Sucrose

1 Nonproprietary Names

BP: Sucrose
JP: Sucrose
PhEur: Saccharum
USPNF: Sucrose

2 Synonyms

Beet sugar; cane sugar; α-D-glucopyranosyl-β-D-fructofuranoside; refined sugar; saccharose; sugar.

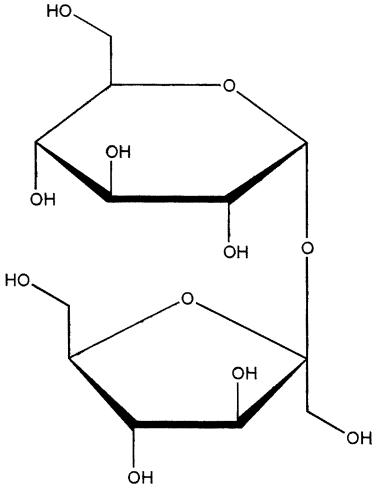
3 Chemical Name and CAS Registry Number

β-D-fructofuranosyl-α-D-glucopyranoside [57-50-1]

4 Empirical Formula and Molecular Weight

Empirical Formula	Molecular Weight
$C_{12}H_{22}O_{11}$	342.30

5 Structural Formula



6 Functional Category

Base for medicated confectionery; granulating agent; sugar coating adjunct; suspending agent; sweetening agent; tablet and capsule diluent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Sucrose is widely used in oral pharmaceutical formulations.

Sucrose syrup, containing 50–67% w/w sucrose, is used in tableting as a binding agent for wet granulation. In the powdered form, sucrose serves as a dry binder (2–20% w/w) or as a bulking agent and sweetener in chewable tablets and lozenges.[1] Tablets that contain large amounts of sucrose may harden to give poor disintegration.

The coprecipitation of sucrose esters with hydrophobic drugs such as nifedipine has been shown to enhance the dissolution of such drugs. Sucrose esters apparently act as a water-soluble carrier upon coprecipitation, thereby allowing hydrophobic drugs to be more readily wetted.[2]

Sucrose syrups are used as tablet-coating agents at concentrations between 50% and 67% w/w. With higher concentrations, partial inversion of sucrose occurs, which makes sugar coating difficult.

Sucrose syrups are also widely used as vehicles in oral liquid-dosage forms to enhance palatability or to increase viscosity.[3]

Because sucrose is nontoxic, biodegradable, and has good emulsifying properties, esters of sucrose have been used increasingly in cosmetic formulations.[4]

Palmitate and stearate esters of sucrose have been used to stabilize suspensions of drugs such as paracetamol. When present at concentrations up to 0.2%, these esters have successfully prevented formation of drug crystals for periods as long as 1 year.[5]

Sucrose is also widely used in foods and confectionery, and therapeutically in sugar pastes that are used to promote wound healing.[6,7] *See* Table I.

Table I: Uses of sucrose.

Use	Concentration (% w/w)
Syrup for oral liquid formulations	67
Sweetening agent	67
Tablet binder (dry granulation)	2–20
Tablet binder (wet granulation)	50–67
Tablet coating (syrup)	50–67

8 Description

Sucrose is a sugar obtained from sugar cane (*Saccharum officinarum* Linné (Fam. Gramineae)), sugar beet (*Beta vulgaris* Linné (Fam. Chenopodiaceae)), and other sources. It contains no added substances. Sucrose occurs as colorless crystals, as crystalline masses or blocks, or as a white crystalline powder; it is odorless and has a sweet taste.

9 Pharmacopeial Specifications

See Table II.

10 Typical Properties

Density (bulk):
0.93 g/cm^3 (crystalline sucrose)
0.60 g/cm^3 (powdered sucrose)
Density (tapped):
1.03 g/cm^3 (crystalline sucrose)
0.82 g/cm^3 (powdered sucrose)
Density (true): 1.6 g/cm^3
Dissociation constant: pK_a = 12.62
Flowability: crystalline sucrose is free flowing, whereas powdered sucrose is a cohesive solid.
Melting point: 160–186°C (with decomposition)

