Amlodipine and Valsartan Tablets

**Type of Posting** | Revision Bulletin  
**Posting Date** | 27–May–2016  
**Official Date** | 01–Jun–2016  
**Expert Committee** | Chemical Medicines Monographs 2  
**Reason for Revision** | Compliance

In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Chemical Medicines Monographs 2 Expert Committee has revised the Amlodipine and Valsartan Tablets monograph. The purpose of this revision is to be consistent with the FDA-approved drug products and is described below:

- The acceptance criteria under *Definition* and *Assay* is widened from “NLT 95.0% and NMT 105.0%” to “NLT 90.0% and NMT 110.0%” for both amlodipine and valsartan.
- The acceptance criterion for total degradation products is widened from NMT 0.8% to NMT 1.2%.
- A *Dissolution Test 2* is added. The liquid chromatographic procedure is validated using an Inertsil ODS 3V brand of L1 column. The typical retention times for amlodipine and valsartan are about 4.3 min and 7.0 min respectively.
- A *Dissolution Test 3* is added. The liquid chromatographic procedure is validated using an Oyster ODS 3 brand of L1 column. The typical retention times for amlodipine and valsartan are about 3.0 min and 3.5 min respectively.

Minor editorial changes have been made to update the monograph to the current *USP* style.

The Amlodipine and Valsartan Tablets Revision Bulletin supersede the currently official Amlodipine and Valsartan Tablets monograph. The Revision Bulletin will be incorporated in the *USP 40–NF 35*.

Should you have any questions, please contact Sujatha Ramakrishna, Ph.D., MBA. Senior Scientific Liaison (301–816–8349 or sxr@usp.org)
Amlodipine and Valsartan Tablets

**DEFINITION**

Change to read:

Amlodipine and Valsartan Tablets contain \*NLT 90.0% and NMT 110.0% ± (88 1-Jun-2016) of the labeled amount of amlodipine (C_{20}H_{25}ClN_{2}O_{5}) and valsartan (C_{24}H_{29}N_{5}O_{3}).

**IDENTIFICATION**

- **A.** The UV absorption spectra of the major peaks of Sample solution A and Sample solution B and those of the Standard solution exhibit maxima and minima at the same wavelengths, as obtained in the Assay.
- **B.** The retention times of the major peaks of Sample solution A and Sample solution B correspond to those of the Standard solution, as obtained in the Assay.

**ASSAY**

**Change to read:**

- **PROCEDURE**
  
  **Solution A:** Water and triethylamine (1000:10). Adjust with phosphoric acid to a pH of 2.8.
  
  **Solution B:** Methanol and acetonitrile (700:300)
  
  **Mobile phase:** See Table 1.

  **Table 1**

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution A (%)</th>
<th>Solution B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>15</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>20</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>20.1</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>25</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

  **Diluent:** Solution A and Solution B (50:50)
  
  **Standard solution:** 0.14 mg/mL of USP Amlodipine Besylate RS and 0.16 mg/mL of USP Valsartan RS. Add methanol to 5% of the final volume to dissolve, and dilute with Diluent to volume.

  **Sample stock solution:** Transfer NLT 10 Tablets into a suitable volumetric flask. Initially dissolve in methanol to 40% of the final volume, and sonicate to disperse as needed. Add Diluent, using about 70% of the final volume, and shake for up to 45 min to disperse. Following dispersion, sonicate for 15 min, and shake for 30 min. Dilute with Diluent to volume to obtain a solution containing known nominal concentrations of 0.1–0.2 mg/mL of amlodipine and 1.6–6.4 mg/mL of valsartan. Centrifuge the solution for about 10 min at 3000 rpm.

  **Sample solution A:** Nominally equivalent to 0.1 mg/mL of amlodipine in Diluent from Sample stock solution
  
  **Sample solution B:** Nominally equivalent to 0.16 mg/mL of valsartan in Diluent from Sample stock solution

  **Chromatographic system**
  
  (See Chromatography (621), System Suitability.)
  
