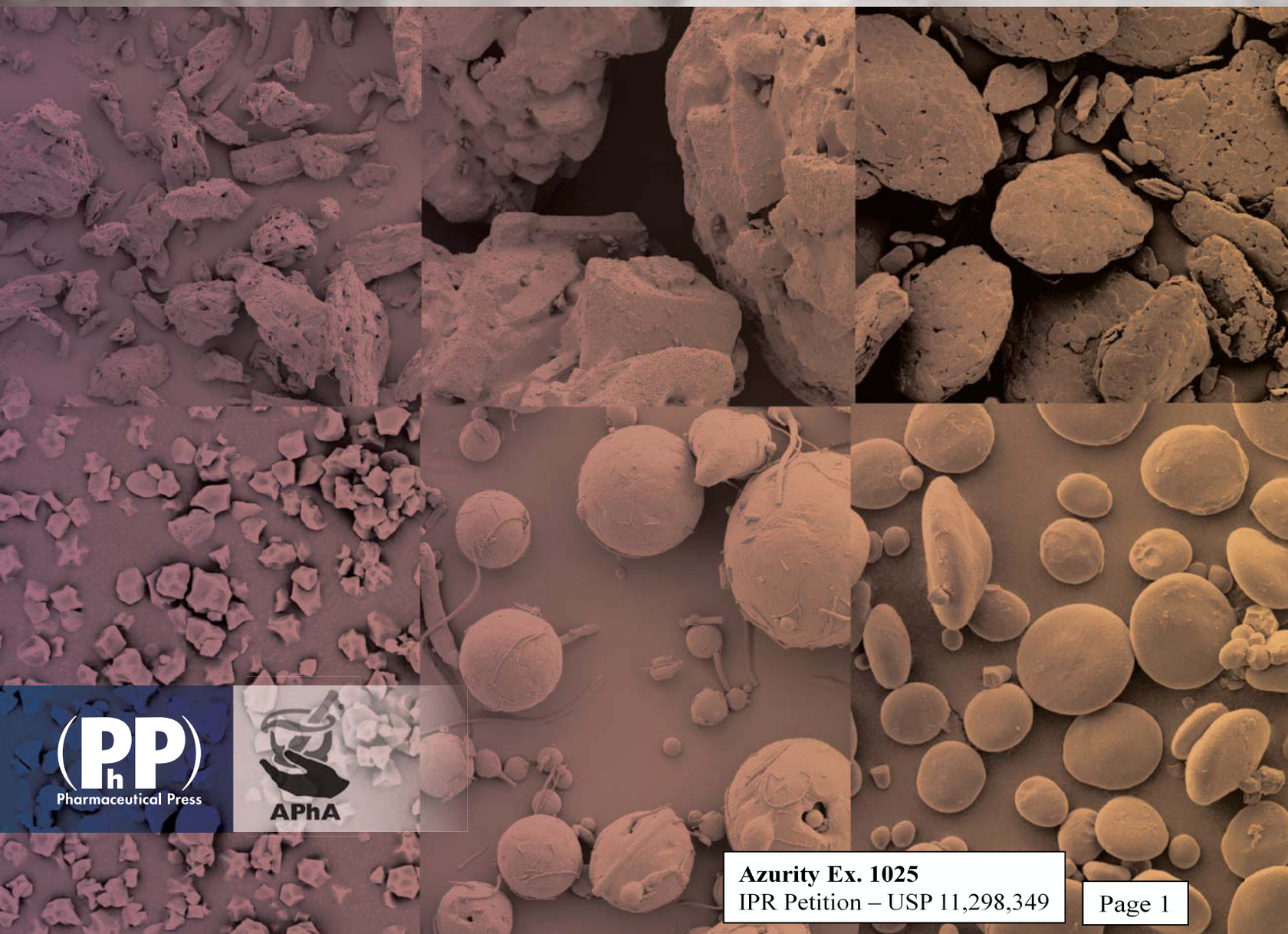
Handbook of Pharmaceutical Excipients

Sixth edition

Edited by
Raymond C Rowe, Paul J Sheskey and Marian E Quinn



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Page 1

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Preface

Pharmaceutical dosage forms contain both pharmacologically active compounds and excipients added to aid the formulation and manufacture of the subsequent dosage form for administration to patients. Indeed, the properties of the final dosage form (i.e. its bioavailability and stability) are, for the most part, highly dependent on the excipients chosen, their concentration and interaction with both the active compound and each other. No longer can excipients be regarded simply as inert or inactive ingredients, and a detailed knowledge not only of the physical and chemical properties but also of the safety, handling and regulatory status of these materials is essential for formulators throughout the world. In addition, the growth of novel forms of delivery has resulted in an increase in the number of the excipients being used and suppliers of excipients have developed novel coprocessed excipient mixtures and new physical forms to improve their properties. The *Handbook of Pharmaceutical Excipients* has been conceived as a systematic, comprehensive resource of information on all of these topics.

The first edition of the *Handbook* was published in 1986 and contained 145 monographs. This was followed by the second edition in 1994 containing 203 monographs, the third edition in 2000 containing 210 monographs and the fourth edition in 2003 containing 249 monographs. Since 2000, the data has also been available on CD-ROM, updated annually, and from 2004 online. The fifth edition with its companion CD-ROM, *Pharmaceutical Excipients 5*, contained 300 monographs and was published in 2006. This new edition contains 340 excipient monographs with a new text design and enhanced online features, compiled by over 140 experts in pharmaceutical formulation or excipient manufacture from Australia, Europe, India, Japan, and the USA. All the monographs have been reviewed and revised in the light of current knowledge. There has been a greater emphasis on including published data from primary sources although some data from laboratory projects included in previous editions have been retained where relevant. Variations in test methodology can have significant effects on the data generated (especially in the case of the compactability of an excipient), and thus cause confusion. As a consequence, the editors have been more selective in including data relating to the physical properties of an excipient. However, comparative data that show differences between either source or batch of a specific excipient have been retained as this was considered relevant to the behavior of a material in practice. Over the past few years, there has been an increased emphasis on the harmonization of excipients. For information on the current status for each excipient selected for harmonization, the reader is directed to the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website (http://www.edq-m.eu), and also the General Information Chapter 8 in the JP XV. The Suppliers Directory (Appendix I) has also been completely updated with many more international suppliers included.

In a systematic and uniform manner, the *Handbook of Pharmaceutical Excipients* collects essential data on the physical properties of excipients such as: boiling point, bulk and tap density, compression characteristics, hygroscopicity, flowability, melting point, moisture content, moisture-absorption isotherms, particle size distribution, rheology, specific surface area, and solubility. Scanning electron microphotographs (SEMs) are also included for many of the excipients. This edition contains over 130 near-infrared (NIR) spectra specifically generated for the *Handbook*. The *Handbook* contains information from various international sources and personal observation and comments from monograph authors, steering committee members, and the editors.

All of the monographs in the *Handbook* are thoroughly cross-referenced and indexed so that excipients may be identified by either a chemical, a nonproprietary, or a trade name. Most monographs list related substances to help the formulator to develop a list of possible materials for use in a new dosage form or product. Related substances are not directly substitutable for each other but, in general, they are excipients that have been used for similar purposes in various dosage forms.

The *Handbook of Pharmaceutical Excipients* is a comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients, and is an essential reference source for those involved in the development, production, control, or regulation of pharmaceutical preparations. Since many pharmaceutical excipients are also used in other applications, the *Handbook of Pharmaceutical Excipients* will also be of value to persons with an interest in the formulation or production of confectionery, cosmetics, and food products.

Abbreviations

Some units, terms, and symbols are not included in this list as they are defined in the text. Common abbreviations have been omitted. The titles of journals are abbreviated according to the general style of the *Index Medicus*.

≈	approximately.
Ad	Addendum.
ADI	acceptable daily intake.
approx	approximately.
atm	atmosphere.
BAN	British Approved Name.
bp	boiling point.
BP	British Pharmacopoeia.
BS	British Standard (specification).
BSI	British Standards Institution.
cal	calorie(s).
CAS	Chemical Abstract Service.
CFC	chlorofluorocarbon.
cfu	colony-forming unit
cm	centimeter(s).
cm^2	square centimeter(s).
cm^3	cubic centimeter(s).
cmc	critical micelle concentration.
CNS	central nervous system.
cP	centipoise(s).
cSt	centistoke(s).
CTFA	Cosmetic, Toiletry, and Fragrance Association.
d	particle diameter (d_{10} at 10 percentile; d_{50} at 50 percentile; d_{90} at 90 percentile).
D&C	designation applied in USA to dyes permitted for use in drugs and cosmetics.
DoH	Department of Health (UK).
DSC	differential scanning calorimetry.
EC	European Community.
e.g.	*exemplit gratia*, 'for example'.
EINECS	European Inventory of Existing Commercial Chemical Substances.
et al	*et alii*, 'and others'.
EU	European Union.
FAO	Food and Agriculture Organization of the United Nations.
FAO/WHO	Food and Agriculture Organization of the United Nations *and the* World Health Organization.
FCC	Food Chemicals Codex.
FDA	Food and Drug Administration of the USA.
FD&C	designation applied in USA to dyes permitted for use in foods, drugs, and cosmetics.
FFBE	Flat face beveled edge.
g	gram(s).
GMP	Good Manufacturing Practice.
GRAS	generally recognized as safe by the Food and Drug Administration of the USA.
HC	hydrocarbon.
HCFC	hydrochlorofluorocarbon.
HFC	hydrofluorocarbon.
HIV	human immunodeficiency virus.
HLB	hydrophilic–lipophilic balance.
HSE	Health and Safety Executive (UK).
i.e.	*id est*, 'that is'.
IM	intramuscular.
INN	International Nonproprietary Name.
IP	intraperitoneal.
ISO	International Organization for Standardization.
IU	International Units.
IV	intravenous.
J	joule(s).
JP	Japanese Pharmacopeia.
JPE	Japanese Pharmaceutical Excipients
kcal	kilocalorie(s).
kg	kilogram(s).
kJ	kilojoule(s).
kPa	kilopascal(s).
L	liter(s).
LAL	*Limulus* amoebocyte lysate.
LC_{50}	a concentration in air lethal to 50% of the specified animals on inhalation.
LD_{50}	a dose lethal to 50% of the specified animals or microorganisms.
Ld_{Lo}	lowest lethal dose for the specified animals or microorganisms.
m	meter(s).
m^2	square meter(s).
m^3	cubic meter(s).
M	molar.
max	maximum.
MCA	Medicines Control Agency (UK).
mg	milligram(s).
MIC	minimum inhibitory concentration.
min	minute(s) *or* minimum.
mL	milliliter(s).
mm	millimeter(s).
mM	millimolar.
mm^2	square millimeter(s).
mm^3	cubic millimeter(s).
mmHg	millimeter(s) of mercury.
mmol	millimole(s).
mN	millinewton(s).
mol	mole(s).
mp	melting point.
mPa	millipascal(s).
MPa	megapascal(s).
µg	microgram(s).
µm	micrometer(s).
N	newton(s) *or* normal (concentration).
NIR	near-infrared.
nm	nanometer(s).
o/w	oil-in-water.
o/w/o	oil-in-water-in-oil.
Pa	pascal(s).
pH	the negative logarithm of the hydrogen ion concentration.
PhEur	European Pharmacopeia.
pK_a	the negative logarithm of the dissociation constant.
pph	parts per hundred.
ppm	parts per million.
psia	pounds per square inch absolute.
R	reflectance.
RDA	recommended dietary allowance (USA).
rpm	revolutions per minute.
s	second(s).
SC	subcutaneous.
SEM	scanning electron microscopy *or* scanning electron microphotograph.

