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Liquid Glucose

CAS RN®: 8027-56-3.

Change to read:

DEFINITION

Liquid Glucose is a product obtained by the incomplete hydrolysis of starch. It consists chiefly of dextrose, dextrins, maltose, and water. ▲The dextrose equivalent (DE) of Liquid Glucose is NLT 20 and NMT 100 and 90.0%–110.0% of the labeled value.▲ (NF 1-Aug-2024)

IDENTIFICATION

• **A.** It meets the requirements in the *Assay* for *Reducing Sugars (Dextrose Equivalent)*.

ASSAY

Change to read:

• **Reducing Sugars (Dextrose Equivalent)**

▲**Mobile phase:** Water

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

Standard solution B: Prepare a solution in *Mobile phase*, containing a total of 10% (w/v) of saccharide solids, by diluting USP Corn Syrup DE 42 RS with *Mobile phase*.

Sample solution: Dilute a known weight of Liquid Glucose, determined from the result of the test for *Water Determination*, with *Mobile phase* to have 10% (w/v) of solids.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Columns

Guard: 4.6-mm × 3-cm[1]

Analytical: 7.8-mm × 30-cm; two analytical columns, 25-µm packing L124[2]

Temperatures

Column: 85°

[Note—For high-maltose corn syrup made by enzyme hydrolysis, a column temperature of 60 ± 1° may be needed. Column and detector temperatures (±1°) will help achieve system suitability requirements.]

Detector: 45°

Flow rate: 0.4 mL/min

Injection volume: 20 µL

Run time: 60 min

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Table 1

[a] DP_1, monosaccharides, primarily dextrose, in liquid glucose or corn syrup; DP_2, disaccharides, primarily maltose; DP_3, trisaccharides, primarily maltotriose; DP_4, maltotetraose; DP_{5+}, oligosaccharides and polysaccharides.

Degree of Polymerization (DP_X)[a]	Relative Retention Time
1	1.00
2	0.88
3	0.78
4	0.71
5	0.64
6	0.59
7	0.55
8	0.51
9	0.49
10	0.46
11	0.45
12	0.43
13	0.42
14	0.41
15	0.37

uitability requirement

Resolution: NLT 2.0 between the dextrose and maltose peaks using vertical drop-down integration, *Standard solution A*; NLT 0.2 between DP_9 and DP_{10} using vertical drop-down integration, *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* using vertical drop-down integration.

Calculate the percentage of each saccharide (S_x) in the portion of Liquid Glucose taken:

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

r_A = peak response of each saccharide from the *Sample solution*

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

The expected DE values for each component are listed in *Table 2*.

Table 2

Degree of Polymerization (DP_X)	Expected DE 25 Products	Expected DE 36 and DE 42 Products	Expected DE ≥ 63 Products
1	100.00	100.00	100.00

Degree of Polymerization (DP_X)	Expected DE 25 Products	Expected DE 36 and DE 42 Products	Expected DE ≥ 63 Products
2	58.00	58.00	58.00
3	39.50	39.50	39.50
4	29.80	29.80	29.80
5	24.20	24.20	24.20
6	20.80	20.80	20.80
7	19.00	19.50	20.00
8	17.50	17.70	18.00
9	16.50	16.70	17.00
10	15.30	15.50	16.00
11	14.30	14.70	15.00
11–20	13.20	14.00	14.50
21+	9.00	11.00	13.00

Due to the fact that the HPLC analysis using two analytical columns cannot further distinguish polysaccharides greater than DP_{21}, the value for DP_{21+} was estimated as the average of the expected DE values for DP_{21}–DP_{50}. Typically, there is too much overlap for distinct peaks to be observed for DP_{12}–DP_{20} due to their low amounts, whereas DP_{11} is a distinct peak roughly half of the time; the analysis includes all of these overlapped peak areas into a single peak labeled $DP_{11–20}$. If DP_{11} is distinguished, then use the expected DE for DP_{11} for this calculation; if DP_{11} is not distinguished, use the expected DE for $DP_{11–20}$ instead.

Calculate the DE:

$$DE = \Sigma[(E_{DE})_{DPX} \times (S_x/100)_{DPX}]$$

E_{DE} = expected DE as defined in *Table 2*

S_x = calculated above

Acceptance criteria: The DE of Liquid Glucose is NLT 20 and NMT 100 and 90.0%–110.0% of the labeled value.▲ (NF 1-Aug-2024)

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

• **Sulfite**

Sample solution: 5 g in 50 mL of water

Analysis: To the *Sample solution* add 0.2 mL of 0.1 N iodine, then add 0.5 mL of starch TS.

Acceptance criteria: A blue color is produced.

• **Starch**

Sample solution: 5 g in 50 mL of water

Analysis: Boil the *Sample solution* for 1 min, cool, and add 0.2 mL of 0.1 N iodine.

Acceptance criteria: No blue color is produced.

SPECIFIC TESTS

• **Acidity**

Sample solution: 5.0 g in 15 mL of water

Analysis: To the *Sample solution* add 5 drops of phenolphthalein TS, and titrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 0.60 mL of 0.10 N sodium hydroxide is required to produce a pink color.

• **Water Determination** ⟨921⟩, *Method I, Method Ia*

Sample: 100 mg

Acceptance criteria: NMT 21.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tightly closed containers. No storage requirements specified.

• **Labeling:** Label it to indicate the natural source of starch. Label it to indicate its nominal dextrose equivalent.

Change to read:

• **USP Reference Standards** ⟨11⟩

▲USP Corn Syrup DE 42 RS▲ (NF 1-Aug-2024)

USP Dextrose RS

▲USP Maltose Monohydrate RS▲ (NF 1-Aug-2024)

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[1] Suitable microguard de-ashing refill cartridges #1250118, H^+ (cation) and CO_3^- (anion) form, (H^+ first and then CO_3^- in series using de-ashing cartridge holder #1250139), can be found at www.bio-rad.com.

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

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

Topic/Question	Contact	Expert Committee
LIQUID GLUCOSE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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