 mg of Amlodipine Besylate in 5 mL of hydrogen peroxide, and heat at 70° C for 45 minutes
<b>Standard Preparation</b>	Dissolve USP Amlodipine Besylate RS in mobile phase to obtain a concentration of 0.003 mg/mL
<b>Test Solution</b>	Dissolve 50 mg of Amlodipine Besylate in a 50 mL volumetric flask and dilute to volume with mobile phase

### Column

<b>Size</b>	150 x 3.9mm
<b>Stationary Phase</b>	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>	pH 3.0 Buffer, Methanol and acetonitrile (50:35:15)
<b>Flow Rate</b>	1.0 mL/min
<b>Detection</b>	Spectrophotometer @ 237 nm
<b>Injection</b>	10 µL

### Relative Retention with Reference to Amlodipine\*

<b>Benzene Sulfonate</b>	about 0.2
<b>Impurity A</b>	about 0.5

### System Suitability

Minimum resolution of 4.5 between Amlodipine and Impurity A

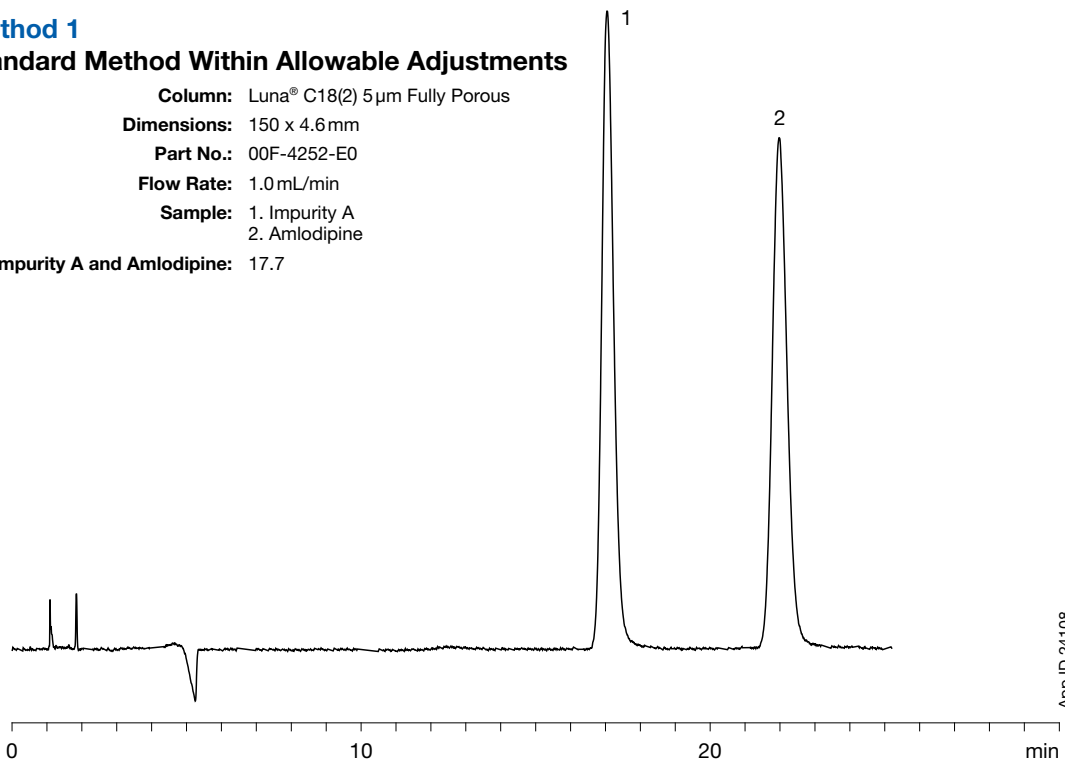
\* Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.