SI	Statutory Instrument *or* Système International d'Unites (International System of Units).
TD_{Lo}	lowest toxic dose for the specified animals or microorganisms.
TPN	total parental nutrition.
TWA	time weighted average.
UK	United Kingdom.
US *or* USA	United States of America.
USAN	United States Adopted Name.
USP	The United States Pharmacopeia.
USP–NF	The United States Pharmacopeia National Formulary.
UV	ultraviolet.
v/v	volume in volume.
v/w	volume in weight.
WHO	World Health Organization.
w/o	water-in-oil.
w/o/w	water-in-oil-in-water.
w/v	weight in volume.
w/w	weight in weight.

14 Safety

Hydrogenated castor oil is used in oral and topical pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material.

Acute oral toxicity studies in animals have shown that hydrogenated castor oil is a relatively nontoxic material. Irritation tests with rabbits show that hydrogenated castor oil causes mild, transient irritation to the eye.

LD_{50} (rat, oral): >10 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Accepted in the USA as an indirect food additive. Included in the FDA Inactive Ingredients Database (oral capsules, tablets, and sublingual tablets).

Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Castor oil; vegetable oil, hydrogenated.

18 Comments

Various different grades of hydrogenated castor oil are commercially available, the composition of which may vary considerably. *Sterotex K* (Karlshamns Lipid Specialities), for example, is a mixture of hydrogenated castor oil and hydrogenated cottonseed oil. *See* Vegetable Oil, hydrogenated for further information.

The EINECS number for hydrogenated castor oil is 232-292-2.

19 Specific References

1 Kline CH. Thixcin R-thixotrope. *Drug Cosmet Ind* 1964; **95**(6): 895–897.
2 Yonezawa Y *et al*. Release from or through a wax matrix system. III: Basic properties of release through the wax matrix layer. *Chem Pharm Bull (Tokyo)* 2002; **50**(6): 814–817.
3 Vergote GJ *et al*. An oral controlled release matrix pellet formulation containing microcrystalline ketoprofen. *Int J Pharm* 2002; **219**: 81–87.
4 Danish FQ, Parrott EL. Effect of concentration and size of lubricant on flow rate of granules. *J Pharm Sci* 1971; **60**: 752–754.
5 Hölzer AW, Sjögren J. Evaluation of some lubricants by the comparison of friction coefficients and tablet properties. *Acta Pharm Suec* 1981; **18**: 139–148.

20 General References

—

21 Author

RT Guest.

22 Date of Revision

11 February 2009.

Cellulose, Microcrystalline

1 Nonproprietary Names

BP: Microcrystalline Cellulose
JP: Microcrystalline Cellulose
PhEur: Cellulose, Microcrystalline
USP-NF: Microcrystalline Cellulose

2 Synonyms

Avicel PH; *Cellets*; *Celex*; cellulose gel; hellulosum microcristallinum; *Celphere*; *Ceolus KG*; crystalline cellulose; E460; *Emcocel*; *Ethispheres*; *Fibrocel*; *MCC Sanaq*; *Pharmacel*; *Tabulose*; *Vivapur*.

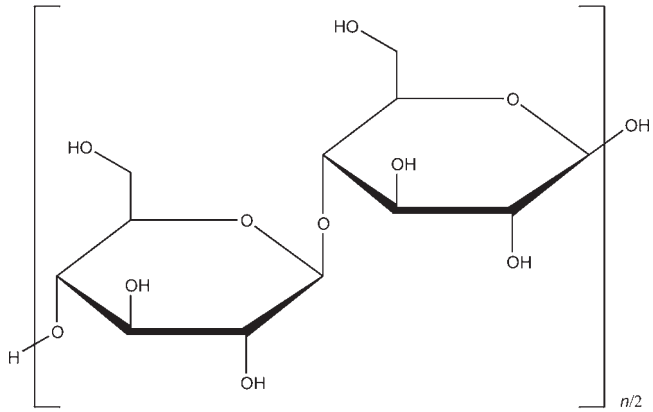
3 Chemical Name and CAS Registry Number

Cellulose [9004-34-6]

4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_5)_n$ ≈36 000
where $n \approx 220$.

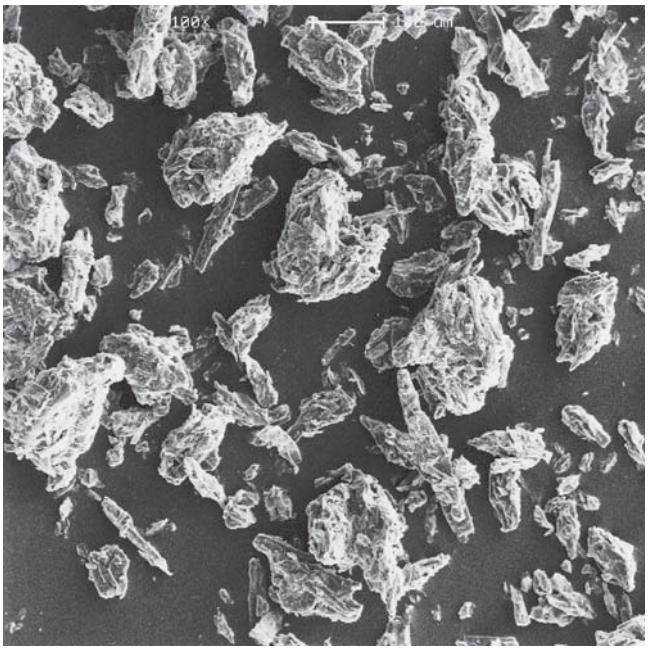
5 Structural Formula



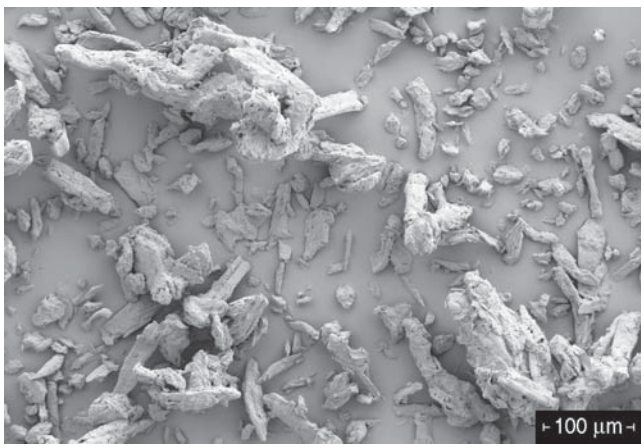
6 Functional Category

Adsorbent; suspending agent; tablet and capsule diluent; tablet disintegrant.

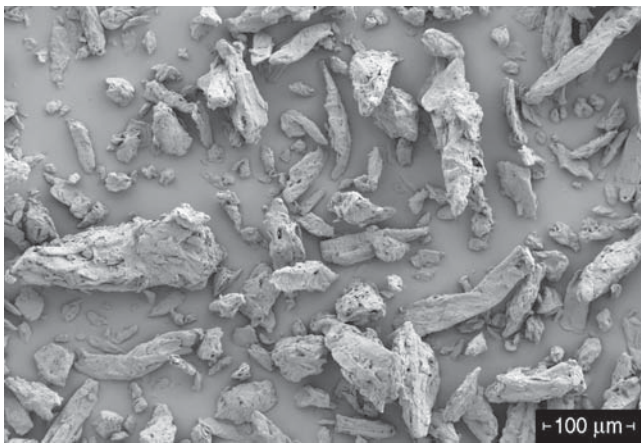
SEM 1: Excipient: microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: 98662; magnification: 100×.



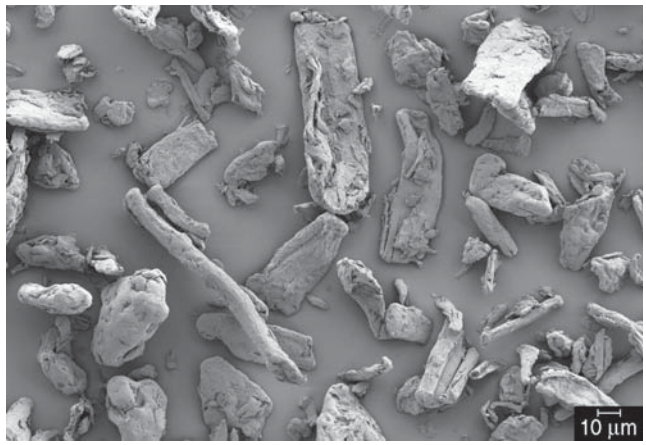
SEM 2: Excipient: microcrystalline cellulose (*Avicel PH-101*); manufacturer: FMC Biopolymer. magnification: 200×; voltage: 3 kV.



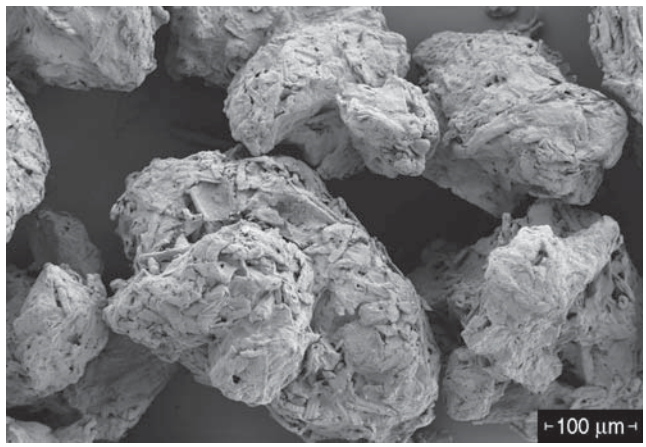
SEM 3: Excipient: microcrystalline cellulose (*Avicel PH-102*); manufacturer: FMC Biopolymer. magnification: 200×; voltage: 3 kV.



