Dextrose

1 Nonproprietary Names

BP: Glucose monohydrate
JP: Glucose
PhEur: Glucosum monohydricum
USP: Dextrose

2 Synonyms

Blood sugar; *Caridex*; corn sugar; *Dextrofin*; D-(+)-glucopyranose monohydrate; grape sugar; *Lycadex PF*; *Roferose*; starch sugar; *Tabfine D-100*.

3 Chemical Name and CAS Registry Number

D-(+)-Glucose monohydrate [5996-10-1]
See also Section 17.

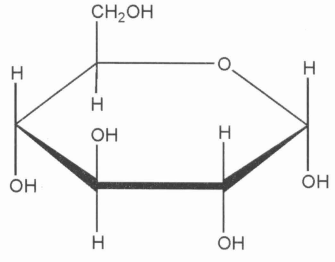
4 Empirical Formula

$C_6H_{12}O_6 \cdot H_2O$
See also Section 17.

Molecular Weight

198.17 (for monohydrate)

5 Structural Formula



Anhydrous material shown.

6 Functional Category

Tablet and capsule diluent; therapeutic agent; tonicity agent; sweetening agent.

7 Applications in Pharmaceutical Formulation or Technology

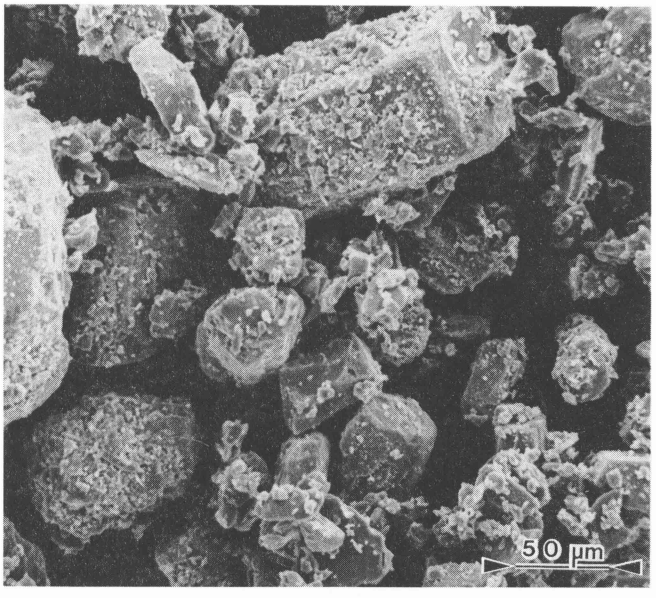
Dextrose is widely used in solutions to adjust tonicity and as a sweetening agent. Dextrose is also used as a direct-compression tablet diluent and binder, primarily in chewable tablets. Although dextrose is comparable as a tablet diluent to lactose, tablets produced with dextrose monohydrate require more lubrication, are less friable, and have a tendency to harden.[1–3] The mildly reducing properties of dextrose may be used when tableting to improve the stability of active materials that are sensitive to oxidation.

Dextrose is also used therapeutically and is the preferred source of carbohydrate in parenteral nutrition regimens.

8 Description

Dextrose occurs as odorless, sweet-tasting, colorless crystals or as a white crystalline or granular powder.

SEM: 1
Excipient: Dextrose anhydrous (granular)
Manufacturer: Mallinckrodt Speciality Chemicals Co.
Lot No.: KLKZ
Magnification: 180×



9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for dextrose.

Test	JP 2001	PhEur 2002	USP 25
Identification	+	+	+
Characters	—	+	—
Color of solution	+	+	+
Specific rotation	—	+52.5° to +53.3°	+52.6° to +53.2°
Acidity	+	+	+
Organic volatile impurities	—	—	+
Water			
for monohydrate	—	7.0–9.5%	7.5–9.5%
for anhydrous	≤1.0%	—	≤0.5%
Residue on ignition	≤0.1%	≤0.1%	≤0.1%
Chloride	≤0.018%	≤125 ppm	≤0.018%
Sulfate	≤0.024%	≤200 ppm	≤0.025%
Arsenic	≤1.3 ppm	≤1 ppm	≤1 ppm
Barium	—	+	—
Calcium	—	≤200 ppm	—
Heavy metals	≤4 ppm	—	≤5 ppm
Lead	—	≤0.5 ppm	—
Dextrin	+	+	+
Soluble starch, and sulfites	+	+	+
Pyrogens[a]	—	+	—
Assay (dried basis)	≥99.5%	—	—

[a] If intended for large volume parenteral use.

10 Typical Properties

Data are shown for dextrose monohydrate; *see* Section 17 for data for dextrose anhydrous.
Acidity/alkalinity: pH = 3.5–5.5 (20% w/v aqueous solution)
Density (bulk): 0.826 g/cm^3
Density (tapped): 1.020 g/cm^3
Density (true): 1.54 g/cm^3
Heat of solution: 105.4 J/g (25.2 cal/g)
Melting point: 83°C
Moisture content: anhydrous dextrose absorbs significant amounts of moisture at 25°C and a relative humidity of about 85% to form the monohydrate. The monohydrate similarly only absorbs moisture at around 85% relative humidity and 25°C. *See* Figure 1.
Osmolarity: a 5.51% w/v aqueous solution is isoosmotic with serum. However, it is not isotonic since dextrose can pass through the membrane of red cells and cause hemolysis.
Solubility: *see* Table II.

Table II: Solubility of dextrose monohydrate.