Table II: Pharmacopeial specifications for sucrose.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	+
Characters	—	+	—
Appearance of solution	+	+	—
Acidity or alkalinity	+	+	—
Specific optical rotation	+66.3° to +67.0°	+66.3° to +67.0°	⩾+65.9°
Conductivity	+	+	—
Water	⩽0.1%	⩽0.1%	—
Endotoxins[a]	⩽0.25 IU/mg	⩽0.25 IU/mg	—
Dextrins[a]	+	+	—
Dextrose and invert sugar	—	+	—
Invert sugar	+	—	+
Chloride	—	—	⩽0.0035%
Sulfate	—	—	⩽0.006%
Sulfites	⩽15 ppm	⩽15 ppm	—
Calcium	—	—	+
Heavy metals	—	—	⩽5 ppm
Lead	⩽0.5 ppm	⩽0.5 ppm	—
Residue on ignition	—	—	⩽0.05%
Organic volatile impurities	—	—	+

[a] If sucrose is to be used in large volume infusions.

Moisture content: finely divided sucrose is hygroscopic and absorbs up to 1% water.[8] *See* Figure 1.

Osmolarity: a 9.25% w/v aqueous solution is isoosmotic with serum.

Particle size distribution: powdered sucrose is a white, irregular-sized granular powder. The crystalline material consists of colorless crystalline, roughly cubic granules. *See* Figure 2 and Figure 3.

Refractive index: n_D^{25} = 1.34783 (10% w/v aqueous solution)

Solubility: *see* Table III.

Table III: Solubility of sucrose.

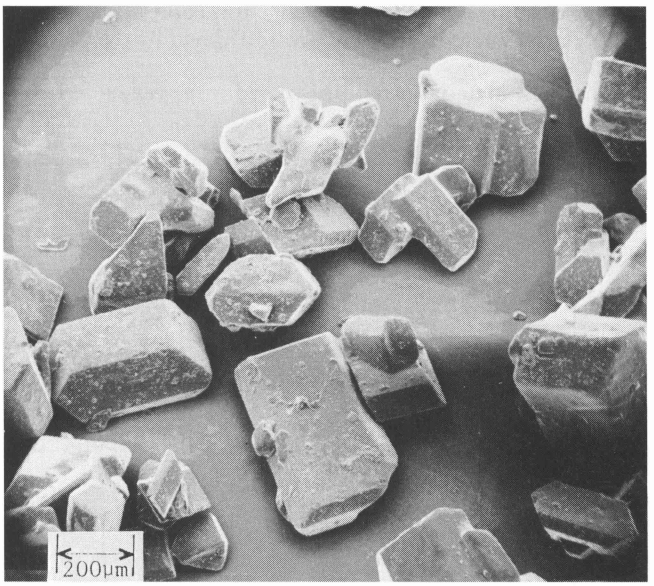
Solvent	Solubility at 20°C unless otherwise stated
Chloroform	Practically insoluble
Ethanol	1 in 400
Ethanol (95%)	1 in 170
Propan-2-ol	1 in 400
Water	1 in 0.5
	1 in 0.2 at 100°C

Specific gravity: *see* Table IV.

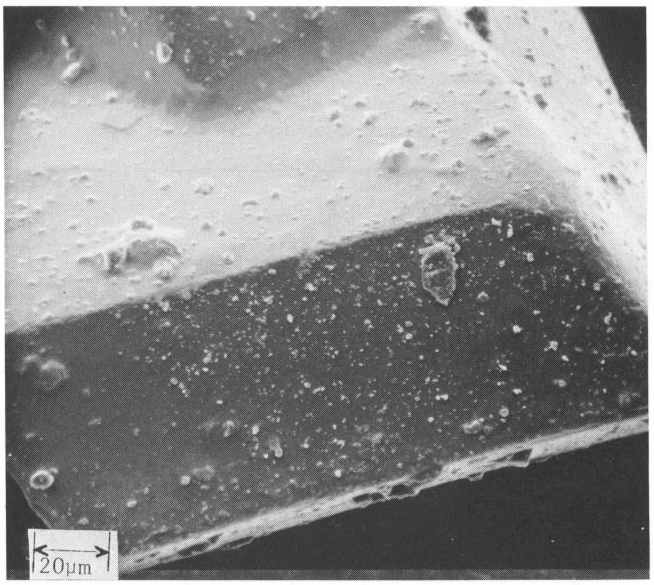
Table IV: Specific gravity of aqueous sucrose solutions.

