

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2023
 Document Type: USP Monographs
 DocId: GUID-0DDE4730-11FB-4112-81A2-5ED29B319A72_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M118_04_01
 DOI Ref: pz373

© 2025 USPC
 Do not distribute

Acarbose Tablets

DEFINITION

Acarbose Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of acarbose ($C_{25}H_{43}NO_{18}$).

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.

Change to read:

- **B. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#):** The spectrum obtained from the ▲sample preparation▲ (ERR 1-May-2023) shows IR maxima in the regions of 3500–3200, 2950–2890, 1653–1633, and 1070–1000 cm^{-1} .

ASSAY

PROCEDURE

Buffer: 0.6 mg/mL of [monobasic potassium phosphate](#) and 0.35 mg/mL of [dibasic sodium phosphate](#) in water. Filter and degas.

Mobile phase: [Acetonitrile](#) and *Buffer* (75:25)

System suitability solution: 20 mg/mL of [USP Acarbose System Suitability Mixture RS](#) in water

Standard solution: 10 mg/mL of [USP Acarbose RS](#)

Sample solution: Nominally 10 mg/mL of acarbose in water, prepared as follows. Transfer a portion of the powder, from NLT 20 Tablets, equivalent to 100 mg of acarbose to a suitable volumetric flask and add water to 50%–70% of the flask volume. Sonicate to dissolve and dilute with water to volume. Pass through a suitable filter of 0.45- μm pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.0-mm $\times$ 25-cm; 5- μm packing [L8](#)

Column temperature: 35°

Flow rate: 2 mL/min

Injection volume: 10 μL

Run time: NLT 2.5 times the retention time of acarbose

System suitability

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

Suitability requirements

Peak-to-valley ratio: The ratio of the height of the impurity A peak to the height of the valley between the impurity A peak and the acarbose peak is NLT 1.2, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of acarbose ($C_{25}H_{43}NO_{18}$) in the portion of Tablets taken:

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

r_U = peak response of acarbose from the *Sample solution*

r_S = peak response of acarbose from the *Standard solution*

C_S = concentration of [USP Acarbose RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)

Medium: Water, 900 mL, deaerated

Apparatus 2: 75 rpm

Time: 30 min

Determine the percentage of the labeled amount of acarbose ($C_{25}H_{43}NO_{18}$) dissolved by using the following procedure.

Buffer: 0.6 mg/mL of [monobasic potassium phosphate](#) and 0.35 mg/mL of [dibasic sodium phosphate](#) in water, adjusted to a pH of 6.8. Filter and degas.

Mobile phase: [Acetonitrile](#) and *Buffer* (5:95)

Standard stock solution: 10 mg/mL of [USP Acarbose RS](#) in *Medium*

Standard solution A (for Tablets labeled to contain 100 mg of acarbose): 0.1 mg/mL of [USP Acarbose RS](#) from the *Standard stock solution* in *Medium*

Standard solution B (for Tablets labeled to contain 50 mg of acarbose): 0.05 mg/mL of [USP Acarbose RS](#) from *Standard solution A* in *Medium*

Standard solution C (for Tablets labeled to contain 25 mg of acarbose): 0.025 mg/mL of [USP Acarbose RS](#) from *Standard solution A* in *Medium*

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

Chromatographic system

(See [Chromatography \(621\), System Suitability](#))

Mode: LC

Detector: UV 210 nm

Column: 4.0-mm × 12.5-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.8 mL/min

Injection volume: 100 μL

System suitability

Samples: *Standard solution A*, *Standard solution B*, or *Standard solution C*

Suitability requirements

Relative standard deviation: NMT 2.0% for the acarbose peak of *Standard solution A*, *Standard solution B*, or *Standard solution C*

Analysis

Samples: *Standard solution A*, *Standard solution B*, or *Standard solution C*; and *Sample solution*

Calculate the percentage of the labeled amount of acarbose ($C_{25}H_{43}NO_{18}$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from *Standard solution A*, *Standard solution B*, or *Standard solution C*

C_S = concentration of [USP Acarbose RS](#) in *Standard solution A*, *Standard solution B*, or *Standard solution C* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of acarbose ($C_{25}H_{43}NO_{18}$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

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

Standard solution 1: Prepare a 0.2-mg/mL solution of [USP Acarbose RS](#) in water by pipetting 1.0 mL of the *Standard solution* from the Assay into a 50-mL volumetric flask. Dilute with water to volume.

Sensitivity solution: Prepare a 0.02-mg/mL solution of [USP Acarbose RS](#) in water by pipetting 10.0 mL of *Standard solution 1* into a 100-mL volumetric flask. Dilute with water to volume.

System suitability

Samples: *System suitability solution*, *Standard solution 1*, and *Sensitivity solution*

Suitability requirements

Peak-to-valley ratio: The ratio of the height of the impurity A peak to the height of the valley between the impurity A peak and the acarbose peak is NLT 1.2, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution 1*

Relative standard deviation: NMT 2.0%, *Standard solution 1*

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

Analysis