



COSMOSIL

# U.S. Pharmacopeia Methods for HPLC

Technical Note

## Applications in accordance with U.S. Pharmacopeia Methods

Applications of USP Standards using COSMOSIL columns in accordance with the condition specified in USP-PF(Pharmacopoeial Forum) online is available on our website. For more information, please visit our web site at <http://www.nacalai.co.jp/global/cosmosil/>.



- **Quickly establish QC processes for pharmaceuticals**
- **Easily optimize analytical condition such as elution time etc.**
- **Clearly identify your target peaks**

**Amlodipine**

Monographs	Tests	Columns
34(5) In-Process Revision Amlodipine Besylate	Assay	5C <sub>18</sub> -MS-II

**USP Methods**

**29(5) In-Process Revision: Chlorothiazide**

Column; COSMOSIL 5C18-MS-II (5-µm packing L1)  
 Column size; 4.6mm I.D. x 250mm  
 Mobile phase\*; 0.1M Monobasic Sodium Phosphate buffer\*\*  
 Acetonitrile = 90 : 10 (pH3.0)  
 \*Mobile phase  
 \*\*0.1M monobasic sodium phosphate buffer\*\*\* and acetonitrile (9:1), adjust the pH to 3.0 ± 0.1 with phosphoric acid. Filter with Milicap-HV of 0.45-µm pore size.  
 \*\*\*0.1M Monobasic Sodium Phosphate buffer  
 Dissolve 11.958 g of monobasic sodium phosphate in 1 L of water.  
 Flow rate; 1.2 mL/min  
 Detection; UV254nm  
 Temperature; 40°C

Standard preparation\*\*\*;  
 Chlorothiazide (0.15mg/mL) / mobile phase

Resolution solution;  
 Chlorothiazide (0.15mg/mL),  
 Benzothiadiazine related compound A (1.5µg/mL) / mobile phase

Injection size;  
 (1) Standard preparation: 20µL  
 (2) Resolution solution: 20µL

(1) Standard preparation

Peak  
 No.1: Chlorothiazide

	System suitability	Result (1)
Relative standard deviation (Peak No.1) (n = 5)	≤ 1.5%	0.3%

(2) Resolution solution

Peak  
 No.1: Benzothiadiazine related compound A  
 No.2: Chlorothiazide

	System suitability	Result (2)
Resolution (Peak No.1 and 2)	≥ 3.5	4.4

The Application have .....

**System suitability and results**

**Complicated adjusting method of mobile phase and samples and etc..**

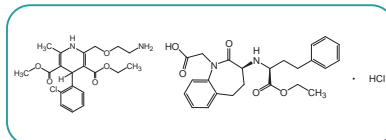
## USP Standard List

- |                             |                             |
|-----------------------------|-----------------------------|
| 1. Amlodipine               | 11. Hydrochlorothiazide     |
| 2. Amlodipine Besylate      | 12. Losartan Potassium      |
| 3. Amoxicillin              | 13. Hydrochlorothiazide     |
| 4. Benazepril Hydrochloride | 14. Losartan Potassium      |
| 5. Chlorothiazide           | 15. Metformin Hydrochloride |
| 6. Clavulanate Potassium    | 16. Omeprazole              |
| 7. Chlorpheniramine Maleate | 17. Pantoprazole            |
| 8. Esomeprazole Magnesium   | 18. Pantoprazole Sodium     |
| 9. Gabapentin               | 19. Ramipril                |
| 10. Glimepiride Glyburide   | 20. Valsartan               |

\*New Applications will be added accordingly.

## USP methods

### 38(1) In-Process Revision: Amlodipine and Benazepril Hydrochloride Capsules



#### Impurities

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$  m packing L1)

**Column size;** 4.6mm.I.D.-250mm

**Mobile phase;** A: Acetonitrile : Buffer 1\* = 20 : 80  
B: Methanol : Buffer 2\*\* = 80 : 20

**\*Buffer 1**

0.7%(v/v) Triethylamine buffer (pH3.0) including tetrabutyl ammonium hydrogen sulfate. Dissolve 7.0mL of triethylamine in 800mL of water. Adjust the pH to 3.0  $\pm$  0.1 with phosphoric acid. Add 1.2 g of tetrabutyl ammonium hydrogen sulfate, then dilute with water to 1 L, filter with Millicup-HV of 0.45- $\mu$  m pore size.