### Method 1

#### Standard Method Within Allowable Adjustments

**Column:** Luna<sup>®</sup> C18(2) 5µm Fully Porous  
**Dimensions:** 150 x 4.6mm  
**Part No.:** 00F-4252-E0  
**Flow Rate:** 1.0 mL/min  
**Sample:** 1. Impurity A  
 2. Amlodipine

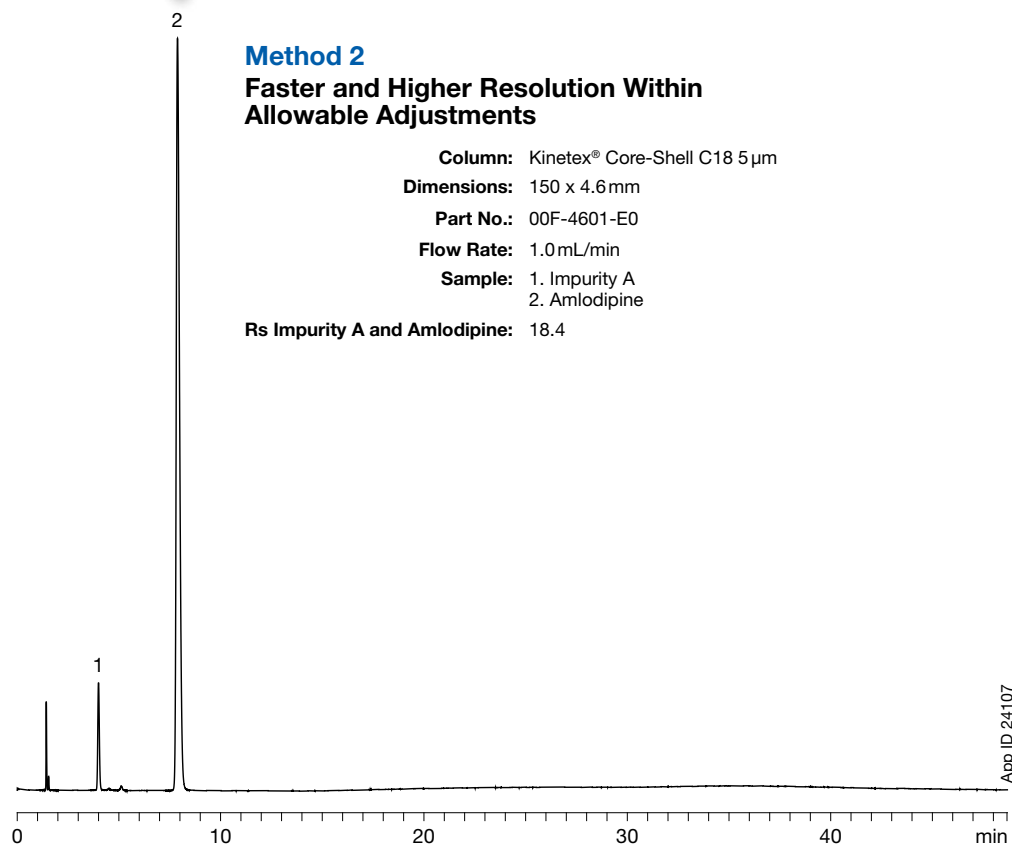
**Rs Impurity A and Amlodipine:** 17.7



App ID 24108



Reduce run times by >50% with  
Kinetex Core-Shell Columns



**Method 2**  
**Faster and Higher Resolution Within Allowable Adjustments**

**Column:** Kinetex<sup>®</sup> 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. Impurity A  
 2. Amlodipine  
**Rs Impurity A and Amlodipine:** 18.4

App ID 24107

**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	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	237 nm (as specified)	As specified
Injection Volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements	10 $\mu$ L (as specified)	As specified
Column Temperature	$\pm 10^\circ\text{C}$	Ambient (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 (+18%)	4.6 mm (+18%)
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 (as specified)	As specified

\*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 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	/10pk AJO-4287 for ID: 2.0-3.0 mm    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	/3pk AJO-7221 for ID: 3.2-8.0 mm    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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