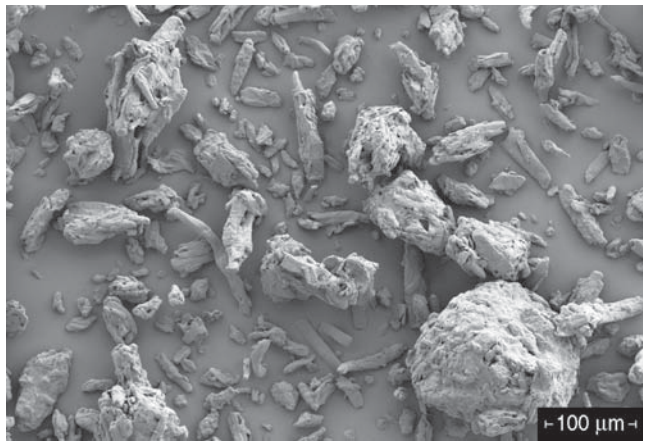
SEM 4: Excipient: microcrystalline cellulose (*Avicel PH-105*); manufacturer: FMC Biopolymer. magnification: 500×; voltage: 3 kV.



SEM 5: Excipient: microcrystalline cellulose (*Avicel PH-200*); manufacturer: FMC Biopolymer. magnification: 200×; voltage: 3 kV.



SEM 6: Excipient: microcrystalline cellulose (*Avicel PH-302*); manufacturer: FMC Biopolymer. magnification: 200×; voltage: 3 kV.



7 Applications in Pharmaceutical Formulation or Technology

Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder/diluent in oral tablet and capsule formulations where it is used in both wet-granulation and direct-compression processes.[1–7] In addition to its use as a binder/diluent, microcrystalline cellulose also has some lubricant[8] and disintegrant properties that make it useful in tableting.

Microcrystalline cellulose is also used in cosmetics and food products; *see* Table I.

8 Description

Microcrystalline cellulose is a purified, partially depolymerized cellulose that occurs as a white, odorless, tasteless, crystalline powder composed of porous particles. It is commercially available in different particle sizes and moisture grades that have different properties and applications.

Table I: Uses of microcrystalline cellulose.

Use	Concentration (%)
Adsorbent	20–90
Antiadherent	5–20
Capsule binder/diluent	20–90
Tablet disintegrant	5–15
Tablet binder/diluent	20–90

9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

Table II: Pharmacopeial specifications for microcrystalline cellulose.

Test	JP XV	PhEur 6.3	USP32–NF27
Identification	+	+	+
Characters	+	+	–
pH	5.0–7.5	5.0–7.5	5.0–7.5
Bulk density	+	–	+
Loss on drying	⩽7.0%	⩽7.0%	⩽7.0%
Residue on ignition	⩽0.1%	–	⩽0.1%
Conductivity	+	+	+
Sulfated ash	–	⩽0.1%	–
Ether-soluble substances	⩽0.05%	⩽0.05%	⩽0.05%
Water-soluble substances	+	⩽0.25%	⩽0.25%
Heavy metals	⩽10 ppm	⩽10 ppm	⩽0.001%
Microbial limits	+	+	+
Aerobic	$\leqslant 10^3$ cfu/g	$\leqslant 10^3$ cfu/g	$\leqslant 10^3$ cfu/g
Molds and yeasts	$\leqslant 10^2$ cfu/g	$\leqslant 10^2$ cfu/g	$\leqslant 10^2$ cfu/g
Solubility	–	+	–
Particle size distribution	–	–	+

10 Typical Properties

Angle of repose
49° for *Ceolus KG*;
34.4° for *Emcocel 90M*.[9]

Density (bulk)
0.337 g/cm^3;
0.32 g/cm^3 for *Avicel PH-101*;[10]
0.80 ± 5 g/cm^3 for *Cellets 100*, *200*, *350*, *500*, *700*, *1000*;
0.29 g/cm^3 for *Emcocel 90M*;[9]
0.26–0.31 g/cm^3 for *MCC Sanaq 101*;
0.28–0.33 g/cm^3 for *MCC Sanaq 102*;
0.29–0.36 g/cm^3 for *MCC Sanaq 200*;
0.34–0.45 g/cm^3 for *MCC Sanaq 301*;
0.35–0.46 g/cm^3 for *MCC Sanaq 302*;
0.13–0.23 g/cm^3 for *MCC Sanaq UL-002*;
0.29 g/cm^3 for *Vivapur 101*.

Density (tapped)
0.478 g/cm^3;
0.45 g/cm^3 for *Avicel PH-101*;
0.35 g/cm^3 for *Emcocel 90M*.[9]

Density (true) 1.512–1.668 g/cm^3;

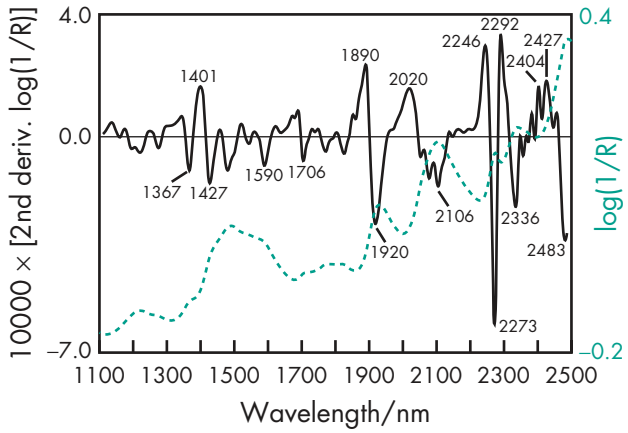


Figure 1: Near-infrared spectrum of cellulose, microcrystalline measured by reflectance.

1.420–1.460 g/cm^3 for *Avicel PH-102*.[11]

Flowability 1.41 g/s for *Emcocel 90M*.[9]

Melting point Chars at 260–270°C.

Moisture content Typically less than 5% w/w. However, different grades may contain varying amounts of water. Microcrystalline cellulose is hygroscopic.[12] *See* Table III.

NIR spectra *see* Figure 1.

Particle size distribution Typical mean particle size is 20–200 µm. Different grades may have a different nominal mean particle size; *see* Table III.

Solubility Slightly soluble in 5% w/v sodium hydroxide solution; practically insoluble in water, dilute acids, and most organic solvents.

Specific surface area
1.06–1.12 m^2/g for *Avicel PH-101*;
1.21–1.30 m^2/g for *Avicel PH-102*;
0.78–1.18 m^2/g for *Avicel PH-200*.

11 Stability and Storage Conditions

Microcrystalline cellulose is a stable though hygroscopic material. The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Microcrystalline cellulose is incompatible with strong oxidizing agents.

13 Method of Manufacture

Microcrystalline cellulose is manufactured by controlled hydrolysis with dilute mineral acid solutions of α-cellulose, obtained as a pulp from fibrous plant materials. Following hydrolysis, the hydrocellulose is purified by filtration and the aqueous slurry is spray-dried to form dry, porous particles of a broad size distribution.

14 Safety

Microcrystalline cellulose is widely used in oral pharmaceutical formulations and food products and is generally regarded as a relatively nontoxic and nonirritant material.

Microcrystalline cellulose is not absorbed systemically following oral administration and thus has little toxic potential. Consumption of large quantities of cellulose may have a laxative effect, although this is unlikely to be a problem when cellulose is used as an excipient in pharmaceutical formulations.

Deliberate abuse of formulations containing cellulose, either by inhalation or by injection, has resulted in the formation of cellulose granulomas.[13]

Table III: Properties of selected commercially available grades of microcrystalline cellulose.

Grade	Nominal mean particle size (μm)	Particle size analysis		Moisture content (%)
		Mesh size	Amount retained (%)	
Avicel PH-101 [(a)]	50	60	⩽1.0	⩽5.0
		200	⩽30.0	
Avicel PH-102 [(a)]	100	60	⩽8.0	⩽5.0
		200	⩾45.0	
Avicel PH-103 [(a)]	50	60	⩽1.0	⩽3.0
		200	⩽30.0	
Avicel PH-105 [(a)]	20	400	⩽1.0	⩽5.0
Avicel PH-112 [(a)]	100	60	⩽8.0	⩽1.5
Avicel PH-113 [(a)]	50	60	⩽1.0	⩽1.5
		200	⩽30.0	
Avicel PH-200 [(a)]	180	60	⩾10.0	⩽5.0
		100	⩾50.0	
Avicel PH-301 [(a)]	50	60	⩽1.0	⩽5.0
		200	⩽30.0	
Avicel PH-302 [(a)]	100	60	⩽8.0	⩽5.0
		200	⩾45.0	
Celex 101 [(b)]	75	60	⩽1.0	⩽5.0
		200	⩾30.0	
Ceolus KG-802 [(c)]	50	60	⩽0.5	⩽6.0
		200	⩽30.0	
Emcocel 50M [(d)]	50	60	⩽0.25	⩽5.0
		200	⩽30.0	
Emcocel 90M [(d)]	91	60	⩽8.0	⩽5.0
		200	⩾45.0	
MCC Sanaq 101 [(e)]	50	60	⩽1.0	⩽6.0
		200	⩽30.0	
MCC Sanaq 102 [(e)]	100	60	⩽8.0	⩽6.0
		200	⩾45.0	
MCC Sanaq 200 [(e)]	180	60	⩾10.0	⩽6.0
		100	⩾50.0	
MCC Sanaq 301 [(e)]	50	60	⩽1.0	⩽6.0
		200	⩾30.0	
MCC Sanaq 302 [(e)]	100	60	⩽8.0	⩽6.0
		200	⩾45.0	
MCC Sanaq UL-002 [(e)]	50	60	<0.5	⩽6.0
		100	<5.0	
		200	<5.0–30.0	
Vivapur 101 [(d)]	50	60	⩽1.0	⩽5.0
		200	⩽30.0	
Vivapur 102 [(d)]	90	60	⩽8.0	⩽5.0
		200	⩾45.0	
Vivapur 12 [(d)]	160	38	⩽1.0	⩽5.0
		94	⩽50.0	

Suppliers:
(a) FMC Biopolymer
(b) International Specialty Products
(c) Asahi Kasei Corporation
(d) JRS Pharma
(e) Pharmatrans Sanaq AG

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Microcrystalline cellulose may be irritant to the eyes. Gloves, eye protection, and a dust mask are recommended. In the UK, the workplace exposure limits for cellulose have been set at 10 mg/m^3 long-term (8-hour TWA) for total inhalable dust and 4 mg/m^3 for respirable dust; the short-term limit for total inhalable dust has been set at 20 mg/m^3.[14]

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (inhalations; oral capsules, powders, suspensions, syrups, and tablets; topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Microcrystalline cellulose and carrageenan; microcrystalline cellulose and carboxymethylcellulose sodium; microcrystalline cellulose and guar gum; powdered cellulose; silicified microcrystalline cellulose.