**\*\*Buffer 2**

0.7%(v/v) Triethylamine buffer (pH3.0). Dissolve 7.0mL of triethylamine in 800mL of water. Adjust the pH to 3.0  $\pm$  0.1 with phosphoric acid, and dilute with water to 1 L, filter with Millicup-HV of 0.45- $\mu$  m pore size.

**Gradient;**

B conc. 15 $\rightarrow$ 70% (0 $\rightarrow$ 100min), 70 $\rightarrow$ 15% (100 $\rightarrow$ 101min), 15% (101 $\rightarrow$ 110min)

**Flow rate;** 1.2 mL/min

**Detection;** UV237nm

**Temperature;** 40°C

**Standard solution;**

Amlodipine Besylate (1  $\mu$  g/mL),  
Amlodipine related compound A (1  $\mu$  g/mL),  
Benazepril-HCl (3  $\mu$  g/mL),  
Benazepril related compound C (3  $\mu$  g/mL) / diluent\*\*\*\*

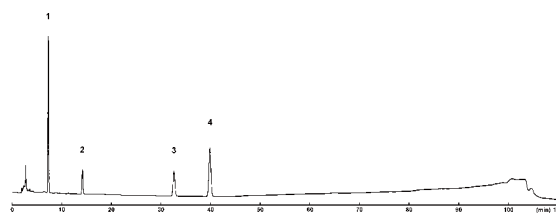
**\*\*\*\*Diluent**

Acetonitrile : Methanol : Buffer 2 = 20 : 30 : 50

**Injection size;** 40  $\mu$  L

**Peak**

- No.1: Benazepril related compound C
- No.2: Amlodipine related compound A
- No.3: Amlodipine
- No.4: Benazepril

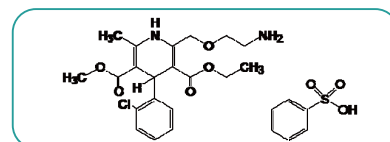


	System suitability	Result
Resolution (Peak No.3 and 4)	$\geq 2.0$	9.2
Tailing factor (Peak No.3)	$\leq 2.0$	1.0
Tailing factor (Peak No.4)	$\leq 2.0$	1.0

USP-127

## USP methods

### 34(5) In-Process Revision: Amlodipine Besylate



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$  m packing L1)

**Column size;** 4.6mm.I.D.-150mm

**Mobile phase;**

Methanol : Acetonitrile : 0.7%(v/v) Triethylamine buffer (pH3.0)\*  
= 35 : 15 : 50

**\*0.7%(v/v) Triethylamine buffer (pH3.0)**

Dissolve 7.0mL of triethylamine in 800mL of water. Adjust the pH to 3.0  $\pm$  0.1 with phosphoric acid, and dilute with water to 1 L, filter with Millicup-HV of 0.45- $\mu$  m pore size.

**Flow rate;** 1.0 mL/min

**Detection;** UV237nm

**Temperature;** 40°C

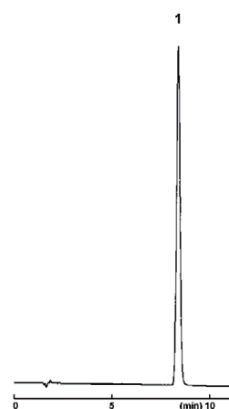
**Standard preparation;**

Amlodipine Besylate (0.05mg/mL) / mobile phase

**Injection size;** 10  $\mu$  L

**Peak**

- No.1: Amlodipine

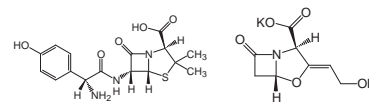


	System suitability	Result
Relative standard deviation (n = 5)	$\leq 2.0\%$	0.4%

USP-046

## USP methods

### 36(4) In-Process Revision: Amoxicillin and Clavulanate Potassium for Oral Suspension



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$ m packing L1)

**Column size;** 4.6mm I.D.-250mm

**Mobile phase;** Methanol : pH 4.4 Sodium Phosphate buffer\* = 5 : 95

\* pH 4.4 Sodium Phosphate buffer  
Dissolve 7.8 g of monobasic sodium phosphate in 900mL of water, adjust the pH to 4.4  $\pm$  0.1 with phosphoric acid, dilute with water to make 1000 mL, and mix.

