Dextrose Anhydrous

D

1 Nonproprietary Names

BP: Glucose

JP: Glucose

PhEur: Glucose

USP–NF: Dextrose

2 Synonyms

Anhydrous dextrose; anhydrous glucose; *Cerelose 2401*; corn sugar; dextrosol; dextrosum anhydricum; D-glucose.

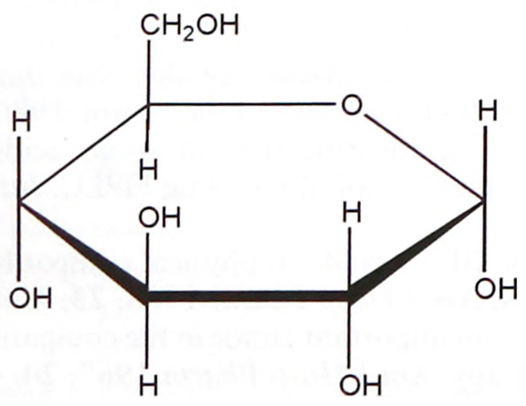
3 Chemical Name and CAS Registry Number

D-(+)-Glucopyranose anhydrous [50-99-7]

4 Empirical Formula and Molecular Weight

$C_6H_{12}O_6$ 180.2

5 Structural Formula



6 Functional Category

Tablet and capsule binder; tablet and capsule diluent; tonicity agent; sweetening agent.

7 Applications in Pharmaceutical Formulation or Technology

Dextrose anhydrous is used in tablet formulations as a binder and diluent in both direct-compression and wet-granulation processes.[1] It is also used in solutions to adjust tonicity and as a sweetening agent. Dextrose anhydrous has the sweetening power of about 70% that of sucrose.[2]

The water content of dextrose anhydrous has an impact on the compression properties of the material depending on the point of the sorption cycle. An initial increase in tensile strength and tablet toughness is observed with increasing water content, before a substantial decrease is seen. For the monohydrate, any increase in moisture content results in a decrease in these properties.[3] Dehydration of the monohydrate has shown an increased crushing strength as the moisture content decreases.[4]

8 Description

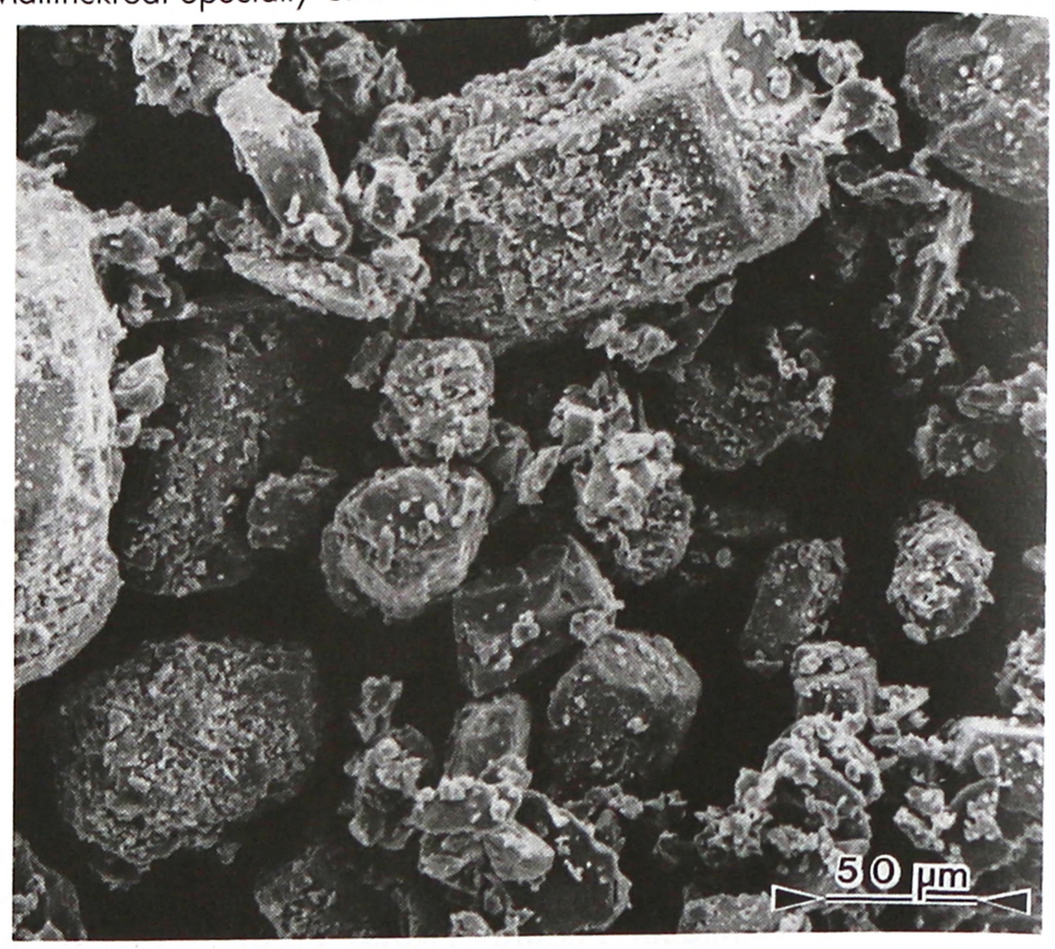
Dextrose anhydrous occurs as colorless crystals or as a white, crystalline or granular powder. It is odorless and has a sweet taste.

The JP XVII describes dextrose anhydrous as α-D-glucopyranose, β-D-glucopyranose, or a mixture of these, and when dried, it contains not less than 99.5% of $C_6H_{12}O_6$.

Information for the crystal structure is described in the literature.[5,6]

For the monohydrate form *see* Dextrose.

SEM 1: Excipient: dextrose anhydrous (granular); manufacturer: Mallinckrodt Specialty Chemicals Co.; lot no.: KLKZ; magnification: 180×.



9 Pharmacopeial Specifications

The PhEur 9.2 provides individual monographs for Glucose Monohydrate and Glucose Anhydrous, whereas the USP 40–NF 35 S1 describes both Dextrose Monohydrate and Dextrose Anhydrous in the specification for Dextrose. The pharmacopeial specifications for both dextrose monohydrate and dextrose anhydrous have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table I.

10 Typical Properties

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

Glass Transition Temperature ≈38°C[7]

Melting point 146°C; also reported as 150–152°C.[8] Further information on melting behavior is described in the literature.[9,10]

Moisture content Dextrose anhydrous absorbs significant amounts of moisture at 25°C and a relative humidity of about 85% to form the monohydrate. *See* Figure 1.

NIR spectra *see* Figure 2.

Osmolarity A 5.05% w/v aqueous solution is isoosmotic with serum.

Refractive Index n_D^{20} = 1.3479 (10% w/v aqueous solution)

Solubility *see* Table II.

Specific gravity *see* Table III.

Specific surface area 0.22–0.29 m^2/g

11 Stability and Storage Conditions

Store in tightly closed containers in a cool, dry, and well-ventilated place.

12 Incompatibilities

Dextrose anhydrous is incompatible with strong oxidizing agents.