Microcrystalline cellulose and carrageenan

Synonyms *Lustre Clear.*

Comments *Lustre Clear* (FMC Biopolymer) is an aqueous film coating combining microcrystalline cellulose and carrageenan.

Microcrystalline cellulose and guar gum

Synonyms *Avicel CE-15.*

Comments *Avicel CE-15* (FMC Biopolymer) is a coprocessed mixture of microcrystalline cellulose and guar gum used in chewable tablet formulations.

18 Comments

Microcrystalline cellulose is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Several different grades of microcrystalline cellulose are commercially available that differ in their method of manufacture,[15,16] particle size, moisture, flow, and other physical properties.[17–29] The larger-particle-size grades generally provide better flow properties in pharmaceutical machinery. Low-moisture grades are used with moisture-sensitive materials. Higher-density grades have improved flowability.

Several coprocessed mixtures of microcrystalline cellulose with other excipients such as carrageenan, carboxymethylcellulose sodium, and guar gum are commercially available; *see* Section 17.

Celphere (Asahi Kasei Corporation) is a pure spheronized microcrystalline cellulose available in several different particle size ranges. *Balocel Sanaq* (Pharmatrans Sanaq AG) is an excipient used mainly in the production of pellets and granulates in direct tableting, which contains lactose, microcrystalline cellulose, and sodium carboxymethylcellulose.

According to PhEur 6.3, microcrystalline cellulose has certain functionality related characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient. Non-mandatory testing procedures have been described for particle size distribution (2.9.31 or 2.9.38) and powder flow (2.9.36).

A specification for microcrystalline cellulose is contained in the Food Chemicals Codex (FCC).[30] The PubChem Compound ID (CID) for microcrystalline cellulose is 14055602.

19 Specific References

1 Enézian GM. [Direct compression of tablets using microcrystalline cellulose.] *Pharm Acta Helv* 1972; **47**: 321–363[in French].
2 Lerk CF, Bolhuis GK. Comparative evaluation of excipients for direct compression I. *Pharm Weekbl* 1973; **108**: 469–481.
3 Lerk CF *et al*. Comparative evaluation of excipients for direct compression II. *Pharm Weekbl* 1974; **109**: 945–955.
4 Lamberson RF, Raynor GE. Tableting properties of microcrystalline cellulose. *Manuf Chem Aerosol News* 1976; **47**(6): 55–61.

5 Lerk CF *et al*. Effect of microcrystalline cellulose on liquid penetration in and disintegration of directly compressed tablets. *J Pharm Sci* 1979; **68**: 205–211.
6 Chilamkurti RN *et al*. Some studies on compression properties of tablet matrices using a computerized instrumented press. *Drug Dev Ind Pharm* 1982; **8**: 63–86.
7 Wallace JW *et al*. Performance of pharmaceutical filler/binders as related to methods of powder characterization. *Pharm Technol* 1983; **7**(9): 94–104.
8 Omray A, Omray P. Evaluation of microcrystalline cellulose as a glidant. *Indian J Pharm Sci* 1986; **48**: 20–22.
9 Celik M, Okutgen E. A feasibility study for the development of a prospective compaction functionality test and the establishment of a compaction data bank. *Drug Dev Ind Pharm* 1993; **19**: 2309–2334.
10 Parker MD *et al*. Binder–substrate interactions in wet granulation 3: the effect of excipient source variation. *Int J Pharm* 1992; **80**: 179–190.
11 Sun CC. True density of microcrystalline cellulose. *J Pharm Sci* 2005; **94**(10): 2132–2134.
12 Callahan JC *et al*. Equilibrium moisture content of pharmaceutical excipients. *Drug Dev Ind Pharm* 1982; **8**: 355–369.
13 Cooper CB *et al*. Cellulose granulomas in the lungs of a cocaine sniffer. *Br Med J* 1983; **286**: 2021–2022.
14 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). http://www.hse.gov.uk/coshh/table1.pdf (accessed 5 February 2009).
15 Jain JK *et al*. Preparation of microcrystalline cellulose from cereal straw and its evaluation as a tablet excipient. *Indian J Pharm Sci* 1983; **45**: 83–85.
16 Singla AK *et al*. Evaluation of microcrystalline cellulose prepared from absorbent cotton as a direct compression carrier. *Drug Dev Ind Pharm* 1988; **14**: 1131–1136.
17 Doelker E *et al*. Comparative tableting properties of sixteen microcrystalline celluloses. *Drug Dev Ind Pharm* 1987; **13**: 1847–1875.
18 Bassam F *et al*. Effect of particle size and source on variability of Young's modulus of microcrystalline cellulose powders. *J Pharm Pharmacol* 1988; **40**: 68P.
19 Dittgen M *et al*. Microcrystalline cellulose in direct tabletting. *Manuf Chem* 1993; **64**(7): 17, 19, 21.
20 Landin M *et al*. Effect of country of origin on the properties of microcrystalline cellulose. *Int J Pharm* 1993; **91**: 123–131.
21 Landin M *et al*. Effect of batch variation and source of pulp on the properties of microcrystalline cellulose. *Int J Pharm* 1993; **91**: 133–141.
22 Landin M *et al*. Influence of microcrystalline cellulose source and batch variation on tabletting behavior and stability of prednisone formulations. *Int J Pharm* 1993; **91**: 143–149.
23 Podczeck F, Révész P. Evaluation of the properties of microcrystalline and microfine cellulose powders. *Int J Pharm* 1993; **91**: 183–193.
24 Rowe RC *et al*. The effect of batch and source variation on the crystallinity of microcrystalline cellulose. *Int J Pharm* 1994; **101**: 169–172.
25 Hasegawa M. Direct compression: microcrystalline cellulose grade 12 versus classic grade 102. *Pharm Technol* 2002; **26**(5): 50, 52, 54, 56, 58, 60.
26 Kothari SH *et al*. Comparative evaluations of powder and mechanical properties of low crystallinity celluloses, microcrystalline celluloses, and powdered celluloses. *Int J Pharm* 2002; **232**: 69–80.
27 Levis SR, Deasy PB. Production and evaluation of size-reduced grades of microcrystalline cellulose. *Int J Pharm* 2001; **213**: 13–24.
28 Wu JS *et al*. A statistical design to evaluate the influence of manufacturing factors on the material properties and functionalities of microcrystalline cellulose. *Eur J Pharm Sci* 2001; **12**: 417–425.
29 Suzuki T, Nakagami H. Effect of crystallinity of microcrystalline cellulose on the compactability and dissolution of tablets. *Eur J Pharm Biopharm* 1999; **47**: 225–230.
30 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 187.

20 General References

Asahi Kasei Corporation. *Ceolus KG*, *Celphere*. http://www.ceolus.com (accessed 6 November 2008).
Doelker E. Comparative compaction properties of various microcrystalline cellulose types and generic products. *Drug Dev Ind Pharm* 1993; **19**: 2399–2471.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 5 February 2009).
FMC Biopolymer. Problem Solver: *Avicel PH*, 2000.
International Specialty Products. Material Safety data sheet: *Celex 101*, 2003.
JRS Pharma LP. Technical literature: *Emcocel*, 2003.
Pharmatrans Sanaq AG. Product literature: *Cellets*. http://www.cellets.com (accessed 6 November 2008).
Pharmatrans Sanaq AG. Product literature: *MCC Sanaq*. http://www.pharmatrans-sanaq.com/prod.html (accessed 6 November 2008).
Smolinske SC. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992; 71–74.
Staniforth JN *et al*. Effect of addition of water on the rheological and mechanical properties of microcrystalline celluloses. *Int J Pharm* 1988; **41**: 231–236.

21 Author

A Guy.

22 Date of Revision

5 February 2009.

Cellulose, Silicified Microcrystalline

1 Nonproprietary Names

None adopted.

2 Synonyms

ProSolv.

3 Chemical Name and CAS Registry Number

See Section 8.

4 Empirical Formula and Molecular Weight

See Section 8.

5 Structural Formula

See Section 8.

6 Functional Category

Tablet and capsule diluent.

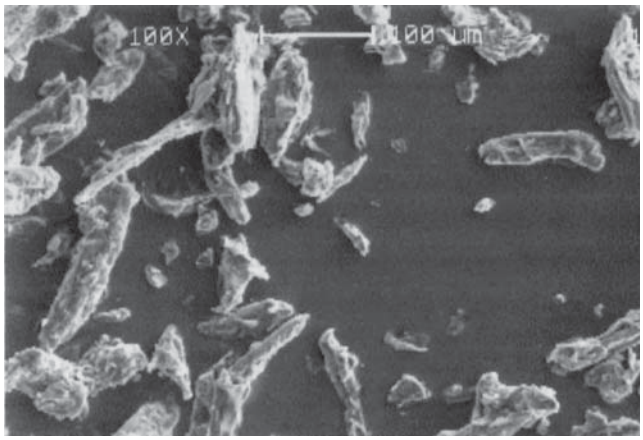
7 Applications in Pharmaceutical Formulation or Technology

Silicified microcrystalline cellulose is used as a filler in the formulation of capsules and tablets. It has improved compaction properties in both wet granulation and direct compression compared to conventional microcrystalline cellulose.[1–5] Silicified microcrystalline cellulose was specifically developed to address the loss of compaction that occurs with microcrystalline cellulose after wet granulation. Silicified microcrystalline cellulose also appears to have beneficial properties for use in the formulation of powder-filled capsules.[6,7]

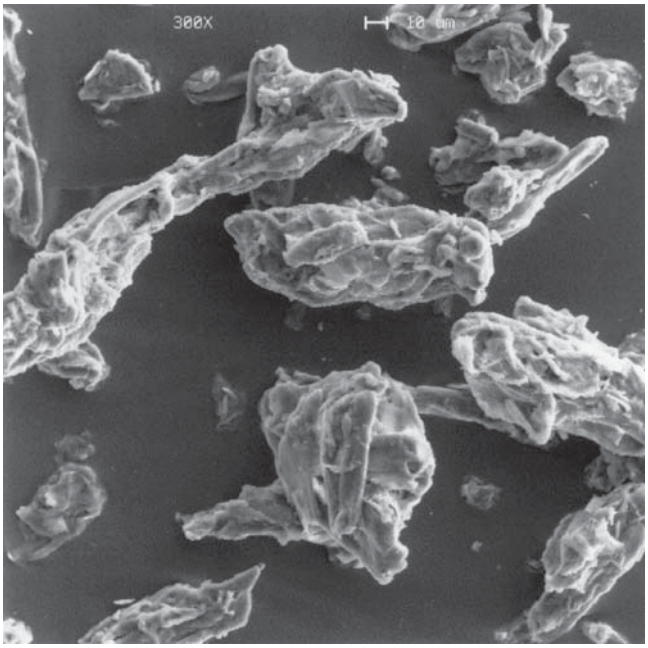
8 Description

Silicified microcrystalline cellulose is a synergistic, intimate physical mixture of two components: microcrystalline cellulose and colloidal silicon dioxide (for further information *see* Cellulose, Microcrystalline and Colloidal Silicon Dioxide). Silicified microcrystalline cellulose contains 2% w/w colloidal silicon dioxide.