**Flow rate;** 2.0 mL/min

**Detection;** UV220nm

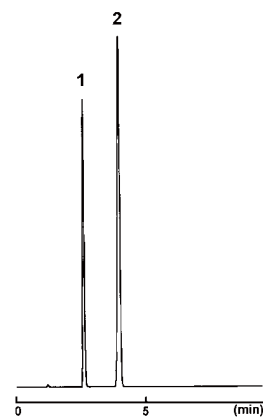
**Temperature;** 40°C

**Resolution solution;**

Clavulanate Lithium (0.20mg/ml),  
Amoxicillin (0.50mg/ml) / Water

**Injection size;** 20  $\mu$  L

Peak  
No.1: Clavulanate Acid  
No.2: Amoxicillin

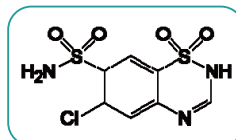


	System suitability	Result (Peak No.1)	Result (Peak No.2)
Resolution (Peak No.1/No.2)	$\geq 3.5$	8.7	
Tailing factor	$\leq 1.5$	1.5	1.0
Relative standard deviation (n=6)	$\leq 2.0\%$	0.3%	0.2%

USP-099

## USP methods

### 29(5) In-Process Revision: Chlorothiazide



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$ m packing L1)

**Column size;** 4.6mm I.D.-250mm

**Mobile phase\*;**

0.1M Monobasic Sodium Phosphate buffer\*\* : Acetonitrile = 90 : 10 (pH3.0)

\*Mobile phase  
Mix 0.1M monobasic sodium phosphate buffer\*\* and acetonitrile (9:1), adjust the pH to 3.0  $\pm$  0.1 with phosphoric acid. Filter with Millicup-HV of 0.45- $\mu$ m pore size.

\*\*0.1M Monobasic Sodium Phosphate buffer  
Dissolve 11.998 g of monobasic sodium phosphate in 1 L of water.

**Flow rate;** 1.2 mL/min

**Detection;** UV254nm

**Temperature;** 40°C

**Standard preparation\*\*\*;**

Chlorothiazide (0.15mg/mL) / mobile phase

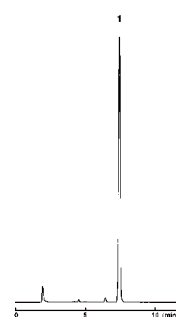
\*\*\*Standard preparation  
First, make 0.75mg/mL of chlorothiazide solution. Dissolve 1.5mg of chlorothiazide to 200  $\mu$  L of acetonitrile, add 1800  $\mu$  L of mobile phase and mix well. Second, dilute 0.75mg/mL of chlorothiazide solution with mobile phase to make 0.15mg/mL solution.

**Resolution solution;**

Chlorothiazide (0.15mg/mL),  
Benzothiadiazine related compound A (1.5  $\mu$ g/mL) / mobile phase

**Injection size;** (1) Standard preparation: 20  $\mu$  L  
(2) Resolution solution: 20  $\mu$  L

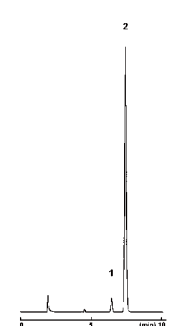
(1) Standard preparation



Peak  
No.1: Chlorothiazide

	System suitability	Result (1)
Relative standard deviation (Peak No.1) (n = 5)	$\leq 1.5\%$	0.3%

(2) Resolution solution

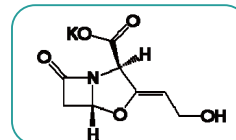


Peak  
No.1: Benzothiadiazine related compound A  
No.2: Chlorothiazide

	System suitability	Result (2)
Resolution (Peak No.1 and 2)	$\geq 3.5$	4.4

## USP methods

### 34(6) In-Process Revision: Clavulanate Potassium



#### Chromatographic purity (1)

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$  m packing L1)

**Column size;** 4.6mm I.D.-100mm

**Mobile phase;** A: 50mmol/l NaH<sub>2</sub>PO<sub>4</sub> with H<sub>3</sub>PO<sub>4</sub> (pH4.0)  
B: Methanol : mobile phase A = 50 : 50

