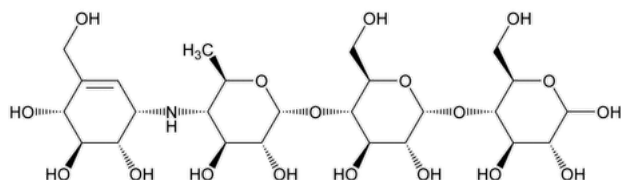


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Acarbose



$C_{25}H_{43}NO_{18}$ 645.60

D-Glucose, O-4,6-dideoxy-4-[[[1S-(1 α ,4 α ,5 β ,6 α)]-4,5,6-trihydroxy-3-(hydroxymethyl)-2-cyclohexen-1-yl]amino]- α -D-glucopyranosyl-(1 \rightarrow 4)-O- α -D-glucopyranosyl-(1 \rightarrow 4)-;
 O-4,6-Dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)-2-cyclohexen-1-yl]amino]- α -D-glucopyranosyl-(1 \rightarrow 4)-O- α -D-glucopyranosyl-(1 \rightarrow 4)-D-glucose CAS RN®: 56180-94-0; UNII: T58MSI464G.

DEFINITION

Acarbose is produced by certain strains of *Actinoplanes utahensis*. It contains NLT 95.0% and NMT 102.0% of acarbose ($C_{25}H_{43}NO_{18}$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: 0.6 mg/mL of monobasic potassium phosphate and 0.35 mg/mL of dibasic sodium phosphate in water

Mobile phase: Acetonitrile and *Solution A* (3:1)

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

Standard solution: 20 mg/mL of [USP Acarbose RS](#) in water

Sample solution: 20 mg/mL of Acarbose in water

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm \times 25-cm; packing L8

Column temperature: 35°

Flow rate: 2 mL/min

Injection volume: 10 μ L

System suitability

Sample: *System suitability solution*

Identify the acarbose peak and the peaks due to the impurities listed in [Table 1](#).

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.

Chromatogram comparability: The chromatogram obtained is similar to the chromatogram provided with [USP Acarbose System Suitability Mixture RS](#) for the known impurities found.

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_u = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#).

Sample: 1.0 g

Acceptance criteria: NMT 0.2%

Change to read:

• **CHROMATOGRAPHIC PURITY**

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

Diluted sample solution: Dilute 1.0 mL of the *Sample solution* with water to 100.0 mL.

Analysis

Samples: *Sample solution* and *Diluted sample solution*

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

$$\text{Result} = (r_u/r_A) \times (1/F) \blacktriangle \blacktriangle \text{ (ERR 1-Jan-2024)}$$

r_u = peak response of each impurity from the *Sample solution*

r_A = peak response of the main acarbose peak from the *Diluted sample solution*

F = relative response factor for each impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Impurity A ^a	0.9	1	0.6
Impurity B ^b	0.8	1.6	0.5
Impurity C ^c	1.2	1	1.5
Impurity D ^d	0.5	1.33	1.0
Impurity E ^e	1.7	0.8	0.2
Impurity F ^f	1.9	0.8	0.3
Impurity G ^g	2.2	0.8	0.3
Impurity H ^h	0.6	1	0.2
Any individual unknown impurity	—	—	0.2
Total impurities	—	—	3.0

^a O-4,6-Dideoxy-4-([(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino)-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-arabino-hex-2-ulopyranose.

^b (1R,4R,5S,6R)-4,5,6-Trihydroxy-2-(hydroxymethyl)cyclohex-2-enyl 4-O-[4,6-dideoxy-4-([(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino)-α-D-glucopyranosyl]-α-D-glucopyranoside.

^c α-D-Glucopyranosyl 4-O-[4,6-dideoxy-4-([(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino)-α-D-glucopyranosyl]-α-D-glucopyranoside.

^d 4-O-[4,6-Dideoxy-4-([(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino)-α-D-glucopyranosyl]-D-glucopyranose.

- e O-4,6-Dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino]-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-arabino-hex-2-ulopyranose (4-O-α-acarbosyl-D-fructopyranose).
- f O-4,6-Dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino]-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-glucopyranose (4-O-α-acarbosyl-D-glucopyranose).
- g α-D-Glucopyranosyl O-4,6-dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino]-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranoside (α-D-glucopyranosyl α-acarboside).
- h O-4,6-Dideoxy-4-[[[(1S,4R,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-enyl]amino]-α-D-glucopyranosyl-(1→4)-O-6-deoxy-α-D-glucopyranosyl-(1→4)-D-glucopyranose.

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation\(781S\)](#)

Sample solution: 10 mg/mL in water

Acceptance criteria: +168° to +183°

- [pH \(791\)](#)

Sample solution: 50 mg/mL

Acceptance criteria: 5.5–7.5

- [WATER DETERMINATION, Method Ic\(921\)](#) : NMT 4.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [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	Julie Zhang Associate Science & Standards Liaison	BI032020 Biologics Monographs 3 - Complex Biologics and Vaccines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BI032020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: [Chromatographic Database](#)

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