  **Mode:** LC
  
  **Detector:** UV 237 nm
  
  **Identification A:** Diode array, \*UV 200–400 nm ± (88 1-Jun-2016)

**Column:** 3.9-mm × 15-cm; 5-μm packing L1

**Temperatures**

**Autosampler:** 10°

**Column:** 30°

**Flow rate:** 1.0 mL/min

**Injection volume:** 10 μL

**System suitability**

**Sample:** Standard solution

**Suitability requirements**

- **Tailing factor:** NMT 1.5 for both amlodipine and valsartan
- **Relative standard deviation:** NMT 2.0% for amlodipine and valsartan

**Analysis**

**Samples:** Standard solution, Sample solution A, and Sample solution B

Calculate the percentage of the labeled amount of amlodipine (C_{20}H_{25}ClN_{2}O_{5}) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_d}{r_u} \right) \times \left( \frac{C_d}{C_u} \right) \times \left( \frac{M_{1d}}{M_{1u}} \right) \times 100
\]

\[
r_d = \text{peak response of amlodipine from Sample solution A}
\]

\[
r_u = \text{peak response of amlodipine from the Standard solution}
\]

\[
C_d = \text{concentration of USP Amlodipine Besylate RS in the Standard solution (mg/mL)}
\]

\[
C_u = \text{nominal concentration of amlodipine in Sample solution A (mg/mL)}
\]

\[
M_{1d} = \text{molecular weight of amlodipine, 408.88}
\]

\[
M_{1u} = \text{molecular weight of amlodipine besylate, 567.05}
\]

Calculate the percentage of the labeled amount of valsartan (C_{24}H_{29}N_{5}O_{3}) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_d}{r_u} \right) \times \left( \frac{C_d}{C_u} \right) \times 100
\]

\[
r_d = \text{peak response of valsartan from Sample solution B}
\]

\[
r_u = \text{peak response of valsartan from the Standard solution}
\]

\[
C_d = \text{concentration of USP Valsartan RS in the Standard solution (mg/mL)}
\]

\[
C_u = \text{nominal concentration of valsartan in Sample solution B (mg/mL)}
\]

**Acceptance criteria:** \*90.0%–110.0% ± (88 1-Jun-2016)

**PERFORMANCE TESTS**

**Change to read:**

**Dissolution (711)**

**Test 1 ± (88 1-Jun-2016)**

**Buffer:** Dissolve 6.805 g of monobasic potassium phosphate and 0.896 g of sodium hydroxide or 1 M phosphoric acid to a pH of 6.8. Add water to 1000 mL. Adjust with 0.2 N sodium hydroxide or 1 M phosphoric acid to a pH of 6.8.

**Medium:** Buffer, 1000 mL

**Apparatus 2:** 75 rpm

**Time:** 30 min

**Mobile phase:** Acetonitrile, water, and trifluoroacetic acid (500:500:2)

**Diluent:** 1 mg/mL of polysorbate 80 in Buffer

**System suitability solution:** 0.4 mg/mL each of USP Amlodipine Besylate RS and USP Valsartan RS prepared as follows. Initially dissolve in methanol to 40% of the total volume, and dilute with Buffer to volume.

**Standard stock solution A:** 0.072 mg/mL of USP Amlodipine Besylate RS prepared as follows. Initially dissolve in methanol to 40% of the total volume, and dilute with Buffer to volume.

**Injection volume:** 10 μL

**Suitability requirements**

- **Retention time:** NMT 1.0 min for amlodipine and NMT 1.8 min for valsartan
- **System suitability**
  
  - **Tailing factor:** NMT 1.5 for both amlodipine and valsartan
  - **Relative standard deviation:** NMT 2.0% for amlodipine and valsartan

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Amlodipine

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dissolve in methanol to 4% of the final volume, and dilute with Diluent to volume.

**Standard stock solution B:** 2.2 mg/mL of USP Val- sartan RS in methanol

**Standard solution:** \((L_1/1000)\) mg/mL of amlodipine and \((L_2/1000)\) mg/mL of valsartan in Diluent from Standard stock solution A and Standard stock solution B, where \(L_1\) is the label claim of amlodipine in mg/Tablet, and \(L_2\) is the label claim of valsartan in mg/Tablet.

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Discard the first 10 mL of the filtrate.

