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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 × 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

Samples: *Sample solution* and *Standard solution 1*

Calculate the percentage of each impurity in the portion of Tablets taken:

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

r_U = peak response of any individual impurity from the *Sample solution*

r_S = peak response of acarbose from *Standard solution 1*

C_S = concentration of USP Acarbose RS in *Standard solution 1* (mg/mL)

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

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Impurity D[a]	0.5	1.3	1.2
Impurity B[b]	0.8	1.6	0.5
Impurity A[c]	0.9	1.0	1.6
Impurity C[d]	1.2	1.0	1.0
Any unspecified impurity	—	1.0	0.2
Total impurities	—	—	3.0

[a] 4-*O*-(4,6-Dideoxy-4-{[(1*S*,4*R*,5*S*,6*S*)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-en-1-yl]amino}-α-D-glucopyranosyl)-D-glucose.

[b] (1*R*,4*R*,5*S*,6*R*)-4,5,6-Trihydroxy-2-(hydroxymethyl)cyclohex-2-en-1-yl 4-*O*-(4,6-dideoxy-4-{[(1*S*,4*R*,5*S*,6*S*)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-en-1-yl]amino}-α-D-glucopyranosyl)-α-D-glucopyranoside.

[c] *O*-4,6-Dideoxy-4-{[(1*S*,4*R*,5*S*,6*S*)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-en-1-yl]amino}-α-D-glucopyranosyl-(1→4)-*O*-α-D-glucopyranosyl-(1→4)-D-arabino-2-hexulopyranose.

[d] α-D-Glucopyranosyl 4-*O*-(4,6-dideoxy-4-{[(1*S*,4*R*,5*S*,6*S*)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-en-1-yl]amino}-α-D-glucopyranosyl)-α-D-glucopyranoside.

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^3 cfu/g, and the total combined yeasts and molds count is NMT 10^2 cfu/g. It meets the requirements of the testing of products for the absence of *Escherichia coli* (per gram).

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Acarbose RS

USP Acarbose System Suitability Mixture RS

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

Topic/Question	Contact	Expert Committee
ACARBOSE TABLETS	Julie Zhang Associate Science & Standards Liaison	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines

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