**Gradient;** B conc. 0%(0→4min), 0→50%(4→15min),  
50%(15→18min)

**Flow rate;** 1.0 mL/min

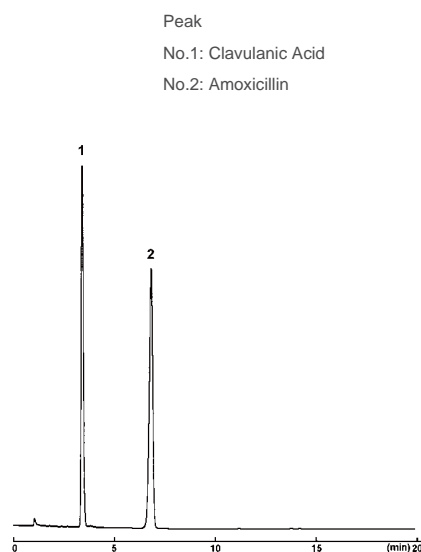
**Detection;** UV230nm

**Temperature;** 40°C

**Resolution solution;**

Clavulanate Lithium (0.1mg/ml),  
Amoxicillin (0.1mg/ml) / mobile phase A

**Injection size;** 20  $\mu$  L



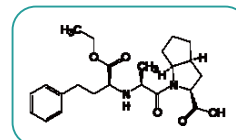
Peak  
No.1: Clavulanate  
No.2: Amoxicillin

	System suitability	Result
Tailing factor (Peak No.1)	$\leq 2.0$	1.6
Theoretical plates (Peak No.1)	$\geq 2,000$	4,900
Resolution (Peak No.1/No.2)	$\geq 13$	13

USP-052

## USP methods

### 31(3) In-Process Revision: Ramipril



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-PAQ (5- $\mu$  m packing L1)

**Column size;** 4.6mm I.D.-150mm

**Mobile phase\*;**

0.1% Sodium Dodecyl Sulfate Solution\*\* : Acetonitrile = 55 : 45

**\*Mobile phase**

Mix the 0.1% sodium dodecyl sulfate solution\*\* and acetonitrile, adjust the pH to 2.75  $\pm$  0.1 with phosphoric acid.

**\*\*0.1% Sodium Dodecyl Sulfate Solution**

Prepare 0.1% solution of sodium dodecyl sulfate. Adjust the pH to 2.4  $\pm$  0.1 with phosphoric acid, then filter with Millicup-HV of 0.45- $\mu$  m pore size.

**Flow rate;** 1.8 mL/min

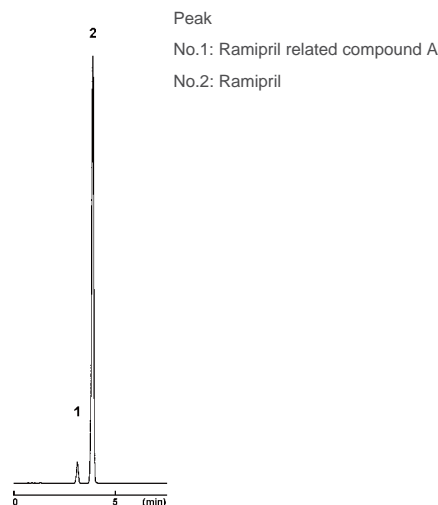
**Detection;** UV210nm

**Temperature;** 40°C

**System suitability preparation;**

Ramipril (0.2mg/mL),  
Ramipril related compound A (0.01mg/mL) / mobile phase

**Injection size;** System suitability preparation: 20  $\mu$  L



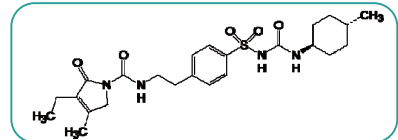
Peak  
No.1: Ramipril related compound A  
No.2: Ramipril

	System suitability	Result
Resolution (Peak No.1 and 2)	$\geq 2.0$	4.0
Theoretical plates (Peak No.2)	$\geq 4,000$	7,000
Relative standard deviation (n = 5) (Peak No.2)	$\leq 1.0\%$	0.3%

USP-009

## USP methods

### 33(3) In-Process Revision: Glimepiride Tablets



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mmI.D.-150mm

**Mobile phase;** Acetonitrile : Phosphate buffer\* = 50 : 50

\*Phosphate buffer  
8.335mM monobasic sodium phosphate buffer (pH2.1 to 2.7). Dissolve 0.5 g of monobasic sodium phosphate in 500mL of water. Adjust the pH to approx. 2.6 with 10% phosphoric acid.

