

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2023
 Document Type: USP Monographs
 DocId: GUID-246E8105-39F4-49F7-B242-025D04DAD23C_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M2004_05_01
 DOI Ref: td4if

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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*