Concentration of aqueous sucrose solution (% w/w)	Specific gravity at 20°C
2	1.0060
6	1.0219
10	1.0381
20	1.0810
30	1.1270
40	1.1764
50	1.2296
60	1.2865
70	1.3471
76	1.3854

SEM: 1
Excipient: Sucrose
Manufacturer: Great Western Sugar Co.
Lot No.: 1-2-80
Magnification: 60×
Voltage: 10 kV



SEM: 2
Excipient: Sucrose
Manufacturer: Great Western Sugar Co.
Lot No.: 1-2-80
Magnification: 600×
Voltage: 10 kV



11 Stability and Storage Conditions

Sucrose has good stability at room temperature and at moderate relative humidity. It absorbs up to 1% moisture, which is released upon heating at 90°C. Sucrose caramelizes when heated to temperatures above 160°C. Dilute sucrose solutions are liable to fermentation by microorganisms but resist decomposition at higher concentrations, e.g., above 60%

w/w concentration. Aqueous solutions may be sterilized by autoclaving or filtration.

When sucrose is used as a base for medicated confectionery, the cooking process, at temperatures rising from 110 to 145°C, causes some inversion to form dextrose and fructose (invert sugar). The fructose imparts stickiness to confectionery but prevents cloudiness due to graining. Inversion is accelerated particularly at temperatures above 130°C and by the presence of acids.

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

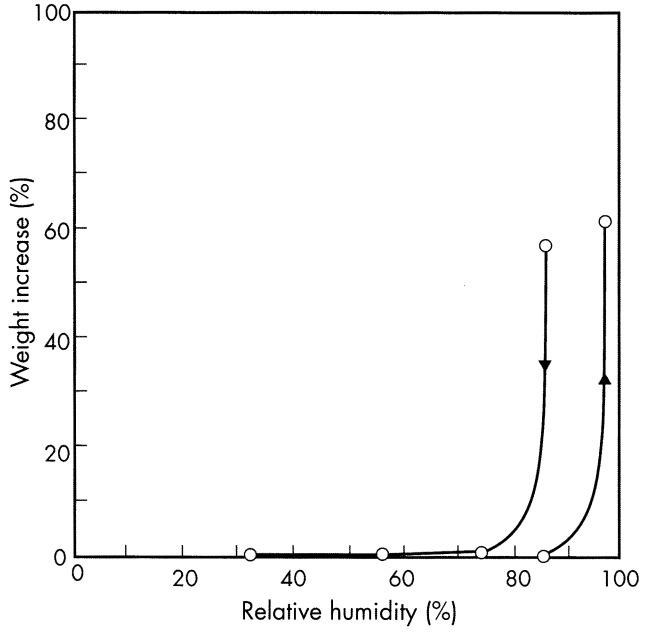


Figure 1: Moisture sorption–desorption isotherm of powdered sucrose.
Samples dried initially at 60°C over silica gel for 24 hours.
Note: at 90% relative humidity, sufficient water was absorbed to cause dissolution of the solid.

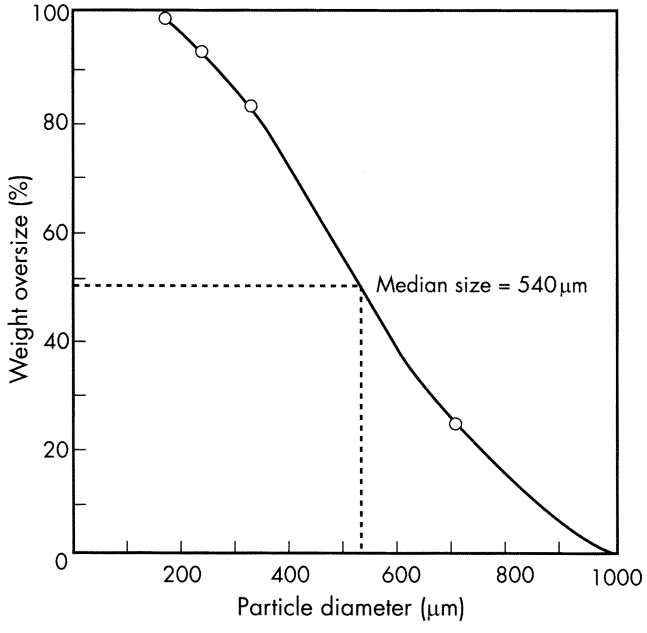


Figure 2: Particle size distribution of crystalline sucrose.