**Flow rate;** 1.0 mL/min

**Detection;** UV228nm

**Temperature;** 40°C

#### System suitability preparation;

Glimepiride (0.1mg/mL),  
Glimepiride related compound B (0.02mg/mL),  
Glimepiride related compound C (0.02mg/mL) / diluent\*\*

\*\*Diluent

Acetonitrile : Water = 90 : 10

#### Standard preparation;

Glimepiride (0.1mg/mL) / diluent\*\*

#### Injection size;

(1) System suitability preparation: 10 μ L  
(2) Standard preparation: 10 μ L

(1) System suitability preparation (2) Standard preparation

Peak

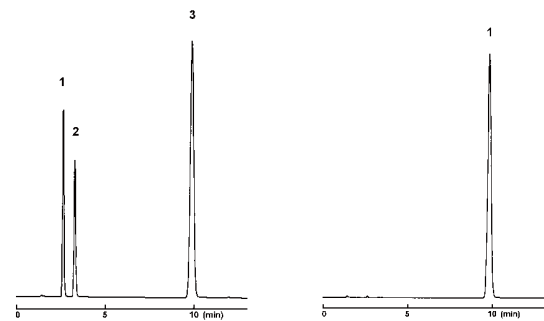
No.1: Glimepiride related compound B

No.2: Glimepiride related compound C

No.3: Glimepiride

Peak

No.1: Glimepiride

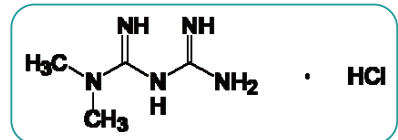


	System suitability	Result (1)		System suitability	Result (2)
Resolution (Peak No.1 and 2)	≥ 1.5	3.8	Relative standard deviation (n = 5)(Peak No.1)	≤ 2.0%	0.2%
Tailing factor (Peak No.3)	≤ 2.0	1.2			

USP-019

## USP methods

### 35(6) In-Process Revision: Glyburide and Metformin Hydrochloride Tablets



#### Assay - Metformin Hydrochloride

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mmI.D.-250mm

**Mobile phase;** Acetonitrile : Buffer (pH3.85)\* = 1 : 9

\*Buffer (pH3.85)  
0.5%(w/v) sodium heptanesulfonate / 0.5%(w/v) sodium chloride buffer. Dissolve 1.0 g of sodium heptanesulfonate and 1.0 g of sodium chloride in approx. 1.8 L of water, and mix. Adjust the pH to 3.85 with 0.06M phosphoric acid, dilute with water to 2 L, filter with Millicup-HV of 0.45- μ m pore size.

**Flow rate;** 1.0 mL/min

**Detection;** UV218nm

**Temperature;** 30°C

#### Standard solution;

Metformin-HCl (0.25mg/mL) / Diluent\*\*

\*\*Diluent

Acetonitrile : water = 1 : 40

#### System suitability stock solution;

Metformin related compound B

Metformin related compound C

25 μ g/mL each / Diluent\*\*

#### System suitability solution\*\*\*;

Metformin-HCl (0.25mg/ml),

Metformin related compound B (0.25 μ g/mL),

Metformin related compound C (0.25 μ g/mL) / Diluent\*\*

\*\*\*System suitability solution

Add standard solution to 0.5mL of system suitability stock solution to make 50mL

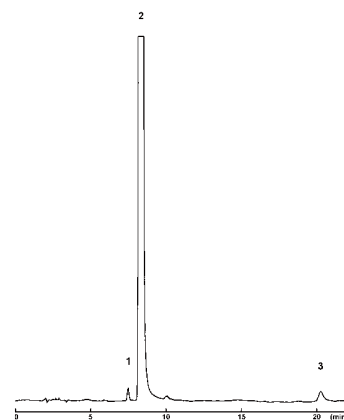
**Injection size;** 5 μ L

Peak

No.1: Metformin-related compound B

No.2: Metformin

No.3: Metformin related compound C

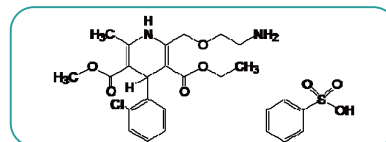


	System suitability	Result
Resolution (Peak No.1 and 2)	≥ 1.5	2.7
Tailing factor (Peak No.2)	0.8~2.0	2.0
Relative standard deviation (n = 6) (Peak No.1)	≤ 10%	2%
Relative standard deviation (n = 6) (Peak No.2)	≤ 1.5%	0.5%
Relative standard deviation (n = 6) (Peak No.3)	≤ 10%	6%