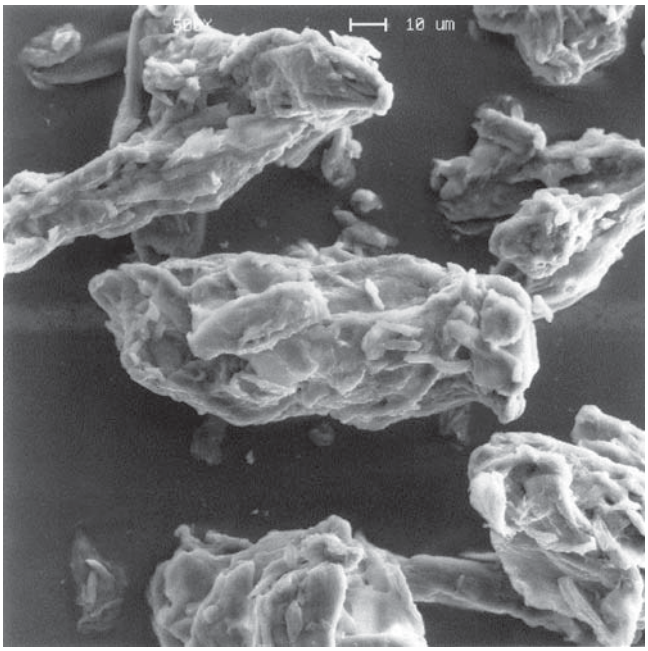
SEM 1: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 100×.



SEM 2: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 300×.



SEM 3: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 500×.



9 Pharmacopeial Specifications

Both colloidal silicon dioxide and microcrystalline cellulose are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not listed. *See* Cellulose, Microcrystalline and Colloidal Silicon Dioxide. *See also* Section 18.

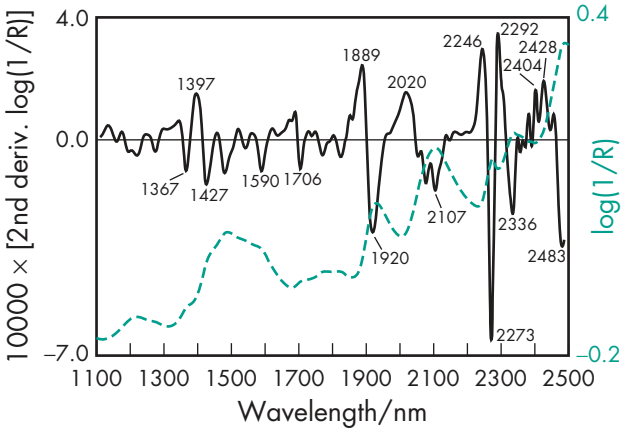


Figure 1: Near-infrared spectrum of silicified microcrystalline cellulose measured by reflectance.

10 Typical properties

Acidity/alkalinity pH = 5.0–7.5 (10% w/v suspension)
Density 1.58 g/cm[5]
Density (bulk) 0.31 g/cm^3
Density (tapped) 0.39 g/cm[5]
Melting point The microcrystalline cellulose component chars at 260–270°C.
Moisture content Typically less than 6% w/w.
NIR spectra *see* Figure 1.
Particle size distribution Typical particle size is 20–200 µm. Different grades may have a different normal mean particle size.
Solubility Practically insoluble in water, dilute acids, and most organic solvents. The microcrystalline cellulose component is slightly soluble in 5% w/w sodium hydroxide solution.

11 Stability and Storage Conditions

Silicified microcrystalline cellulose is stable when stored in a well-closed container in a cool, dry place.

12 Incompatibilities

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

13 Method of Manufacture

Silicified microcrystalline cellulose is manufactured by co-drying a suspension of microcrystalline cellulose particles and colloidal silicon dioxide such that the dried finished product contains 2% w/w colloidal silicon dioxide.

The colloidal silicon dioxide appears physically bound onto the surface and inside the silicified microcrystalline cellulose particles. Extensive studies using different spectroscopic methods have failed to show any form of chemical interaction.[4,8,9]

14 Safety

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Handling of silicified microcrystalline cellulose can generate nuisance dusts and the use of a respirator or dust mask may be necessary.

Microcrystalline cellulose may be irritant to the eyes. Gloves, eye protection, and a dust mask are recommended. In the UK the long-term workplace exposure limits (8-hour TWA) have been set at 10 mg/m^3 for total inhalable dust and 4 mg/m^3 for respirable dust; short-term limit for total inhalable dust has been set at 20 mg/m^3.[10]

Since the colloidal silicon dioxide is physically bound to the microcrystalline cellulose the general recommendations of gloves, eye protection, and a dust mask should be followed when handling silicified microcrystalline cellulose.

16 Regulatory Status

Silicified microcrystalline cellulose is a physical mixture of two materials both of which are generally regarded as nontoxic:

Microcrystalline cellulose GRAS listed. Included in the FDA Inactive Ingredients Database (inhalations, oral capsules, powders, suspensions, syrups, and tablets). Included in nonparenteral medicines licensed in Europe and the USA. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

Colloidal silicon dioxide GRAS listed. Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in Europe and the USA. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Cellulose, microcrystalline; colloidal silicon dioxide.

18 Comments

Colloidal silicon dioxide and microcrystalline cellulose are two of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Silicified microcrystalline cellulose has greater tensile strength and requires lower compression pressures than regular grades of microcrystalline cellulose. Furthermore, silicified microcrystalline cellulose maintains its compactability after wet granulation; the compacts exhibit greater stiffness and they require considerably more energy for tensile failure to occur.[4,11,12]

19 Specific References

1 Sherwood BE *et al*. Silicified microcrystalline cellulose (SMCC): a new class of high functionality binders for direct compression. *Pharm Res* 1996; **13**(9): S197.
2 Staniforth JN *et al*. Towards a new class of high functionality tablet binders. II: silicified microcrystalline cellulose (SMCC). *Pharm Res* 1996; **13**(9): S197.
3 Tobyn MJ *et al*. Compaction studies on a new class of high functionality binders: silicified microcrystalline cellulose (SMCC). *Pharm Res* 1996; **13**(9): S198.
4 Habib SY *et al*. Is silicified wet-granulated microcrystalline cellulose better than original wet-granulated microcrystalline cellulose? *Pharm Dev Technol* 1999; **4**(3): 431–437.
5 Tobyn MJ *et al*. Physiochemical comparison between microcrystalline cellulose and silicified microcrystalline cellulose. *Int J Pharm* 1998; **169**: 183–194.
6 Guo M *et al*. Evaluation of the plug information process of silicified microcrystalline cellulose. *Int J Pharm* 2002; **233**: 99–109.
7 Guo M, Augsburger LL. Potential application of silicified microcrystalline cellulose in direct-fill formulations for capsule-filling machines. *Pharm Dev Technol* 2003; **8**: 47–59.
8 Edge S *et al*. The mechanical properties of compacts of microcrystalline cellulose and silicified microcrystalline cellulose. *Int J Pharm* 2000; **200**: 67–72.
9 Buckton G, Yonemochi E. Near IR spectroscopy to quantify the silica content and differences between silicified miicrocrystalline cellulose and physical mixtures of microcrystalline cellulose and silica. *Eur J Pharm Sci* 2000; **10**(1): 77–80.
10 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). http://www.hse.gov.uk/coshh/table1.pdf (accessed 5 February 2009).

11 Buckton G *et al*. Water sorption and near IR spectroscopy to study the differences between microcrystalline cellulose and silicified microcrystalline cellulose after wet granulation. *Int J Pharm* 1999; **181**: 41–47.
12 Mužíková J, Nováková P. A study of the properties of compacts from silicified microcrystalline cellulose. *Drug Dev Ind Pharm* 2007; **33**: 775–781.

20 General References

European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 3 February 2009).
Li JX *et al*. Characterization of wet masses of pharmaceutical powders by triaxial compression test. *J Pharm Sci* 2000; **89**(2): 178–190.
Staniforth JN *et al*. Pharmaceutical excipient having improved compressibility. US Patent 5,585,115, 1996.

21 Author

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22 Date of Revision

5 February 2009.

Cellulose Acetate

1 Nonproprietary Names

BP: Cellulose Acetate
PhEur: Cellulose Acetate
USP-NF: Cellulose Acetate

2 Synonyms

Acetic acid, cellulose ester; acetyl cellulose; cellulose diacetate; cellulose triacetate; cellulosi acetas.

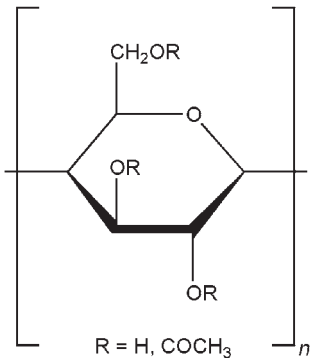
3 Chemical Name and CAS Registry Number

Cellulose acetate [9004-35-7]
Cellulose diacetate [9035-69-2]
Cellulose triacetate [9012-09-3]

4 Empirical Formula and Molecular Weight

Cellulose acetate is cellulose in which a portion or all of the hydroxyl groups are acetylated. Cellulose acetate is available in a wide range of acetyl levels and chain lengths and thus molecular weights; *see* Table I.

