

# Meeting System Suitability for USP Amlodipine and Olmesartan Medoxomil Tablets Assay and Organic Impurities

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## Overview

Amlodipine and Olmesartan Medoxomil in combination are used with other medications to treat hypertension. In this application note, we report the separation of Amlodipine and Olmesartan Medoxomil and their related organic impurities per the USP monograph using a Kinetex 5  $\mu$ m Biphenyl column and a Kinetex 5  $\mu$ m Phenyl-Hexyl column as alternative L11 columns to the ZORBAX 5  $\mu$ m SB-Phenyl column originally used to elucidate the monograph.

System suitability per USP Monograph for Amlodipine and Olmesartan Medoxomil Tablets Assay is a symmetry factor no more than (NMT) 2.0 for the Amlodipine and Olmesartan Medoxomil peaks and a percent relative standard deviation (%RSD) NMT 2.0 % for the Amlodipine and Olmesartan Medoxomil peaks. System suitability per USP Monograph for Amlodipine and Olmesartan Medoxomil Tablets Organic Impurities is a symmetry factor NMT 2.0 for Amlodipine related compound A, Amlodipine, and Olmesartan Medoxomil peaks, a %RSD NMT 5.0 % for Amlodipine related compound A, Amlodipine, and Olmesartan Medoxomil peaks, and a signal-to-noise (S/N) ratio NLT 10 for Amlodipine related compound A, Amlodipine, and Olmesartan Medoxomil peaks.

System suitability requirements for Amlodipine and Olmesartan Medoxomil Tablets Assay and Organic Impurities were met by all columns except for S/N ratio. None of the columns reached a S/N ratio NLT 10. However, all peaks of interest were observed on both Kinetex columns and only one peak was observed on the ZORBAX column for the same solution.

All solutions were prepared as indicated in the USP Monograph for Amlodipine and Olmesartan Medoxomil Tablets. USP Amlodipine Besylate RS (Catalog No. 1029501), USP Amlodipine Related Compound A RS (1029512), and USP Olmesartan Medoxomil RS (Catalog No. 1478367) were purchased from USP.

## LC-UV Conditions

**Columns:** Kinetex™ 5  $\mu$ m Biphenyl ([00G-4627-E0](#))  
Kinetex 5  $\mu$ m Phenyl-Hexyl ([00G-4603-E0](#))  
ZORBAX® 5  $\mu$ m SB-Phenyl

**Dimensions:** 250 x 4.6 mm  
**Mobile Phase:** A: 6.9 g/L of Sodium Phosphate, monobasic, adjusted with Phosphoric Acid to a pH of 2.5  
B: Acetonitrile

Gradient: Time (min)	%
0	32
12	32
15	70
21	70
23	32
25	32

**Flow Rate:** 2 mL/min

**Injection Volume:** 10  $\mu$ L

Temperature: 60 °C

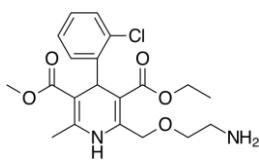
**System:** Agilent® 1290

**Detection:** UV @ 254 nm

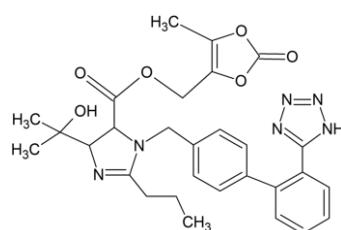
**Table 1.** Preparation of Test and Reference Solutions

Solution	Composition
<b>Diluent</b>	Acetonitrile / Water (50:50, v/v)
<b>Standard Stock Solution (Assay)</b>	0.28 mg/mL of <i>USP Amlodipine Besylate RS</i> and <i>USP Olmesartan Medoxomil RS</i> in <b>Diluent</b> .
Standard Solution (Assay)	0.056 mg/mL of <i>USP Amlodipine Besylate RS</i> and 0.16 mg/mL of <i>USP Olmesartan Medoxomil RS</i> in <b>Diluent</b> from <b>Standard Stock Solution</b> . Pass through a Phenex™ 0.45 µm pore size Nylon filter (Part No.: <a href="#">AF3-3107-12</a> ).
<b>Standard Stock Solution A (Organic Impurities)</b>	28 µg/mL of <i>USP Amlodipine Besylate RS</i> and 80 µg/mL of <i>USP Olmesartan Medoxomil RS</i> in <b>Diluent</b> from <b>Standard Stock Solution</b> .
<b>Standard Stock Solution B (Organic Impurities)</b>	50 µg/mL of <i>USP Amlodipine Related Compound A RS</i> in <b>Diluent</b> .
<b>Standard Solution (Organic Impurities)</b>	1.4 µg/mL of <i>USP Amlodipine Besylate RS</i> , 2.5 µg/mL of <i>USP Amlodipine Related Compound A RS</i> , and 4 µg/mL of <i>USP Olmesartan Medoxomil RS</i> in <b>Diluent</b> from <b>Standard Stock Solution A</b> and <b>Standard Stock Solution B</b> . Pass through a Phenex™ 0.45 µm pore size Nylon filter (Part No.: <a href="#">AF3-3107-12</a> ).
Sensitivity Solution (Organic Impurities)	0.28 µg/mL of <i>USP Amlodipine Besylate RS</i> , 0.5 µg/mL of <i>USP Amlodipine Related Compound A RS</i> , and 0.8 µg/mL of <i>USP Olmesartan Medoxomil RS</i> in <b>Diluent</b> from <b>Standard Solution</b> .