USP-080

## USP methods

### 36(2) In-Process Revision: Amlodipine Besylate Tablets



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mm I.D.-150mm

**Mobile phase;**

Methanol : Acetonitrile : 0.7%(v/v) Triethylamine buffer (pH3.0)\*  
= 35 : 15 : 50

\*0.7%(v/v) Triethylamine buffer (pH3.0)

Dissolve 7.0mL of triethylamine in 800mL of water. Adjust the pH to 3.0 ± 0.1 with phosphoric acid, and dilute with water to 1 L, filter with Millicup-HV of 0.45- μ m pore size.

**Flow rate;** 1.0 mL/min

**Detection;** UV237nm

**Temperature;** 40°C

**System suitability solution;**

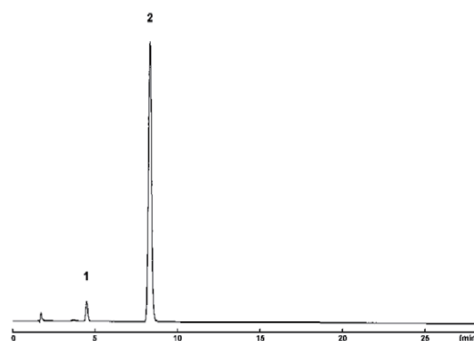
Amlodipine Besylate (20 μ g/mL),  
Amlodipine related compound A (2 μ g/mL) / mobile phase

**Injection size;** 50 μ L

Peak

No.1: Amlodipine related compound A

No.2: Amlodipine

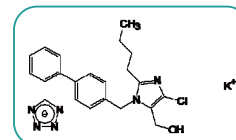


	System suitability	Result
Resolution (Peak No.1 and 2)	≥ 8.5	10.8
Tailing Factor (Peak No.1)	≤ 2.0	1.2
Tailing Factor (Peak No.2)	≤ 2.0	1.3
Relative standard deviation (n = 6) (Peak No.1)	≤ 5.0%	3.5%
Relative standard deviation (n = 6) (Peak No.2)	≤ 1.0%	1.0%

USP-086

## USP methods

### 34(3) In-Process Revision: Losartan Potassium



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mm I.D.-250mm

**Mobile phase;**

0.1% (v/v) Phosphoric Acid\* : Acetonitrile = 60 : 40

\*0.1% (v/v) phosphoric acid

Dissolve 1176.5 μ L of phosphoric acid (85%) to water, add water to 1 L.

**Flow rate;** 1.0 mL/min

**Detection;** UV254nm

**Temperature;** 35°C

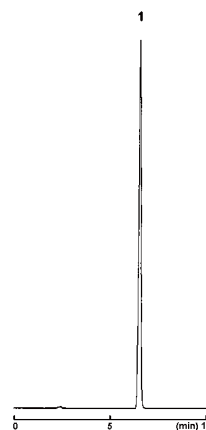
**Standard preparation;**

Losartan Potassium (0.25mg/mL) / Methanol

**Injection size;** 10 μ L

Peak

No.1: Losartan

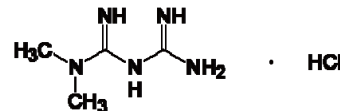


	System suitability	Result
Theoretical plate	≥ 5,600	15,200
Tailing factor	≤ 1.4	1.0
Relative standard deviation (n = 5)	≤ 0.5%	0.4%

USP-031

## USP methods

### 33(2) Second Interim Revision: Metformin Hydrochloride Tablets



#### Dissolution-Test 3

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mm I.D.-250mm

**Mobile phase;** Acetonitrile : Buffer (pH3.0)\* = 1 : 19

\*Buffer (pH3.0)  
10mM Sodium 1-pentanesulfonate / 0.05M monobasic sodium phosphate buffer. Dissolve 1.38 g of monobasic sodium phosphate in approx. 1.8 L of water. Add 3.484 g of 1-pentanesulfonic acid sodium salt, and mix. Adjust the pH to 3.00 ± 0.05 with diluted phosphoric acid. Add water to make 2 L, filter with Millicup-HV of 0.45- μ m pore size.

