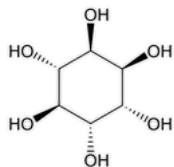


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Add the following:

α-D-chiro-Inositol



$C_6H_{12}O_6$ 180.16

D-chiro-Inositol CAS RN®: 643-12-9; UNII: 6R79WV4R10.

DEFINITION

D-chiro-Inositol contains NLT 97.0% and NMT 103.0% of D-chiro-inositol ($C_6H_{12}O_6$), calculated on the dried basis.

IDENTIFICATION

• **A.** Meets the requirements in the test for *Optical Rotation*

• **B.**

Sample solution: 0.1 mg/mL of D-chiro-Inositol in [water](#)

Analysis: Proceed as directed in the test for *Related Compounds*.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the D-chiro-inositol peak of the *Standard solution*.

• **C.**

Sample solution: 1.0 mg/mL of D-chiro-Inositol in [water](#)

Analysis: Proceed as directed in the test for [Limit of Fructose and myo-Inositol](#).

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the D-chiro-inositol peak of the *Standard solution*.

ASSAY

• PROCEDURE

Mobile phase: [Water](#)

System suitability solution: 0.1 mg/mL each of [USP Dextrose RS](#), [USP Inositol RS](#), [USP Pinitol RS](#), and [USP Sucrose RS](#) and 1.0 mg/mL of [USP D-chiro-Inositol RS](#) in [water](#)

Standard solution: 10.0 mg/mL of [USP D-chiro-Inositol RS](#) in [water](#)

Sample solution: 10.0 mg/mL of D-chiro-Inositol in [water](#)

Chromatographic system

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

Mode: LC

Detector: Refractive index

Columns

Guard: 6-mm × 5-cm; 9-μm packing [L58](#)

Analytical: 7.8-mm × 30-cm; 9-μm packing [L58](#)

Temperatures

Autosampler: 10°

Column: 80°

Detector: 50°

Flow rate: 0.6 mL/min

Injection volume: 6 μL

Run time: NLT 2.5 times the retention time of D-chiro-inositol

System suitability

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

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between glucose (dextrose) and D-chiro-inositol and between any two of the closest specified impurities; NLT 1.3 between D-chiro-inositol and myo-inositol (inositol), *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of D-chiro-inositol ($C_6H_{12}O_6$) in the portion of D-chiro-Inositol taken:

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

r_U = peak area of D-chiro-inositol from the *Sample solution*

r_S = peak area of D-chiro-inositol from the *Standard solution*

C_S = concentration of [USP D-chiro-Inositol RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of D-chiro-Inositol in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- [CHLORIDE AND SULFATE \(221\)](#), *Chloride*

Standard solution: 2.50 mL of 0.020 N hydrochloric acid

Sample: 0.365 g of D-chiro-Inositol

Acceptance criteria: The *Sample* shows no more turbidity than the *Standard solution* (0.5%).

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

RELATED COMPOUNDS

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

Standard solution: 0.1 mg/mL each of [USP Sucrose RS](#), [USP Pinitol RS](#), [USP Dextrose RS](#), and [USP D-chiro-Inositol RS](#) in *water*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each sugar impurity in the portion of D-chiro-Inositol taken:

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

r_U = peak area of sucrose, pinitol, or glucose from the *Sample solution*

r_S = peak area of sucrose, pinitol, or glucose from the *Standard solution*

C_S = concentration of [USP Sucrose RS](#), [USP Pinitol RS](#), or [USP Dextrose RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of D-chiro-Inositol in the *Sample solution* (mg/mL)

Calculate the percentage of chloride and any individual unspecified impurity in the portion of D-chiro-Inositol taken:

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

r_U = peak area of chloride or any individual unspecified impurity from the *Sample solution*

r_S = peak area of D-chiro-inositol from the *Standard solution*

C_S = concentration of [USP D-chiro-Inositol RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of D-chiro-Inositol in the *Sample solution* (mg/mL)

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

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Chloride	0.50	0.5
Sucrose	0.73	1.0