**Chromatographic system**

(See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 230 nm

**Column:** 4.6-mm x 15-cm; 4-μm packing L11

**Column temperature:** 40°

**Flow rate:** 1.2 mL/min

**Injection volume:** 10 μL

**Run time:** NLT 2 times the retention time of amlodipine.

**System suitability**

**Samples:** System suitability solution and Standard solution

**Suitability requirements**

**Resolution:** NLT 2.0 between amlodipine and valsartan, System suitability solution

**Tailing factor:** NMT 2.0 for amlodipine and valsartan, Standard solution

**Relative standard deviation:** NMT 2.0% for amlodipine and valsartan, Standard solution

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of amlodipine \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0}{r_a} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_1} \right) \times 100
\]

\(r_0\) = peak response of amlodipine from the Sample solution

\(r_a\) = peak response of amlodipine from the Standard solution

\(C_5\) = concentration of USP Amlodipine Besylate RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(M_1\) = molecular weight of amlodipine, 408.88

\(M_2\) = molecular weight of amlodipine besylate, 567.05

\(L_1\) = label claim for amlodipine \((\text{mg/Tablet})\)

Calculate the percentage of the labeled amount of valsartan \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0/r_a} {r_0} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_2} \right) \times 100
\]

\(r_0\) = peak response of valsartan from the Sample solution

\(r_a\) = peak response of valsartan from the Standard solution

\(C_5\) = concentration of USP Valsartan RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(L_1\) = label claim for valsartan \((\text{mg/Tablet})\)

**Tolerances:** NLT 80% (Q) of the labeled amount of amlodipine \((C_{24}H_{29}N_5O_3)\) and valsartan \((C_{24}H_{29}N_5O_3)\) is dissolved.

**Test 2:** If the product complies with this test, the labeling indicates that the product meets USP Dissolution Test 2.

**Medium and Time:** Proceed as directed in Dissolution Test 1; 1000 mL

---

**Table 2**

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution A (%)</th>
<th>Solution B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>7</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>10</td>
<td>80</td>
<td>20</td>
</tr>
</tbody>
</table>

**Apparatus 2:** 50 rpm

**Buffer:** Mix 7.0 mL of triethylamine with 1000 mL of water. Adjust with phosphoric acid to a pH of 3.0.

**Solution A:** Acetonitrile and Buffer (10:90)

**Solution B:** Acetonitrile and Buffer (90:10)

**Mobile phase:** See Table 2.

**Standard stock solution A:** 0.14 mg/mL of USP Amlodipine Besylate RS prepared as follows. Initially dissolve in 10% of the final volume of methanol, and dilute with Medium to volume.

**Standard stock solution B:** 1.6 mg/mL of USP Valsartan RS in methanol

**Standard solution:** \((L_1/1000)\) mg/mL of amlodipine and \((L_2/1000)\) mg/mL of valsartan in Diluent from Standard stock solution A and Standard stock solution B, where \(L_1\) is the label claim of amlodipine in mg/Tablet, and \(L_2\) is the label claim of valsartan in mg/Tablet.

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 1-μm pore size.

**Chromatographic system**

(See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 237 nm

**Column:** 4.6-mm x 15-cm; 5-μm packing L1

**Temperatures**

**Autosampler:** 10°

**Column:** 50°

**Flow rate:** 1.5 mL/min

**Injection volume:** 20 μL

**System suitability**

**Sample:** Standard solution

**Suitability requirements**

**Resolution:** NMT 2.0 for amlodipine and valsartan

**Tailing factor:** NMT 2.0% for amlodipine and valsartan

**Relative standard deviation:** NMT 2.0% for amlodipine and valsartan

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of amlodipine \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0}{r_a} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_1} \right) \times 100
\]

\(r_0\) = peak response of amlodipine from the Sample solution

\(r_a\) = peak response of amlodipine from the Standard solution

\(C_5\) = concentration of USP Amlodipine Besylate RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(M_1\) = molecular weight of amlodipine, 408.88

\(M_2\) = molecular weight of amlodipine besylate, 567.05

\(L_1\) = label claim for amlodipine \((\text{mg/Tablet})\)

Calculate the percentage of the labeled amount of valsartan \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0/r_a} {r_0} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_2} \right) \times 100
\]

\(r_0\) = peak response of valsartan from the Sample solution

\(r_a\) = peak response of valsartan from the Standard solution

\(C_5\) = concentration of USP Valsartan RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(M_1\) = molecular weight of valsartan, 408.88

\(M_2\) = molecular weight of amlodipine besylate, 567.05

\(L_1\) = label claim for valsartan \((\text{mg/Tablet})\)

Calculate the percentage of the labeled amount of valsartan \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0}{r_a} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_2} \right) \times 100
\]

\(r_0\) = peak response of amlodipine from the Sample solution

\(r_a\) = peak response of amlodipine from the Standard solution

\(C_5\) = concentration of USP Amlodipine Besylate RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(M_1\) = molecular weight of amlodipine, 408.88