**Flow rate;** 1.0 mL/min

**Detection;** UV230nm

**Temperature;** 40°C

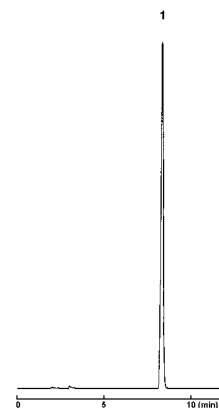
**Standard solution;**

Metformin-HCl (0.1mg/mL) / 0.2M Monobasic Potassium Phosphate buffer (pH6.8)

**Injection size;** 40 μ L

Peak

No.1: Metformin-HCl

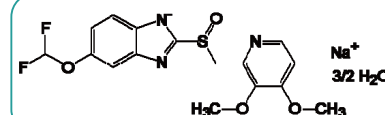


	System suitability	Result
Tailing factor	≤ 2.0	1.1
Theoretical plate	≥ 1,500	17,800
Relative standard deviation (n = 5)	≤ 2.0%	0.2%

USP-016

## USP methods

### 34(3) Third Interim Revision Announcement: Pantoprazole Sodium



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- μ m packing L1)

**Column size;** 4.6mm I.D.-150mm

**Mobile phase;** A; Acetonitrile - Methanol Mixture\* : Buffer\*\* = 15 : 85  
B; Acetonitrile - Methanol Mixture\*

\*Acetonitrile - Methanol Mixture  
Acetonitrile : Methanol = 70 : 30

\*\*Buffer  
10mM Ammonium phosphate buffer. Dissolve 1.32 g of dibasic ammonium phosphate in 1 L of water. Adjust the pH to 7.5 with phosphoric acid. Filter with Millicup-HV of 0.45- μ m pore size.

**Gradient;** B conc. 14% (0→10min), 14→58% (10→35min), 58→14% (35→36min), 14% (36→46min)

**Flow rate;** 1.0 mL/min

**Detection;** UV285nm

**Temperature;** 30°C

**System suitability preparation\*\*\*;**

Pantoprazole-Na  
Pantoprazole related compound A  
Pantoprazole related compound B  
5 μ g/mL each in Acetonitrile : Water = 1 : 1, Diluent†

\*\*\*System suitability preparation  
Dissolve pantoprazole-Na, pantoprazole related compound A and pantoprazole related compound B in the mixture of acetonitrile and water (1:1) to obtain 0.5mg of each component per mL. Dilute this solution with diluent† to obtain 5 μ g of each component per mL.

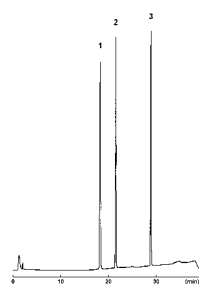
†Diluent  
0.28% Ammonia water. Transfer 2.5mL of ammonia hydroxide to 50-mL volumetric flask, and dilute with water to volume.

**Standard preparation††;**  
Pantoprazole-Na (0.06mg/mL) / Acetonitrile : Water = 1:1, Diluent†

††Standard preparation  
Transfer 4.0mg of pantoprazole-Na to a 10-mL volumetric flask, dissolve in 1.4mL of a mixture of acetonitrile and water (1:1), and dilute with diluent† to volume. Further dilute with diluent† to obtain a solution contains 0.06mg of pantoprazole-Na per mL.

**Injection size;** (1) System suitability preparation: 20 μ L  
(2) Standard preparation: 20 μ L

(1) System suitability preparation



Peak

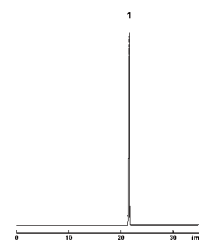
No.1: Pantoprazole related compound A

No.2: Pantoprazole

No.3: Pantoprazole related compound B

	System suitability	Result (1)
Resolution (Peak No.1 and 2)	≥ 10.0	12.5

(2) Standard preparation



Peak

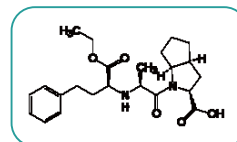
No.1: Pantoprazole

	System suitability	Result (2)
Relative standard deviation (n = 5) (Peak No.1)	≤ 2.0%	0.6%

USP-037

## USP methods

### 31(3) In-Process Revision: Ramipril



#### Assay

**Column;** COSMOSIL 5C<sub>18</sub>-MS-II (5- $\mu$  m packing L1)

**Column size;** 4.6mm I.D.-150mm

**Mobile phase\*;**

0.1% Sodium Dodecyl Sulfate Solution\*\* : Acetonitrile = 55 : 45

**\*Mobile phase**

Mix the 0.1% sodium dodecyl sulfate solution\*\* and acetonitrile, adjust the pH to 2.75  $\pm$  0.1 with phosphoric acid.