5 Structural Formula



6 Functional Category

Coating agent; extended-release agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Cellulose acetate is widely used in pharmaceutical formulations both in sustained-release applications and for taste masking.

Cellulose acetate is used as a semipermeable coating on tablets, especially on osmotic pump-type tablets and implants. This allows for controlled, extended release of actives.[1–5] Cellulose acetate films, in conjunction with other materials, also offer sustained release without the necessity of drilling a hole in the coating as is typical with osmotic pump systems. Cellulose acetate and other cellulose esters have also been used to form drug-loaded microparticles with controlled-release characteristics.[6–8]

Cellulose acetate films are used in transdermal drug delivery systems[9,10] and also as film coatings on tablets[11] or granules for taste masking. For example, acetaminophen granules have been coated with a cellulose acetate-based coating before being processed to provide chewable tablets. Extended-release tablets can also be formulated with cellulose acetate as a directly compressible matrix former.[2] The release profile can be modified by changing the ratio of active to cellulose acetate and by incorporation of plasticizer, but was shown to be insensitive to cellulose acetate molecular weight and particle size distribution.

Therapeutically, cellulose acetate has been used to treat cerebral aneurysms, and also for spinal perimedullary arteriovenous fistulas.[12]

8 Description

Cellulose acetate occurs as a hygroscopic white to off-white, free-flowing powder, pellet, or flake. It is tasteless and odorless, or may have a slight odor of acetic acid.

9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

10 Typical Properties

Density (bulk) Typically 0.4 g/cm^3 for powders.
Glass transition temperature 170–190°C
Melting point Melting range 230–300°C
NIR spectra *see* Figure 1.
Solubility The solubility of cellulose acetate is greatly influenced by the level of acetyl groups present. In general, cellulose acetates are soluble in acetone–water blends of varying ratios, dichloromethane–ethanol blends, dimethyl formamide, and dioxane.

It has been shown that the increased force required to expel coconut oil from plastic syringes was due to uptake of the oil into the rubber plunger; this resulted in swelling of the rubber plunger and an increased resistance to movement down the syringe barrel.[12]

13 Method of Manufacture

Coconut oil is the fixed oil obtained from the seeds of *Cocos nucifera* Linn. (Palmae). This oil is then refined to produce refined coconut oil, which is referred to in the coconut industry as RBD (refined, bleached, and deodorized) coconut oil.

14 Safety

When administered orally, coconut oil is essentially nontoxic, although ingestion of large amounts may cause digestive or gastrointestinal irritation or upset. Coconut oil can act as an irritant when applied to the skin and when in contact with the eyes; it may be absorbed through the skin. Inhalation of mist or vapor may cause respiratory tract irritation.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Coconut oil should be kept away from heat and sources of ignition, and contact with oxidizing agents, acids, and alkalis should be avoided.

If in the solid form, large spillages of coconut oil should be dealt with by shoveling the material into a waste disposal container. For liquid spillages, the oil should be absorbed with an inert material before removal for disposal.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral capsules and tablets; topical creams, solutions, and ointments). Included in scalp ointments and therapeutic shampoos licensed in the UK.

17 Related Substances

Almond oil; canola oil; castor oil; castor oil, hydrogenated; corn oil; cottonseed oil; medium-chain triglycerides; olive oil; peanut oil; sesame oil; soybean oil; sunflower oil.

18 Comments

A specification for coconut oil (unhydrogenated) is contained in the Food Chemicals Codex (FCC).[13]

19 Specific References

1 Hung CF *et al*. The effect of oil components on the physicochemical properties and drug delivery of emulsions: tocol emulsion versus lipid emulsion. *Int J Pharm* 2007; **335**(1–2): 193–202.
2 Garti N, Arkad O. Preparation of cloudy coconut oil emulsions containing dispersed TiO_2 using atomizer. *J Dispersion Sci Technol* 1986; **7**(5): 513–523.
3 Fang JY *et al*. Lipid nano/submicron emulsions as delivery vehicles for topical flurbiprofen delivery. *Drug Deliv* 2004; **11**(2): 97–105.
4 Nielsen HW *et al*. Intranasal administration of different liquid formulations of bumetanide to rabbits. *Int J Pharm* 2000; **204**(1–2): 35–41.
5 Tanabe K *et al*. Effect of different suppository bases on release of indomethacin. *J Pharm Sci Technol Jpn* 1984; **44**: 115–120.
6 Broda H *et al*. Preparation and testing of suppositories with cephradine – evaluation of pharmaceutical availability and biological availability. *Farm Pol* 1993; **49**(11–12): 1–8.
7 Ogbolu DO *et al*. *In vitro* antimicrobial properties of of coconut oil on *Candida* species in Ibadan, Nigeria. *J Med Food* 2007; **10**(2): 384–387.
8 Anonymous. Nitlotion. *Pharm J* 2000; **265**: 345.
9 Pajoumand A *et al*. Survival following severe aluminium phosphide poisoning. *J Pharm Pract Res* 2002; **32**(4): 297–299.
10 Patel HR. Sales of coconut oil. *Pharm J* 1992; **249**: 252.
11 Todd RG, Wade A, eds. *The Pharmaceutical Codex*, 11th edn. London: Pharmaceutical Press, 1979; 214.
12 Dexter MB, Shott MJ. The evaluation of the force to expel oily injection vehicles from syringes. *J Pharm Pharmacol* 1979; **31**: 497–500.
13 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopiea, 2008; 222.

20 General References

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21 Author

CG Cable.

22 Date of Revision

27 February 2009.

Colloidal Silicon Dioxide

1 Nonproprietary Names

BP: Colloidal Anhydrous Silica
JP: Light Anhydrous Silicic Acid
PhEur: Silica, Colloidal Anhydrous
USP-NF: Colloidal Silicon Dioxide

2 Synonyms

Aerosil; *Cab-O-Sil*; *Cab-O-Sil M-5P*; colloidal silica; fumed silica; fumed silicon dioxide; hochdisperses silicum dioxid; SAS; silica colloidalis anhydrica; silica sol; silicic anhydride; silicon dioxide colloidal; silicon dioxide fumed; synthetic amorphous silica; *Wacker HDK*.

3 Chemical Name and CAS Registry Number

Silica [7631-86-9]

4 Empirical Formula and Molecular Weight

SiO_2 60.08

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent; anticaking agent; emulsion stabilizer; glidant; suspending agent; tablet disintegrant; thermal stabilizer; viscosity-increasing agent.

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7 Applications in Pharmaceutical Formulation or Technology

Colloidal silicon dioxide is widely used in pharmaceuticals, cosmetics, and food products; *see* Table I. Its small particle size and large specific surface area give it desirable flow characteristics that are exploited to improve the flow properties of dry powders[1] in a number of processes such as tableting[2–4] and capsule filling.

Colloidal silicon dioxide is also used to stabilize emulsions and as a thixotropic thickening and suspending agent in gels and semisolid preparations.[5] With other ingredients of similar refractive index, transparent gels may be formed. The degree of viscosity increase depends on the polarity of the liquid (polar liquids generally require a greater concentration of colloidal silicon dioxide than nonpolar liquids). Viscosity is largely independent of temperature. However, changes to the pH of a system may affect the viscosity; *see* Section 11.

In aerosols, other than those for inhalation, colloidal silicon dioxide is used to promote particulate suspension, eliminate hard settling, and minimize the clogging of spray nozzles. Colloidal silicon dioxide is also used as a tablet disintegrant and as an adsorbent dispersing agent for liquids in powders.[6] Colloidal silicon dioxide is frequently added to suppository formulations containing lipophilic excipients to increase viscosity, prevent sedimentation during molding, and decrease the release rate.[7,8] Colloidal silicon dioxide is also used as an adsorbent during the preparation of wax microspheres;[9] as a thickening agent for topical preparations;[10] and has been used to aid the freeze-drying of nanocapsules and nanosphere suspensions.[11]

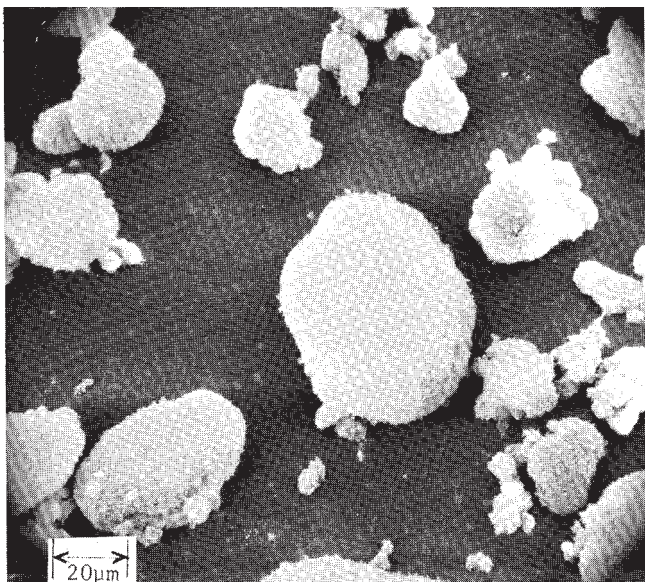
Table I: Uses of colloidal silicon dioxide.

Use	Concentration (%)
Aerosols	0.5–2.0
Emulsion stabilizer	1.0–5.0
Glidant	0.1–1.0
Suspending and thickening agent	2.0–10.0

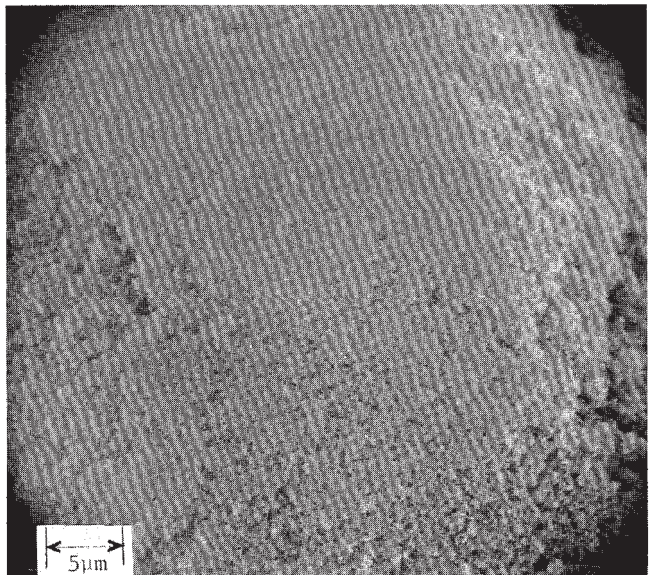
8 Description

Colloidal silicon dioxide is a submicroscopic fumed silica with a particle size of about 15 nm. It is a light, loose, bluish-white-colored, odorless, tasteless, amorphous powder.