Solvent	Solubility at 20°C
Chloroform	Practically insoluble
Ethanol (95%)	1 in 60
Ether	Practically insoluble
Glycerin	Soluble
Water	1 in 1

11 Stability and Storage Conditions

Dextrose has good stability under dry storage conditions. Aqueous solutions may be sterilized by autoclaving. However, excessive heating can cause a reduction in pH and caramelization of solutions.[4–7]

The bulk material should be stored in a well-closed container in a cool, dry place.

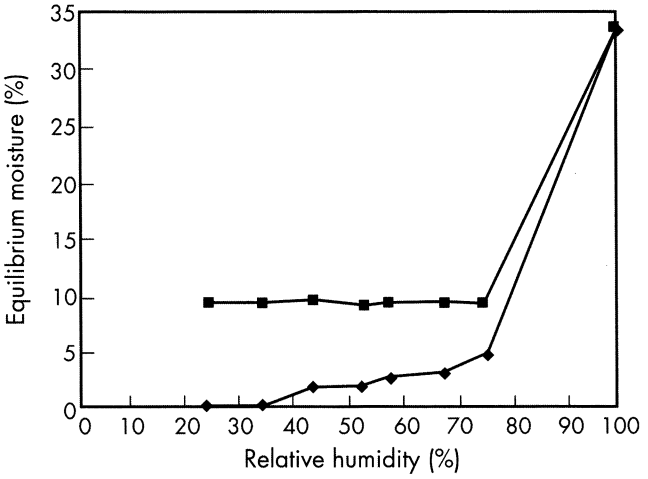


Figure 1: Sorption–desorption isotherm for anhydrous dextrose granules.
◆: Sorption
■: Desorption

12 Incompatibilities

Dextrose solutions are incompatible with a number of drugs such as cyanocobalamin, kanamycin sulfate, novobiocin sodium, and warfarin sodium.[8] Erythromycin gluceptate is unstable in dextrose solutions at a pH less than 5.05.[9] Decomposition of B-complex vitamins may occur if they are warmed with dextrose.

In the aldehyde form, dextrose can react with amines, amides, amino acids, peptides, and proteins. Brown coloration and decomposition occur with strong alkalis.

Dextrose may cause browning of tablets containing amines (Maillard reaction).

13 Method of Manufacture

Dextrose, a monosaccharide sugar, occurs widely in plants and is manufactured on a large scale by the acid or enzymatic hydrolysis of starch, usually maize (corn) starch. Below 50°C α-D-dextrose monohydrate is the stable crystalline form produced; above 50°C the anhydrous form is obtained; and at still higher temperatures β-D-dextrose is formed, which has a melting point of 148–155°C.

14 Safety

Dextrose is rapidly absorbed from the gastrointestinal tract. It is metabolized to carbon dioxide and water with the release of energy.

Concentrated dextrose solutions given by mouth may cause nausea and vomiting. Dextrose solutions of concentration greater than 5% w/v are hyperosmotic and are liable to cause local vein irritation following intravenous administration. Thrombophlebitis has been observed following the intravenous infusion of isoosmotic dextrose solution with low pH, probably owing to the presence of degradation products formed by overheating during sterilization. The incidence of phlebitis may be reduced by adding sufficient sodium bicarbonate to raise the pH of the infusion above pH 7.

LD_{50} (mouse, IV): 9 g/kg[10]
LD_{50} (rat, oral): 25.8 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Dust generation should be minimized to reduce the risk of explosion.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (capsules; inhalations; IM, IV, and SC injections; tablets, oral solutions, and syrups). Included in nonparenteral and parenteral medicines licensed in the UK.

17 Related Substances

Dextrates; dextrin; dextrose anhydrous; fructose; glucose liquid; sucrose.

Dextrose anhydrous
Empirical formula: $C_6H_{12}O_6$
Molecular weight: 180.16
CAS number: [50-99-7]
Synonyms: anhydrous dextrose; anhydrous D-(+)-glucopyranose; anhydrous glucose; dextrosum anhydricum.
Appearance: white, odorless, crystalline powder with a sweet taste.
Acidity/alkalinity: pH = 5.9 (10% w/v aqueous solution)

Density (bulk): 1.3–1.4 g/cm^3
Density (tapped): 1.1–1.2 g/cm^3
Melting point: 146°C
Moisture content: *see* Section 10.
Osmolarity: a 5.05% w/v aqueous solution is isoosmotic with serum. *See also* Section 10.
Refractive index: n_D^{20} = 1.3479 (10% w/v aqueous solution)
Solubility: *see* Table III.

Table III: Solubility of dextrose anhydrous.

Solvent	Solubility at 20°C unless otherwise stated
Ethanol (95%)	Sparingly soluble
Ether	Sparingly soluble
Methanol	1 in 120
Water	1 in 1.1 at 25°C 1 in 0.8 at 30°C 1 in 0.41 at 50°C 1 in 0.28 at 70°C 1 in 0.18 at 90°C

Specific gravity: *see* Table IV.

Table IV: Specific gravity of dextrose anhydrous aqueous solutions.

Concentration of aqueous dextrose solution (% w/v)	Specific gravity at 17.5°C
5	1.019
10	1.038
20	1.076
30	1.113
40	1.149

Specific surface area: 0.22–0.29 m^2/g

18 Comments

The way in which the strengths of dextrose solutions are expressed varies from country to country. The USP 25 requires strengths to be expressed in terms of dextrose monohydrate, while the BP 2001 requires strengths to be expressed in terms of anhydrous dextrose. Approximately 1.1 g of dextrose monohydrate is equivalent to 1 g of anhydrous dextrose.

The EINECS number for dextrose is 200-075-1.

19 Specific References

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20 General References

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21 Author

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22 Date of Revision

17 October 2002.