**Figure 1.** Amlodipine and Olmesartan Medoxomil Structures.



## Amlodipine

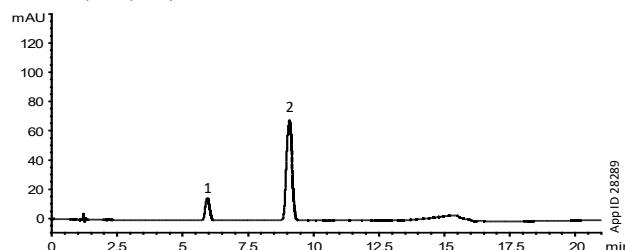


## Olmesartan Medoxomil



**Figure 2.** Standard Solution – Assay

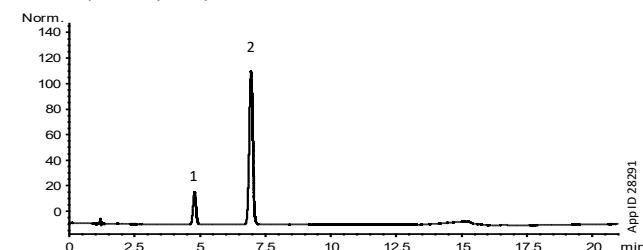
Kinetex™ 5 µm Biphenyl Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine	5.96	174.20	0.23	0.99
2	Olmesartan Medoxomil	9.08	1008.00	0.08	1.01

N=5 Injections

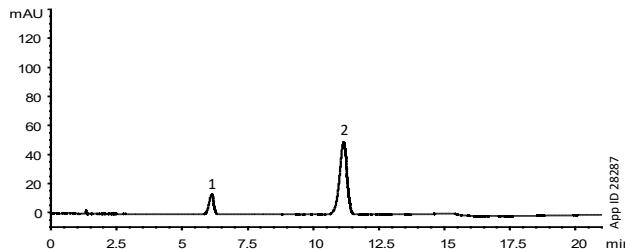
Kinetex 5 µm Phenyl-Hexyl Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine	4.79	169.20	0.20	1.01
2	Olmesartan Medoxomil	6.95	991.30	0.12	1.01

N=5 Injections

ZORBAX® 5 µm SB-Phenyl Column



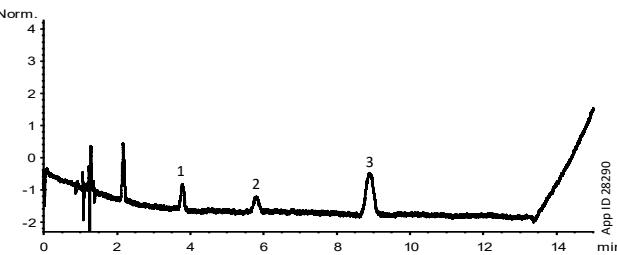
Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine	6.12	168.90	0.99	0.88
2	Olmesartan Medoxomil	11.16	997.20	0.27	0.88

N=5 Injections



**Figure 3.** Standard Solution – Organic Impurities

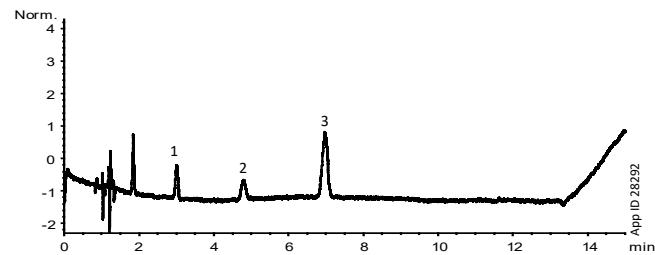
Kinetex™ 5 µm Biphenyl Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine related compound A	3.79	5.10	3.75	1.03
2	Amlodipine	5.79	5.30	4.30	1.11
3	Olmesartan Medoxomil	8.89	18.20	3.08	1.01

N=6 Injections

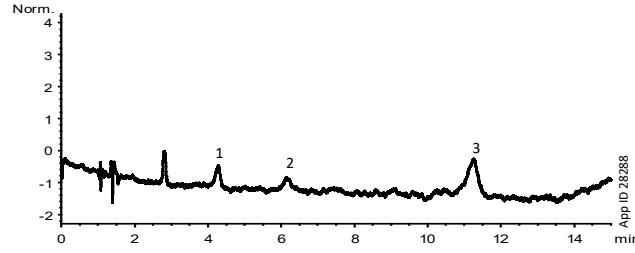
Kinetex 5 µm Phenyl-Hexyl Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine related compound A	3.01	5.00	2.93	0.83
2	Amlodipine	4.79	4.50	1.87	0.81
3	Olmesartan Medoxomil	6.97	18.20	1.66	0.98

N=6 Injections

ZORBAX® 5 µm SB-Phenyl Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD	Symmetry Factor
1	Amlodipine related compound A	4.28	5.40	3.53	1.02
2	Amlodipine	6.13	4.70	3.89	0.90
3	Olmesartan Medoxomil	11.25	20.70	3.37	0.93

N=6 Injections



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