SEM 1: Excipient: colloidal silicon dioxide (*Aerosil A-200*); manufacturer: Evonik Degussa Corp. lot no.: 87A-1 (04169C); magnification: 600×; voltage: 20 kV.



SEM 2: Excipient: colloidal silicon dioxide (*Aerosil A-200*); manufacturer: Evonik Degussa Corp. lot no.: 87A-1 (04169C); magnification: 2400×; voltage: 20 kV.



9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

Table II: Pharmacopeial specifications for colloidal silicon dioxide.

Test	JP XV	PhEur 6.0	USP32–NF27
Identification	+	+	+
Characters	—	+	—
pH (4% w/v dispersion)	—	3.5–5.5	3.5–5.5
Arsenic	⩽5 ppm	—	⩽8 µg/g
Chloride	⩽0.011%	⩽250 ppm	—
Heavy metals	⩽40 ppm	⩽25 ppm	—
Aluminum	+	—	—
Calcium	+	—	—
Iron	⩽500 ppm	—	—
Loss on drying	⩽7.0%	—	⩽2.5%
Loss on ignition	⩽12.0%	⩽5.0%	⩽2.0%
Volume test (5 g sample)	⩾70 mL	—	—
Assay (on ignited sample)	⩾98.0%	99.0–100.5%	99.0–100.5%

10 Typical Properties

Acidity/alkalinity pH = 3.8–4.2 (4% w/v aqueous dispersion) and 3.5–4.0 (10% w/v aqueous dispersion) for *Cab-O-Sil M-5P*

Density (bulk) 0.029–0.042 g/cm^3

Density (tapped) *see* Tables III, IV, and V.

Melting point 1600°C

Moisture content *see* Figure 1.[12,13]

Particle size distribution Primary particle size is 7–16 nm. *Aerosil* forms loose agglomerates of 10–200 µm. *See also* Figure 2.

Refractive index 1.46

Solubility Practically insoluble in organic solvents, water, and acids, except hydrofluoric acid; soluble in hot solutions of alkali hydroxide. Forms a colloidal dispersion with water. For *Aerosil*, solubility in water is 150 mg/L at 25°C (pH 7).

Specific gravity 2.2

Specific surface area

100–400 m^2/g depending on grade. *See also* Tables III, IV,and V.

Several grades of colloidal silicon dioxide are commercially available, which are produced by modifying the manufacturing process. The modifications do not affect the silica content,

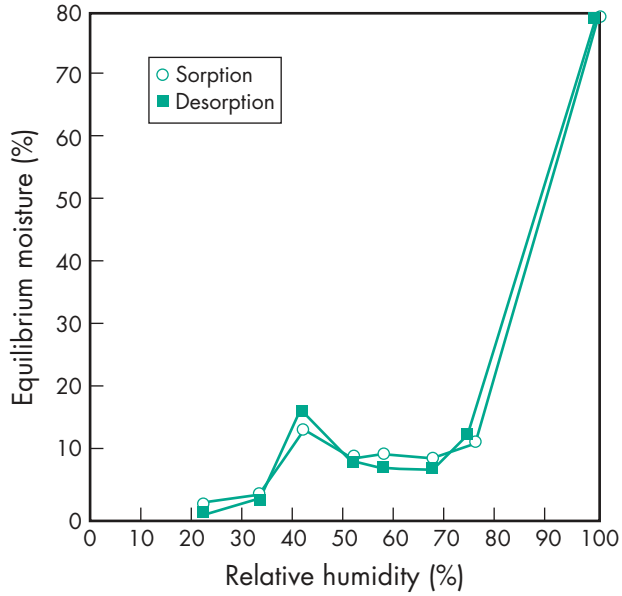


Figure 1: Sorption–desorption isotherm for colloidal silicon dioxide.

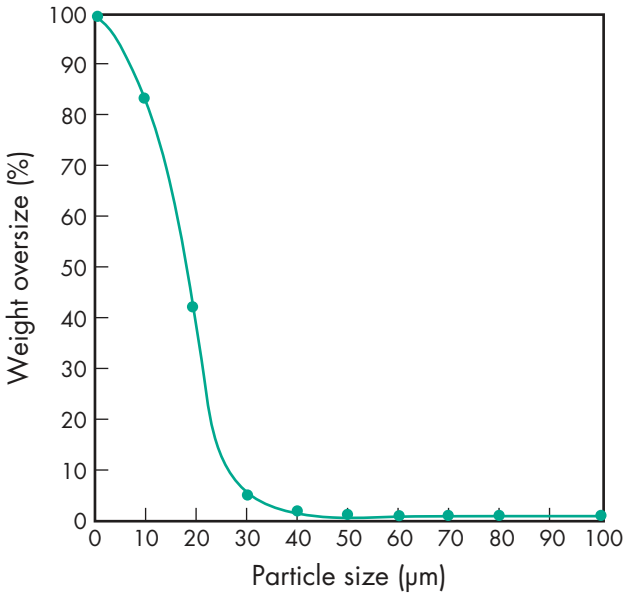


Figure 2: Particle size distribution of colloidal silicon dioxide (*Aerosil A-200*, Evonik Degussa Corp.).

specific gravity, refractive index, color, or amorphous form. However, particle size, surface areas, and densities are affected. The physical properties of three commercially available colloidal silicon dioxides, *Aerosil* (Evonik Degussa Corp.), *Cab-O-Sil* (Cabot Corporation), and *Wacker HDK* (Wacker-Chemie GmbH) are shown in Tables III, IV and V, respectively.

11 Stability and Storage Conditions

Colloidal silicon dioxide is hygroscopic but adsorbs large quantities of water without liquefying. When used in aqueous systems at a pH 0–7.5, colloidal silicon dioxide is effective in increasing the viscosity of a system. However, at a pH greater than 7.5 the viscosity-increasing properties of colloidal silicon dioxide are reduced; and at a pH greater than 10.7 this ability is lost entirely since the silicon dioxide dissolves to form silicates.[14] Colloidal silicon dioxide powder should be stored in a well-closed container.

Table III: Physical properties of *Aerosil*.

Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
130	130 ± 25	0.05
130v	130 ± 25	0.12
200	200 ± 25	0.05
200v	200 ± 25	0.12
300	300 ± 30	0.05
300	300 ± 30	0.12
380	380 ± 30	0.05
380	380 ± 30	0.12

(a) BET method.

Table IV: Physical properties of *Cab-O-Sil*.

Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
LM-5	130 ± 25	0.04
LM-50	150 ± 25	0.04
M-5	200 ± 25	0.04
H-5	325 ± 25	0.04
EH-5	390 ± 40	0.04
M-7D	200 ± 25	0.10

(a) BET method.

Table V: Physical properties of *Wacker HDK*.

Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
S13	125 ± 15	0.05
V15	150 ± 20	0.05
N20	200 ± 30	0.04
T30	300 ± 30	0.04
T40	400 ± 40	0.04
H15	120 ± 20	0.04
H20	170 ± 30	0.04
H30	250 ± 30	0.04
H2000	140 ± 30	0.22
H3004	210 ± 30	0.08
H2015	110 ± 30	0.20
H2050	110 ± 30	0.20

(a) BET method.

12 Incompatibilities

Incompatible with diethylstilbestrol preparations.[15]

13 Method of Manufacture

Colloidal silicon dioxide is prepared by the flame hydrolysis of chlorosilanes, such as silicon tetrachloride, at 1800°C using a hydrogen–oxygen flame. Rapid cooling from the molten state during manufacture causes the product to remain amorphous.

14 Safety

Colloidal silicon dioxide is widely used in oral and topical pharmaceutical products and is generally regarded as an essentially nontoxic and nonirritant excipient. However, intraperitoneal and subcutaneous injection may produce local tissue reactions and/or granulomas. Colloidal silicon dioxide should therefore not be administered parenterally.

LD_{50} (rat, IV): 0.015 g/kg[16]

LD_{50} (rat, oral): 3.16 g/kg

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15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Considered a nuisance dust, precautions should be taken to avoid inhalation of colloidal silicon dioxide. In the absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.

Inhalation of colloidal silicon dioxide dust may cause irritation to the respiratory tract but it is not associated with fibrosis of the lungs (silicosis), which can occur upon exposure to crystalline silica.

16 Regulatory Acceptance

GRAS listed. Included in the FDA Inactive Ingredients Database (oral capsules, suspensions, and tablets; transdermal, rectal, and vaginal preparations). Also approved by the FDA as a food additive and for food contact. Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Hydrophobic colloidal silica.

18 Comments

Colloidal silicon dioxide is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

The PhEur 6.0 also contains a specification for hydrated colloidal silicon dioxide. The incidence of microbial contamination of colloidal silicon dioxide is low[17] due to the high production temperatures and inorganic precursor materials.

Note that porous silica gel particles may also be used as a glidant, thickener, dispersant and to adsorb moisture, which may be an advantage for some formulations. *Syloid 244FP* meets the USP–NF requirements for silicon dioxide, and *Syloid 244 FP-BU* meets the PhEur and JP requirements for silicon dioxide.[18]

Another CAS number that is used for colloidal silicon dioxide is 112945-52-5.

The EINECS number for colloidal silicon dioxide is 231-545-4. The PubChem Compound ID (CID) for colloidal silicon dioxide is 24261.