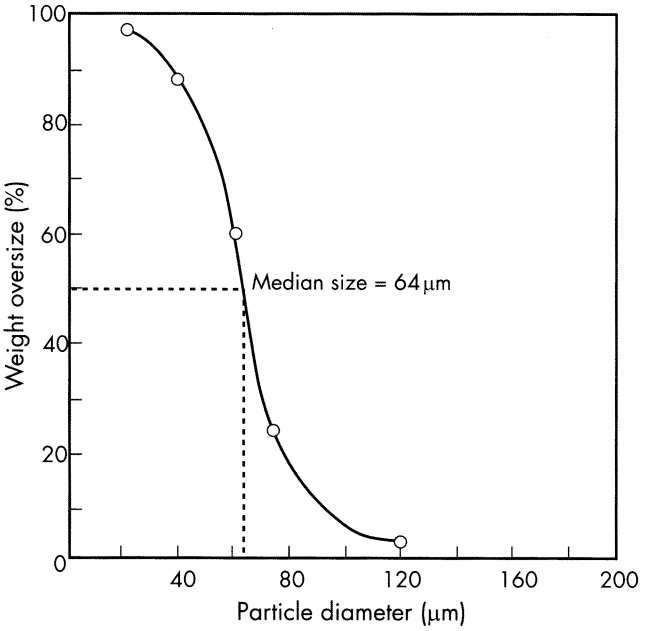


Figure 3: Particle size distribution of powdered sucrose.

12 Incompatibilities

Powdered sucrose may be contaminated with traces of heavy metals, which can lead to incompatibility with active ingredients, e.g., ascorbic acid. Sucrose may also be contaminated with sulfite from the refining process. With high sulfite content, color changes can occur in sugar-coated tablets; for certain colors used in sugar-coating the maximum limit for sulfite content, calculated as sulfur, is 1 ppm. In the presence of dilute or concentrated acids, sucrose is hydrolyzed or inverted to dextrose and fructose (invert sugar). Sucrose may attack aluminum closures.[9]

13 Method of Manufacture

Sucrose is obtained from the sugar cane plant, which contains 15–20% sucrose, and sugar beet, which contains 10–17% sucrose. Juice from these sources is heated to coagulate water-soluble proteins, which are removed by skimming. The resultant solution is then decolorized with an ion-exchange resin or charcoal and concentrated. Upon cooling, sucrose crystallizes out. The remaining solution is concentrated again and yields more sucrose, brown sugar, and molasses.

14 Safety

Sucrose is hydrolyzed in the small intestine by the enzyme sucrase to yield dextrose and fructose, which are then absorbed. When administered intravenously, sucrose is excreted unchanged in the urine.

Although sucrose is very widely used in foods and pharmaceutical formulations, sucrose consumption is a cause of concern and should be monitored in patients with diabetes mellitus or other metabolic sugar intolerance.[10]

Sucrose is also considered to be more cariogenic than other carbohydrates since it is more easily converted to dental plaque. For this reason, its use in oral pharmaceutical formulations is declining.

Although sucrose has been associated with obesity, renal damage, and a number of other diseases, conclusive evidence

linking sucrose intake with some diseases could not be established.[11,12] It was, however, recommended that sucrose intake in the diet should be reduced.[12]

LD_{50} (mouse, IP): 14 g/kg[13]
LD_{50} (rat, oral): 29.7 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. In the UK, the occupational exposure limit for sucrose is 10 mg/m^3 long-term (8-hour TWA) and 20 mg/m^3 short-term.[14]

16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral capsules, solutions, syrups, and tablets). Included in nonparenteral and parenteral medicines licensed in the UK.

17 Related Substances

Compressible sugar; confectioner's sugar; invert sugar; sugar spheres.

Invert sugar
Empirical formula: $C_6H_{12}O_6$
Molecular weight: 180.16
CAS number: [8013-17-0]
Comments: an equimolecular mixture of dextrose and fructose prepared by the hydrolysis of sucrose with a suitable mineral acid such as hydrochloric acid. Invert sugar may be used as a stabilizing agent to help prevent crystallization of sucrose syrups and graining in confectionery. A 10% aqueous solution is also used in parenteral nutrition.

18 Comments

For typical boiling points of sucrose syrups, without inversion of the sugar, *see* Table V.

The EINECS number for sucrose is 200-334-9.

Table V: Boiling points of sucrose syrups.

Sucrose concentration (% w/v)	Boiling point (°C)
50	101.5
60	103
64	104
72	105.5
75	107
77.5	108.5
80	110.5

19 Specific References

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21 Author

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22 Date of Revision

17 October 2002.