\(M_2\) = molecular weight of amlodipine besylate, 567.05

\(L_1\) = label claim for amlodipine \((\text{mg/Tablet})\)

Calculate the percentage of the labeled amount of valsartan \((C_{24}H_{29}N_5O_3)\) dissolved:

\[
\text{Result} = \left( \frac{r_0/r_a} {r_0} \right) C_5 \times V \times \left( \frac{M_1/M_2}{1/L_2} \right) \times 100
\]

\(r_0\) = peak response of valsartan from the Sample solution

\(r_a\) = peak response of valsartan from the Standard solution

\(C_5\) = concentration of USP Valsartan RS in the Standard solution \((\text{mg/mL})\)

\(V\) = volume of Medium, 1000 mL

\(M_1\) = molecular weight of valsartan, 408.88

\(M_2\) = molecular weight of amlodipine besylate, 567.05

\(L_1\) = label claim for valsartan \((\text{mg/Tablet})\)
Amlodipine

Test 3:
Indicates that the product meets USP valsartan (C24H29N5O3) dissolved:

Tolerances:
NLT 75% (Q) of the labeled amount of amlodipine (C20H25ClN2O5) and NLT 80% (Q) of the labeled amount of valsartan (C24H29N5O3) is dissolved.

Mobile phase: Acetonitrile, trifluoroacetic acid, and water (90:0.1:10)

Solution A: Acetonitrile, trifluoroacetic acid, and water (10:0.1:90)

Solution B: Acetonitrile, trifluoroacetic acid, and water (90:0.1:10)

Mobile phase: See Table 3,

![Table 3](https://example.com/table3.png)

Diluent: Acetonitrile and water (50:50)

Standard stock solution A: 0.14 mg/mL of USP Amlodipine Besylate RS prepared as follows. Initially dissolve in Diluent about 4% of the final volume, and dilute with Medium to volume.

Standard stock solution B: 1.6 mg/mL of USP Valsartan RS prepared as follows. Initially dissolve in about 20% of the final volume of Diluent, and dilute with Medium to volume.

Standard solution: (L1/1000) mg/mL of amlodipine and (L2/1000) mg/mL of valsartan in Medium from Standard stock solution A and Standard stock solution B, where L1 is the label claim of amlodipine in mg/Tablet, and L2 is the label claim of valsartan in mg/Tablet.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size and discard the first few mL of the filtrate.

Chromatographic system
(See Chromatography (621), System Suitability.)

Mode: LC
Detector: UV 237 nm for amlodipine and UV 270 nm for valsartan
Column: 4.6-mm × 10-cm; 5-μm packing L1
Flow rate: 1.5 mL/min
Injection volume: 10 μL
System suitability
Sample: Standard solution
Suitability requirements
Tailing factor: NMT 2.0 for amlodipine and valsartan
Relative standard deviation: NMT 2.0% for amlodipine and valsartan

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of the labeled amount of amlodipine (C20H25ClN2O5) dissolved:

Result = \( \frac{r1}{r0} \times C1 \times V \times \left( \frac{M1}{M2} \right) \times \left( \frac{1}{L2} \right) \times 100 \)

\( r0 \) = peak response of amlodipine from the Sample solution
\( C1 \) = concentration of USP Amlodipine Besylate RS in the Standard solution
\( V \) = volume of Medium, 1000 mL
\( L2 \) = label claim for valsartan (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of amlodipine (C20H25ClN2O5) and NLT 80% (Q) of the labeled amount of valsartan (C24H29N5O3) is dissolved.

**IMPURITIES**

**Change to read:**

- **ORGANIC IMPURITIES**
  - Mobile phase, Diluent, Sample solution A, Sample solution B, and Chromatographic system: Proceed as directed in the Assay.
  - System suitability solution: Dissolve a suitable quantity of USP Valsartan Related Compound B RS in Standard stock solution A to obtain a solution containing 0.08 mg/mL of USP Valsartan Related Compound B RS, 0.14 mg/mL of USP Amlodipine Besylate RS, and 0.16 mg/mL of USP Valsartan RS.
  - Sensitivity solution: 0.14 μg/mL of USP Amlodipine Besylate RS and 0.16 μg/mL of USP Valsartan RS in Diluent from Standard stock solution A
  - Standard stock solution B: 0.1 mg/mL of USP Amlodipine Related Compound A RS as free base prepared as follows. Add methanol to 5% of the final volume to dissolve, and dilute with Diluent to volume.
  - Standard solution: 0.0005 mg/mL of USP Amlodipine Related Compound A RS as free base, and 0.0003 mg/mL of each of USP Amlodipine Besylate RS and USP Valsartan RS in Diluent from Standard stock solution A and Standard stock solution B, respectively.

