Interim Revision Announcement Official: March 1, 2021

Ribose

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 $C_5H_{10}O_5$ 150.13 (2*S*,3*R*,4*S*,5*R*)-5-(Hydroxymethyl)oxolane-2,3,4-triol; p-Ribose [50-69-1].

DEFINITION

Ribose contains NLT 98.0% and NMT 102.0% of p-ribose ($C_5H_{10}O_5$), calculated on the dried basis.

IDENTIFICATION

• A. Spectroscopic Identification Tests (197), Infrared Spectroscopy: 197K

• B. It meets the requirements in Specific Tests for Optical Rotation (781S), Procedures, Specific Rotation.

• **C.** 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

Mobile phase: Degassed water

System suitability solution: 20 mg/mL of <u>USP Ribose RS</u> and 0.2 mg/mL of <u>USP Arabinose RS</u> in *Mobile*

phase

Standard solution: 20 mg/mL of USP Ribose RS in Mobile phase

Sample solution: 20 mg/mL of Ribose in *Mobile phase*

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC

Detector: Refractive index

Column: 8.0-mm \times 30-cm; 6- μ m packing L22

Temperatures
Detector: 40°
Column: 80°

Flow rate: 1.0 mL/min Injection volume: 10 µL

System suitability

Samples: System suitability solution and Standard solution

[Note—The relative retention times for arabinose and ribose are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.2 between ribose and arabinose, System suitability solution

Tailing factor: NMT 1.5, Standard solution

Column efficiency: NLT 2500 theoretical plates for the ribose peak, *Standard solution*

Relative standard deviation: NMT 2.0%, Standard solution

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of p-ribose in the portion of Ribose taken:

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

 r_{IJ} = peak response from the Sample solution

 $r_{\rm S}$ = peak response from the Standard solution

 C_S = concentration of <u>USP Ribose RS</u> in the *Standard solution* (mg/mL)

 C_{II} = concentration of Ribose in the Sample solution (mg/mL)

Acceptance criteria: 98.0-102.0% on the dried basis

IMPURITIES

• RESIDUE ON IGNITION (281): NMT 0.2%

• CHLORIDE AND SULFATE (221), Chloride

Standard: 0.10 mL of 0.020 N hydrochloric acid

Sample: 3.6 g of Ribose

Acceptance criteria: NMT 0.002%

• CHLORIDE AND SULFATE ⟨221⟩, Sulfate

Standard: 0.10 mL of 0.020 N sulfuric acid

Sample: 3.3 g of Ribose

Acceptance criteria: NMT 0.003%

• RELATED COMPOUNDS

Mobile phase, System suitability solution, Sample solution, Chromatographic system, and System

suitability: Proceed as directed in the *Assay*.

Standard solution: 0.02 mg/mL of <u>USP Arabinose RS</u> in *Mobile phase*

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of arabinose in the portion of Ribose taken:

Result =
$$(r_{IJ}/r_S) \times (C_S/C_{IJ}) \times 100$$

 r_{II} = peak response of arabinose from the Sample solution

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

 C_S = concentration of <u>USP Arabinose RS</u> in the *Standard solution* (mg/mL)

 C_U = concentration of Ribose in the Sample solution (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Ribose taken:

Result =
$$(r_U/r_T) \times 100$$

 r_U = peak response of any unspecified impurity from the Sample solution

 r_{τ} = sum of all the peak responses from the Sample solution

Acceptance criteria

Arabinose: NMT 1.0%

Unspecified impurity: NMT 0.1%

Total unspecified impurities: NMT 1.0%

SPECIFIC TESTS

• OPTICAL ROTATION (781S), Procedures, Specific Rotation

Sample solution: 20 mg/mL in <u>water</u> **Acceptance criteria:** -18.0° to -22.0°

• Color of Solution

Sample solution: Dissolve 5.0 g of Ribose in 50 mL of water. Centrifuge or filter, if necessary, to obtain a

clear solution.

Blank solution: Water

Analysis: Absorbance at 430 nm in a 1-cm cell

Acceptance criteria: NMT 0.2 AU

Change to read:

• Loss on Drying (731)

Analysis: [▲]Dry at 60° under vacuum of NLT 50 mmHg for 3.5 h. _{▲ (IRA 1-Mar-2021)}

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in tight, light-resistant containers.

• USP REFERENCE STANDARDS (11)

USP Arabinose RS
USP Ribose RS

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Not Applicable

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