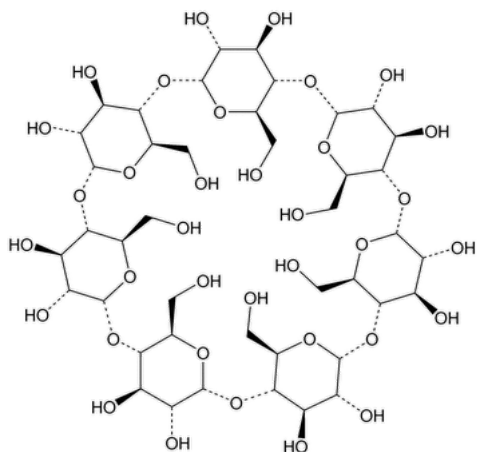


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## Betadex



$(C_6H_{10}O_5)_7$  1134.98

Beta Cyclodextrin CAS RN®: 7585-39-9.

### DEFINITION

Betadex is a nonreducing cyclic compound composed of seven alpha-(1–4) linked D-glucopyranosyl units. It contains NLT 98.0% and NMT 102.0% of betadex  $(C_6H_{10}O_5)_7$ , calculated on the anhydrous basis.

### IDENTIFICATION

*Change to read:*

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020) On undried specimen
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** It meets the requirements of the test for *Optical Rotation*.
- **D.**  
**Sample:** 0.2 g  
**Analysis:** Mix the *Sample* with 2 mL of iodine TS, warm in a water bath to dissolve, and allow to stand at room temperature.  
**Acceptance criteria:** A yellow-brown precipitate is formed.

### ASSAY

#### PROCEDURE

**Mobile phase:** Methanol and water (7:93)

**System suitability solution:** 0.5 mg/mL of [USP Alpha Cyclodextrin RS](#), 0.5 mg/mL of [USP Beta Cyclodextrin RS](#), and 0.5 mg/mL of [USP Gamma Cyclodextrin RS](#)

**Standard solution:** 1.0 mg/mL of [USP Beta Cyclodextrin RS](#)

**Sample stock solution:** Transfer 250 mg of Betadex to a 25-mL volumetric flask, and dissolve in water with the aid of heat if necessary. Cool, and dilute with water to volume.

**Sample solution:** 1 mg/mL of Betadex, prepared from the *Sample stock solution*, diluted with water

#### Chromatographic system

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

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm × 15-cm; 5-μm packing L1

#### Temperatures

**Column:** 30°

**Detector:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 50 µL

### System suitability

**Sample:** *System suitability solution*

[NOTE—The relative retention times for gamma cyclodextrin, alpha cyclodextrin, and beta cyclodextrin are 0.4, 0.5, and 1.0, respectively.]

### Suitability requirements

**Resolution:** NLT 1.5 between the gamma cyclodextrin and alpha cyclodextrin peaks

**Tailing factor:** 0.8–2.0 for the three cyclodextrins

**Relative standard deviation:** NMT 2.0%

### Analysis

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

Calculate the percentage of betadex ( $C_6H_{10}O_5$ ) in the portion of sample 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 Beta Cyclodextrin RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Beta Cyclodextrin in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis

### IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

#### • LIMIT OF REDUCING SUGARS

**Cupric solution:** 150 mg/mL of cupric sulfate

**Tartrate solution:** 25 mg/mL of anhydrous sodium carbonate, 25 mg/mL of potassium sodium tartrate, 20 mg/mL of sodium bicarbonate, and 200 mg/mL of anhydrous sodium sulfate

**Cupric–tartaric solution:** Immediately before use, mix 1 part of *Cupric solution* with 25 parts of *Tartrate solution*.

**Ammonium molybdate solution:** 100 mg/mL of ammonium molybdate

**Disodium arsenate solution:** 60 mg/mL of disodium arsenate

**Ammonium molybdate reagent:** Mix 10 mL of *Disodium arsenate solution*, 50 mL of *Ammonium molybdate solution*, and 90 mL of diluted sulfuric acid, and dilute with water to 200 mL.

**Sample solution:** Transfer 1.0 g of Betadex (as calculated on the anhydrous basis) to a 100-mL volumetric flask. Dissolve in and dilute with water that has been previously boiled and cooled to room temperature to volume, and mix. To 1 mL of this solution add 1 mL of *Cupric–tartaric solution*. Heat on a water bath for 10 min, then cool to room temperature. Add 10 mL of *Ammonium molybdate reagent*, and allow to stand for 15 min.

**Standard stock solution:** 20 mg/L of [USP Dextrose RS](#)

**Standard solution:** Prepare at the same time as the *Sample solution*. To 1 mL of the *Standard stock solution* add 1 mL of *Cupric–tartaric solution*. Heat on a water bath for 10 min, then cool to room temperature. Add 10 mL of *Ammonium molybdate reagent*, and allow to stand for 15 min.

### Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

**Mode:** Vis

**Analytical wavelength:** 740 nm

**Blank:** Water

### Analysis

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

**Acceptance criteria:** 0.2%; the absorbance of the *Sample solution* is NMT that of the *Standard solution*.

#### • LIMIT OF LIGHT-ABSORBING IMPURITIES

**Sample solution:** Transfer 1.0 g of Betadex (as calculated on the anhydrous basis) to a 100-mL volumetric flask. Dissolve in and dilute with water that has been previously boiled and cooled to room temperature to volume. Mix, and pass through a filter of 0.2-µm pore size.

### Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

**Mode:** UV/Vis

**Analytical wavelength:** 230–750 nm

**Cell:** 1 cm

**Blank:** Water

### Analysis

**Sample:** *Sample solution*