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Sugar Spheres

Change to read:

DEFINITION

Sugar Spheres contain NLT 62.5% and NMT 91.5% of sucrose ($C_{12}H_{22}O_{11}$), calculated on the dried basis, the remainder consisting chiefly of ▲corn▲ (NF 1-May-2023) starch. They consist of approximately spherical particles of a labeled nominal size range. They may contain color additives permitted by the FDA for use in drugs.

IDENTIFICATION

- **A.**
Sample suspension: 1:10
Analysis: Add [iodine TS](#) to the *Sample suspension*.
Acceptance criteria: A violet to deep blue color is produced.
- **B.** It meets the requirements of the test for [Optical Rotation \(781S\)](#), [Procedures](#), [Specific Rotation](#) in *Specific Tests*.

ASSAY

- **CONTENT OF SUCROSE**
Mobile phase: [Acetonitrile](#) and [water](#) (80:20, v/v)
System suitability solution: Prepare an aqueous solution containing 20 mg/mL of sucrose, 1.0 mg/mL of dextrose (glucose), 0.6 mg/mL of fructose, 0.6 mg/mL of maltose, and 0.8 mg/mL of lactose using [USP Sucrose RS](#), [USP Dextrose RS](#), [USP Fructose RS](#), [USP Maltose Monohydrate RS](#), and [USP Anhydrous Lactose RS](#).
Standard solution: Dissolve [USP Sucrose RS](#) in water to obtain a solution having a concentration of about 20 mg/mL of sucrose.
Sample solution: 20 mg/mL of Sugar Spheres in water. Pass the solution through a 0.2-µm nylon syringe filter.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: Refractive index
Column: 4.6-mm × 15-cm; 5-µm packing [L8](#)
Temperatures
Column: 45°
Detector: 40°
Flow rate: 2.0 mL/min
Injection volume: 15 µL
System suitability
Samples: *System suitability solution and Standard solution*
[NOTE—See [Table 1](#).]

Table 1

Name	Relative Retention Time
Fructose	0.5

Name	Relative Retention Time
Dextrose (glucose)	0.6
Sucrose	1.0
Maltose	1.3
Lactose	1.5

Suitability requirements

Resolution: NLT 1.3 between all adjacent peaks, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sucrose in the portion of Sugar Spheres 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 Sucrose RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Sugar Spheres in the *Sample solution* (mg/mL)

Acceptance criteria: 62.5%–91.5% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#).

Sample: 2.0 g

Analysis: Ignite at a temperature of 700 ± 25°.

Acceptance criteria: NMT 0.25%

SPECIFIC TESTS

• [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total aerobic microbial count does not exceed 10² cfu/g, and the Sugar Spheres meet the requirements of the tests for absence of *Salmonella* species, *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

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

Sample solution: Transfer 20 g to a 200-mL volumetric flask, add 160 mL of [water](#), shake to dissolve the sucrose, add water to volume, and mix. Pass the solubilized sucrose solution by vacuum filtration through fine filter paper.

Acceptance criteria: +41° to +61°, corresponding to 62.5%–91.5% of sucrose (C₁₂H₂₂O₁₁), calculated on the dried basis

• [LOSS ON DRYING \(731\)](#).

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 4.0%

• [PARTICLE SIZE DISTRIBUTION ESTIMATION BY ANALYTICAL SIEVING \(786\)](#): NLT 90% of it passes the coarser sieve size stated in the labeling; all of it passes the next coarser sieve size listed in [Table 1](#) of the chapter; and NMT 10% passes the finer sieve size stated in the labeling.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **LABELING:** The label states the nominal particle size range. Label it to indicate the name and amount of any added color additives.

• [USP REFERENCE STANDARDS \(11\)](#).

[USP Anhydrous Lactose RS](#)

[USP Dextrose RS](#)

[USP Fructose RS](#)
[USP Maltose Monohydrate RS](#)
[USP Sucrose RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SUGAR SPHERES	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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