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Valsartan Tablets

DEFINITION
Valsartan Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of valsartan ($C_{24}H_{29}N_5O_3$).

IDENTIFICATION
• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2023)

ASSAY

Change to read:

• **Procedure**

Mobile phase: Acetonitrile, water, and glacial acetic acid (50:50: 0.1)

Diluent: Acetonitrile and water (50:50)

System suitability solution: 2 µg/mL of USP Valsartan Related Compound B RS and 20 µg/mL of USP Valsartan RS in *Diluent*

Standard solution: 0.20 mg/mL of USP Valsartan RS in *Diluent*

Sample stock solution: Place NLT 20 Tablets in a suitable volumetric flask and add 10% of the flask volume of water. Stir or shake until the Tablets disintegrate (about 5 min). Add 80% of the flask volume of acetonitrile. Stir or shake for 30 min, and sonicate for 10 min. Cool, and dilute with acetonitrile to volume, mix, and centrifuge a portion of the suspension.

Sample solution: Nominally 0.2 mg/mL of valsartan from the *Sample stock solution* in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2023)

Column: 4.6-mm × 25-cm; 10-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

▲**Run time:** NLT 2 times the retention time of valsartan▲ (USP 1-May-2023)

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between valsartan related compound B and valsartan, *System suitability solution*. ▲[Note—The relative retention times for valsartan related compound B and valsartan are about 0.8 and 1.0, respectively.]▲ (USP 1-May-2023)

Relative standard deviation: NMT ▲1.0▲ (USP 1-May-2023) %, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate 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 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)

C_U = nominal concentration of valsartan in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Test 1

Medium: pH 6.8 phosphate buffer prepared as follows. 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 M sodium hydroxide or 1 M phosphoric acid as required to a pH of 6.8; 1000 mL degassed.

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: (L/1000) mg/mL of USP Valsartan RS in *Medium*, where L is the label claim, in mg/Tablet. [Note—Dilute with *Medium* as needed.]

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Analytical wavelength: 250 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Valsartan RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 1000 mL

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

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

Medium: 0.067 M phosphate buffer prepared as follows. Dissolve 91.2 g of monobasic potassium phosphate and 12 g of sodium hydroxide in 10 L of water. Adjust with 1 N sodium hydroxide or 1 N ▲phosphoric acid▲ (USP 1-May-2023) to a pH of 6.8; 1000 mL.

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.4 mg/mL of USP Valsartan RS prepared as follows. Transfer an appropriate quantity of USP Valsartan RS into a suitable volumetric flask, and add methanol to about 5% of the volume of the flask. Sonicate to dissolve. Dilute with *Medium* to volume.

Standard solution: 0.02 mg/mL of USP Valsartan RS in *Medium* from *Standard stock solution*

Sample solution: Withdraw 10 mL of the solution under test and pass through a suitable filter. Dilute a portion of the solution with *Medium* to the concentration similar to that in the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 250 nm

Cell: 1.0 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Valsartan RS in the *Standard solution* (mg/mL)

V = volume of *Medium*, 1000 mL

D = dilution factor

L = label claim (mg/Tablet)

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

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

Mobile phase, Diluent, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.4 µg/mL of USP Valsartan RS in *Diluent*

Sensitivity solution: 0.1 µg/mL of USP Valsartan RS in *Diluent*, from the *Standard solution*

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between valsartan related compound B and valsartan, *System suitability solution*. ▲[Note—The relative retention times for valsartan related compound B and valsartan are about 0.8 and 1.0, respectively.]▲ (USP 1-May-2023)

Relative standard deviation: NMT ▲5.0▲ (USP 1-May-2023) %, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each ▲degradation product▲ (USP 1-May-2023) in the portion of Tablets taken:

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

r_U = peak response of each ▲degradation product▲ (USP 1-May-2023) 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* (µg/mL)

C_U = nominal concentration of valsartan in the *Sample solution* (µg/mL)

Acceptance criteria: See *Table 1*. Calculate the total degradation products from the sum of all individual degradation products. Disregard any peak due to valsartan related compound B. The reporting threshold is 0.05%.

Table 1

Name	Acceptance Criteria, NMT (%)
▲Any unspecified degradation product▲ (USP 1-May-2023)	0.2

Name	Acceptance Criteria, NMT (%)
Total ▲degradation products▲ (USP 1-May-2023)	0.4

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers.▲Store at controlled room temperature.▲ (USP 1-May-2023)

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

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Valsartan RS

USP Valsartan Related Compound B RS

▲*N*-{[2′-(1*H*-Tetrazol-5-yl)biphenyl-4-yl]methyl}-*N*-butyryl-L-valine; Also known as *N*-Butyryl-*N*-{[2'-(1*H*-tetrazole-5-yl)biphenyl-4-yl]methyl}-L-valine.▲ (USP 1-May-2023)

$C_{23}H_{27}N_5O_3$ ▲421.50▲ (USP 1-May-2023)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VALSARTAN TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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