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Dextrates

Add the following:

▲ CAS RN®: 39404-33-6.▲ (NF 1-May-2023)

Change to read:

DEFINITION

Dextrates is a purified mixture of saccharides resulting from the controlled enzymatic hydrolysis ▲or acid hydrolysis▲ (NF 1-May-2023) of ▲corn, potato, or tapioca▲ (NF 1-May-2023) starch. It is either anhydrous or hydrated. Its dextrose equivalent is NLT 93.0% ▲and NMT 99.0%.▲ (NF 1-May-2023)

Add the following:

▲IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K. Perform the test for Hydrated Dextrates only. Use the undried sample and USP Dextrates Monohydrate RS.

• **B. Melting Range or Temperature ⟨741⟩:** 138°–146°▲ (NF 1-May-2023)

ASSAY

Change to read:

• **Dextrose Equivalent**

▲Mobile phase: Water

Standard solution A: Prepare a solution in *Mobile phase*, containing 2% dextrose and 1.5% maltose, using USP Dextrose RS and USP Maltose Monohydrate RS.

Standard solution B: Prepare a solution in *Mobile phase*, containing a total of 5% of USP Dextrates Monohydrate RS.

Sample solution: 5% of Dextrates in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm analytical; 25-µm packing L124[1]

Temperatures

Column: 85°

Detector: 40°

[Note—Column and detector temperatures (± 1°) will help to achieve *System suitability* requirements.]

Flow rate: 0.5 mL/min

Injection volume: 20 µL

Run time: 30 min

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Resolution: NLT 1.5 between dextrose and maltose peaks in *Standard solution A*; NLT 1.3 between dextrose and maltose in *Standard solution B*

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Identify each saccharide peak in the *Sample solution* based on that in *Standard solution A* and *Standard solution B*.

Calculate the percentage of each saccharide in the portion of Dextrates taken:

$$\% \text{ Area} = (r_A/r_B) \times 100$$

r_A = peak response of each saccharide degree of polymerization (DP_1–DP_3) in the *Sample solution* (If any peaks of DP_4 and above are observed in the sample, take the summation of all peak responses DP_{4+} and use this value as r_{A} ▲*(ERR 1-May-2023)*.)

r_B = sum of all peak responses excluding peak responses due to solvent from the *Sample solution*

The expected dextrose equivalent (DE) values for each component are listed in *Table 1*.

Table 1

Degree of Polymerization	Expected DE
1	100.00
2	61.00
3	40.00
4+	20.90

[NOTE—Due to the fact that the HPLC analysis cannot further distinguish oligosaccharides greater than DP_4, and the naturally low amount of the higher order oligosaccharides present in the sample, the value for DP_{4+} was estimated as the average of the expected DE values for DP_4 and above.]

Calculate the dextrose equivalent (DE):

$$DE = \Sigma[(\text{Expected DE})_{DPx} \times (\%\ \text{Area}/100)_{DPx}$$

Expected DE = defined in *Table 1*

% Area = calculated above▲ (NF 1-May-2023)

Acceptance criteria: ▲NLT 93.0% and NMT 99.0%▲ (NF 1-May-2023)

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **pH ⟨791⟩**
Sample: 200 mg/mL in carbon dioxide-free water
Acceptance criteria: 3.8–5.8

• **Loss on Drying ⟨731⟩**
Analysis: Dry at 105° for 16 h in a convection oven.
Acceptance criteria: For the anhydrous form, NMT 2.0%; for the hydrated form, 7.8%–9.2%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store in a cool, dry place.

• **Labeling:** Label it to state whether it is anhydrous or hydrated.

Change to read:

• **USP Reference Standards ⟨11⟩**
USP Dextrose RS
▲USP Dextrates Monohydrate RS
USP Maltose Monohydrate RS▲ (NF 1-May-2023)

[1] A suitable column is Aminex HPX-42A from www.bio-rad.com.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DEXTRATES	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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