System suitability
Samples: System suitability solution, Sensitivity solution, and Standard solution
Suitability requirements
- Resolution: More than 4.0 between amlodipine and valsartan related compound B and more than 4.0 between valsartan related compound B and valsartan, System suitability solution
- Relative standard deviation: NMT 5.0% for amlodipine related compound A, amlodipine, and valsartan, Standard solution
- Signal-to-noise ratio: NLT 10 for amlodipine and valsartan, Sensitivity solution

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Analysis

Samples: Sample solution A, Sample solution B, and Standard solution
Calculate the percentage of amlodipine related compound A free base in the portion of Tablets taken:
\[ \text{Result} = \left( \frac{r_0}{r_3} \times \frac{(C_1/C_0)}{(M_1/M_2)} \right) \times 100 \]

- \( r_0 \) = peak response of amlodipine related compound A from Sample solution A
- \( r_3 \) = peak response of amlodipine related compound A from the Standard solution
- \( C_1 \) = concentration of USP Amlodipine Related Compound A RS in the Standard solution (mg/mL)
- \( C_0 \) = nominal concentration of amlodipine in Sample solution A (mg/mL)
- \( M_1 \) = molecular weight of amlodipine related compound A free base, 406.86
- \( M_2 \) = molecular weight of amlodipine related compound A fumarate, 522.93

Calculate the percentage of each unspecified degradation product in the portion of Tablets taken:
\[ \text{Result} = \left( \frac{r_0}{r_3} \times \frac{(C_1/C_0)}{(M_1/M_2)} \right) \times 100 \]

- \( r_0 \) = peak response of valsartan related degradation product from Sample solution B
- \( r_3 \) = peak response of valsartan from the Standard solution
- \( C_1 \) = concentration of USP Valsartan RS in the Standard solution (mg/mL)
- \( C_0 \) = nominal concentration of valsartan in Sample solution B (mg/mL)
- \( M_1 \) = molecular weight of valsartan, 408.88
- \( M_2 \) = molecular weight of valsartan related product 3c, 522.93

Acceptance criteria: See Table 4. Disregard valsartan related compound B, the benzenesulfonic acid peak at relative retention time 0.19, and any peaks below 0.1%.

Table 4

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devaleryl valsartan*</td>
<td>0.24</td>
<td>0.2</td>
</tr>
<tr>
<td>Amlodipine related compound A*</td>
<td>0.50</td>
<td>0.5</td>
</tr>
</tbody>
</table>

- *N-[2′-(1H-Tetrazole-5-yl) biphenyl-4-yl]methyl]-l-valine.
- 3-Ethyl, 5-methyl [2-(2-aminoethoxyethyl)-4-(2-chlorophenyl)-6-methyl,3,5-pyridinedicarboxylate].
- These are specified unidentified degradation products. No information is available about chemical structures or chemical names for these impurities.
- N-Butyryl-N-[2′-(1H-tetrazole-5-yl)biphenyl-4-yl]methyl]-l-valine.
- N-Valeryl-N-[2′-(1H-tetrazole-5-yl)biphenyl-4-yl]methyl]-l-valine ethyl ester.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Store at controlled room temperature, in tight containers, and in a dry place.

Add the following:

- **LABELING:** When more than one Dissolution test is given, the labeling states the Dissolution test used only if Test 1 is not used.

- **USP Reference Standards (11)**
  - USP Amlodipine Besylate RS
  - USP Amlodipine Related Compound A RS
  - 3-Ethyl, 5-methyl [2-(2-aminoethoxyethyl)-4-(2-chlorophenyl)-6-methyl,3,5-pyridinedicarboxylate] fumarate.
  - \( C_{20}H_{21}ClN_2O_5 \cdot C_4H_4O_4 = 522.93 \)
  - USP Valsartan RS
  - USP Valsartan Related Compound B RS
  - 3-Ethyl, 5-methyl [2-(2-aminoethoxyethyl)-4-(2-chlorophenyl)-6-methyl,3,5-pyridinedicarboxylate] fumarate.
  - \( C_{21}H_{27}N_5O_3 \cdot C_4H_4O_4 = 421.49 \)

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