**\*\*0.1% Sodium Dodecyl Sulfate Solution**

Prepare 0.1% solution of sodium dodecyl sulfate. Adjust the pH to 2.4  $\pm$  0.1 with phosphoric acid, then filter with Millicup-HV of 0.45- $\mu$  m pore size.

**Flow rate;** 1.8 mL/min

**Detection;** UV210nm

**Temperature;** 40°C

**System suitability preparation;**

Ramipril (0.2mg/mL),

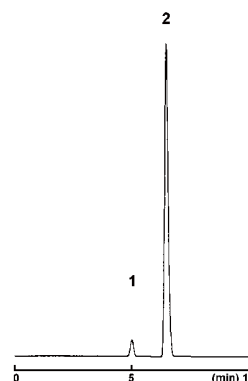
Ramipril related compound A (0.01mg/mL) / mobile phase

**Injection size;** System suitability preparation: 20  $\mu$  L

Peak

No.1: Ramipril related compound A

No.2: Ramipril



	System suitability	Result
Resolution (Peak No.1 and 2)	$\geq 2.0$	5.1
Theoretical plates (Peak No.2)	$\geq 4,000$	8,200
Relative standard deviation (n = 5) (Peak No.2)	$\leq 1.0\%$	0.7%

USP-007

## COSMOSIL USP List

USP No.	Phase	USP Description	Product Name
L01	C <sub>18</sub>	Octadecyl silane <ODS or C <sub>18</sub> > chemically bonded to porous silica or ceramic particles, 1.5 to 10 $\mu$ m in diameter, or a monolithic rod.	COSMOSIL 3C <sub>18</sub> -EB COSMOSIL 5C <sub>18</sub> -MS-II COSMOSIL 5C <sub>18</sub> -AR-II COSMOSIL 5C <sub>18</sub> -PAQ COSMOSIL 5C <sub>18</sub> -AR-300 COSMOSIL 2.5C <sub>18</sub> -MS-II
L03	SIL	Porous silica particles, 5 to 10 $\mu$ m in diameter, or a monolithic rod.	COSMOSIL 5SL-II
L07	C <sub>8</sub>	Octylsilane <C <sub>8</sub> > chemically bonded to porous silica particles, 1.5 to 10 $\mu$ m in diameter, or a monolithic rod.	COSMOSIL 5C <sub>8</sub> -MS COSMOSIL 5C <sub>8</sub> -AR-300
L10	CN	Nitrile groups <CN> chemically bonded to porous silica particles, 3 to 10 $\mu$ m in diameter.	COSMOSIL 5CN-MS
L11	Ph	Phenyl groups chemically bonded to porous silica particles, 1.5 to 10 $\mu$ m in diameter.	COSMOSIL 5PE-MS COSMOSIL 5Ph-AR-300
L13	C <sub>1</sub>	Trimethylsilane <C <sub>1</sub> > chemically bonded to porous silica particles, 3 to 10 $\mu$ m in diameter.	COSMOSIL 5TMS-MS
L20	Diol	Dihydroxypropane groups chemically bonded to porous silica particles, 5 to 10 $\mu$ m in diameter.	COSMOSIL Diol-120-II COSMOSIL Diol-300-II
L26	C <sub>4</sub>	Butyl silane <C <sub>4</sub> > chemically bonded to porous silica particles, 3 to 10 $\mu$ m in diameter.	COSMOSIL 5C <sub>4</sub> -MS COSMOSIL 5C <sub>4</sub> -AR-300
Lxx (Coming soon)	Pyrene	Pyrenyl groups chemically bonded to porous silica particles, 1.5 to 10 $\mu$ m in diameter, or a monolithic rod	COSMOSIL PYE

For research use only, not intended for diagnostic or drug use.

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