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Amlodipine and Valsartan Tablets

DEFINITION

Amlodipine and Valsartan Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) and valsartan ($C_{24}H_{29}N_5O_3$).

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

• **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

Time (min)	Solution A (%)	Solution B (%)
0	50	50
3	50	50
15	30	70
20	30	70
20.1	50	50
25	50	50

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 add [water](#) to 10% 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 the *Sample stock solution*
Sample solution B: Nominally equivalent to 0.16 mg/mL of valsartan in *Diluent* from the *Sample stock solution*
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: LC
Detector: UV 237 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.
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 ($C_{20}H_{25}ClN_2O_5$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

 r_U = peak response of amlodipine from *Sample solution A* r_S = peak response of amlodipine from the *Standard solution* C_S = concentration of [USP Amlodipine Besylate RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of amlodipine in *Sample solution A* (mg/mL) M_{r1} = molecular weight of amlodipine, 408.88 M_{r2} = molecular weight of amlodipine besylate, 567.05Calculate the percentage of the labeled amount of valsartan ($C_{24}H_{29}N_5O_3$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of valsartan from *Sample solution B* r_S = peak response of valsartan from the *Standard solution* C_S = concentration of [USP Valsartan RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of valsartan in *Sample solution B* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS**• [DISSOLUTION \(711\)](#)**Test 1****Buffer:** Dissolve 6.805 g of [monobasic potassium phosphate](#) and 0.896 g of [sodium hydroxide](#) in [water](#), and dilute with [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 4% of the final volume, and dilute with *Diluent* to volume.**Standard stock solution B:** 2.2 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 0.45- μ m 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 $\times$ 15-cm; 4- μ m packing L11**Column temperature:** 40°**Flow rate:** 1.2 mL/min**Injection volume:** 10 μ L**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 ($C_{20}H_{25}ClN_2O_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L_1) \times 100$$

 r_U = peak response of amlodipine from the *Sample solution* r_S = peak response of amlodipine from the *Standard solution* C_S = concentration of [USP Amlodipine Besylate RS](#) in the *Standard solution* (mg/mL) V = volume of *Medium*, 1000 mL M_{r1} = molecular weight of amlodipine, 408.88 M_{r2} = molecular weight of amlodipine besylate, 567.05 L_1 = label claim of amlodipine (mg/Tablet)Calculate the percentage of the labeled amount of valsartan ($C_{24}H_{29}N_5O_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L_2) \times 100$$

 r_U = peak response of valsartan from the *Sample solution* r_S = peak response of valsartan from the *Standard solution* C_S = concentration of [USP Valsartan RS](#) in the *Standard solution* (mg/mL) V = volume of *Medium*, 1000 mL L_2 = label claim of valsartan (mg/Tablet)**Tolerances:** NLT 80% (Q) of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) 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.**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](#).**Table 2**

Time (min)	Solution A (%)	Solution B (%)
0	80	20
7	30	70
8	80	20
10	80	20

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](#)