19 Specific References

1 York P. Application of powder failure testing equipment in assessing effect of glidants on flowability of cohesive pharmaceutical powders. *J Pharm Sci* 1975; **64**: 1216–1221.
2 Lerk CF *et al*. Interaction of lubricants and colloidal silica during mixing with excipients I: its effect on tabletting. *Pharm Acta Helv* 1977; **52**: 33–39.
3 Lerk CF, Bolhuis GK. Interaction of lubricants and colloidal silica during mixing with excipients II: its effect on wettability and dissolution velocity. *Pharm Acta Helv* 1977; **52**: 39–44.
4 Jonat S *et al*. Influence of compacted hydrophobic and hydrophilic colloidal silicon dioxide on tabletting properties of pharmaceutical excipients. *Drug Dev Ind Pharm* 2005; **31**: 687–696.
5 Daniels R *et al*. The stability of drug absorbates on silica. *Drug Dev Ind Pharm* 1986; **12**: 2127–2156.
6 Sherriff M, Enever RP. Rheological and drug release properties of oil gels containing colloidal silicon dioxide. *J Pharm Sci* 1979; **68**: 842–845.
7 Tukker JJ, De Blaey CJ. The addition of colloidal silicon dioxide to suspension suppositories II. The impact on *in vitro* release and bioavailability. *Acta Pharm Technol* 1984; **30**: 155–160.
8 Realdon N *et al*. Effects of silicium dioxide on drug release from suppositories. *Drug Dev Ind Pharm* 1997; **23**: 1025–1041.
9 Mani N *et al*. Microencapsulation of a hydrophilic drug into a hydrophobic matrix using a salting-out procedure. II. Effects of adsorbents on microsphere properties. *Drug Dev Ind Pharm* 2004; **30**(1): 83–93.
10 Gallagher SJ *et al*. Effects of membrane type and liquid/liquid phase boundary on *in vitro* release of ketoprofen from gel formulations. *J Drug Target* 2003; **11**(6): 373–379.
11 Schaffazick SR *et al*. Freeze-drying polymeric colloidal suspensions: nanocapsules, nanospheres and nanodispersion. A comparative study. *Eur J Pharm Biopharm* 2003; **56**(3): 501–505.
12 Ettlinger M *et al*. [Adsorption at the surface of fumed silica.] *Arch Pharm* 1987; **320**: 1–15[in German].
13 Callahan JC *et al*. Equilibrium moisture content of pharmaceutical excipients. *Drug Dev Ind Pharm* 1982; **8**: 355–369.
14 Cabot Corporation. Technical literature: *Cab-O-Sil* fumed silicas, the performance additives, 1995.
15 Johansen H, MÏller N. Solvent deposition of drugs on excipients II: interpretation of dissolution, adsorption and absorption characteristics of drugs. *Arch Pharm Chem Sci Ed* 1977; **5**: 33–42.
16 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3205.
17 Kienholz M. [The behaviour of bacteria in highly pure silicic acid.] *Pharm Ind* 1970; **32**: 677–679[in German].
18 WR Grace & Co. Technical literature: *Syloid 244FP*, 2002.

20 General References

Cabot Corporation. Technical literature PDS171: *Cab-O-Sil M-5P*, 2006.
Evonik Degussa Corp. Technical Bulletin Fine Particles No. 11 TB0011-1: Basic characteristics of *Aerosil* fumed silica, 2006.
Evonik Degussa Corp. Technical literature TI 1281-1: *Aerosil* colloidal silicon dioxide for pharmaceuticals, 2006.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edq-m.eu/site/-614.html (accessed 3 February 2009).
Meyer K, Zimmermann I. Effect of glidants in binary powder mixtures. *Powder Technol* 2004; **139**: 40–54.
Wacker-Chemie GmbH. Technical literature: *Wacker HDK* fumed silica, 1998.
Waddell WW. Silica amorphous.*Kirk-Othmer Encyclopedia of Chemical Technology*, 5th edn, vol. **22**: New York: John Wiley & Sons, 2001; 380–406.
Wagner E, Brunner H. *Aerosil*: its preparation, properties and behaviour in organic liquids. *Angew Chem* 1960; **72**: 744–750.
Yang KY *et al*. Effects of amorphous silicon dioxides on drug dissolution. *J Pharm Sci* 1979; **68**: 560–565.
Zimmermann I *et al*. Nanomaterials as flow regulators in dry powders. *Z Phys Chem* 2004; **218**: 51–102.

21 Author

KP Hapgood.

22 Date of Revision

3 February 2009.

Croscarmellose Sodium

C

1 Nonproprietary Names

BP: Croscarmellose Sodium
JP: Croscarmellose Sodium
PhEur: Croscarmellose Sodium
USP-NF: Croscarmellose Sodium

2 Synonyms

Ac-Di-Sol; carmellosum natricum conexum; crosslinked carboxymethylcellulose sodium; *Explocel*; modified cellulose gum; *Nymcel ZSX*; *Pharmacel XL*; *Primellose*; *Solutab*; *Vivasol*.

3 Chemical Name and CAS Registry Number

Cellulose, carboxymethyl ether, sodium salt, crosslinked [74811-65-7]

4 Empirical Formula and Molecular Weight

Croscarmellose sodium is a crosslinked polymer of carboxymethylcellulose sodium.

See Carboxymethylcellulose sodium.

5 Structural Formula

See Carboxymethylcellulose sodium.

6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant for capsules,[1,2] tablets,[3–13] and granules.

In tablet formulations, croscarmellose sodium may be used in both direct-compression and wet-granulation processes. When used in wet granulations, the croscarmellose sodium should be added in both the wet and dry stages of the process (intra- and extra-granularly) so that the wicking and swelling ability of the disintegrant is best utilized.[11,12] Croscarmellose sodium at concentrations up to 5% w/w may be used as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by a wet-granulation process. *See* Table I.

Table I: Uses of croscarmellose sodium.

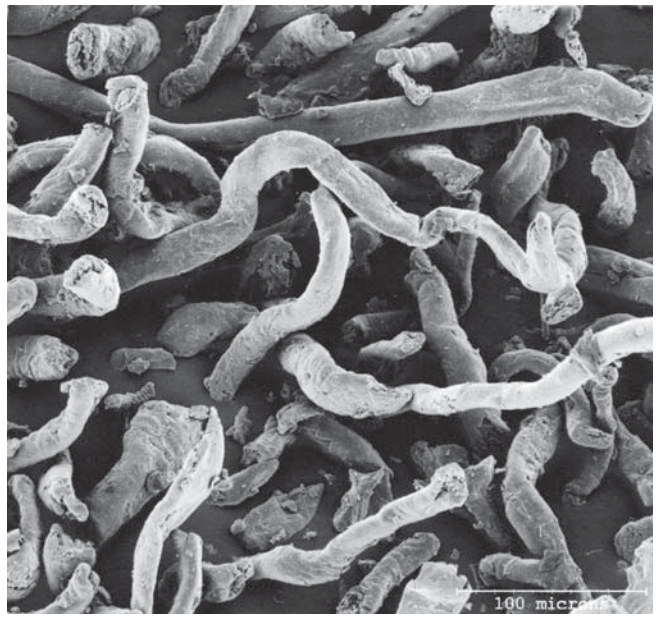
Use	Concentration (%)
Disintegrant in capsules	10–25
Disintegrant in tablets	0.5–5.0

8 Description

Croscarmellose sodium occurs as an odorless, white or grayish-white powder.

SEM 1: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 100×.

SEM 2: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 1000×.



9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–7.0 in aqueous dispersions.
Bonding index 0.0456
Brittle fracture index 0.1000
Density (bulk) 0.529 g/cm^3 for *Ac-Di-Sol*

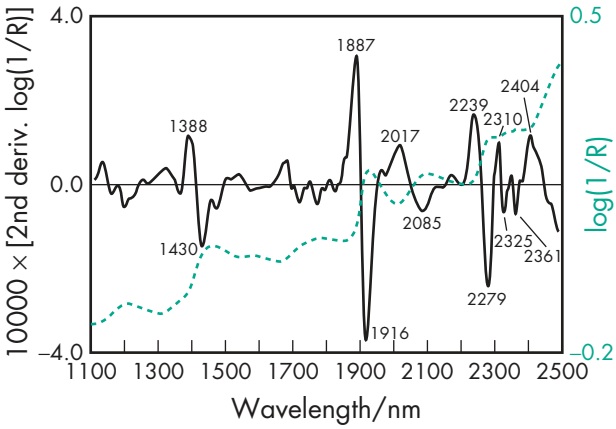


Figure 1: Near-infrared spectrum of croscarmellose sodium measured by reflectance.

Table II: Pharmacopeial specifications for croscarmellose sodium.

Test	JP XV	PhEur 6.5	USP32–NF27
Identification	+	+	+
Characters	+	+	—
pH (1% w/v dispersion)	5.0–7.0	5.0–7.0	5.0–7.0
Loss on drying	⩽10.0%	⩽10.0%	⩽10.0%
Heavy metals	⩽10 ppm	⩽20 ppm	⩽0.001%
Sodium chloride and sodium glycolate	⩽0.5%	⩽0.5%	⩽0.5%
Sulfated ash	—	14.0–28.0%	—
Residue on ignition	14.0–28.0%	—	14.0–28.0%
Degree of substitution	0.60–0.85	0.60–0.85	0.60–0.85
Content of water-soluble material	1.0–10%	⩽10.0%	⩽10.0%
Settling volume	10.0–30.0 mL	10.0–30.0 mL	10.0–30.0 mL
Microbial contamination	—	+	+
Aerobic	—	10^3 cfu/g	10^3 cfu/g
Fungi	—	10^2 cfu/g	10^2 cfu/g

Density (tapped) 0.819 g/cm^3 for *Ac-Di-Sol*
Density (true) 1.543 g/cm^3 for *Ac-Di-Sol*
NIR spectra *see* Figure 1.
Particle size distribution

Ac-Di-Sol: not more than 2% retained on a #200 (73.7 µm) mesh and not more than 10% retained on a #325 (44.5 µm) mesh.

Solubility Insoluble in water, although croscarmellose sodium rapidly swells to 4–8 times its original volume on contact with water. Practically insoluble in acetone, ethanol and toluene.
Specific surface area 0.81–0.83 m^2/g

11 Stability and Storage Conditions

Croscarmellose sodium is a stable though hygroscopic material.

A model tablet formulation prepared by direct compression, with croscarmellose sodium as a disintegrant, showed no significant difference in drug dissolution after storage at 30°C for 14 months.[9]

Croscarmellose sodium should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

The efficacy of disintegrants, such as croscarmellose sodium, may be slightly reduced in tablet formulations prepared by either the wet-granulation or direct-compression process that contain hygroscopic excipients such as sorbitol.[10]

Croscarmellose sodium is not compatible with strong acids or with soluble salts of iron and some other metals such as aluminum, mercury, and zinc.

13 Method of Manufacture

Alkali cellulose is prepared by steeping cellulose, obtained from wood pulp or cotton fibers, in sodium hydroxide solution. The alkali cellulose is then reacted with sodium monochloroacetate to obtain carboxymethylcellulose sodium. After the substitution reaction is completed and all of the sodium hydroxide has been used, the excess sodium monochloroacetate slowly hydrolyzes to glycolic acid. The glycolic acid changes a few of the sodium carboxymethyl groups to the free acid and catalyzes the formation of crosslinks to produce croscarmellose sodium. The croscarmellose sodium is then extracted with aqueous alcohol and any remaining sodium chloride or sodium glycolate is removed. After purification, croscarmellose sodium of purity greater than 99.5% is obtained.[4] The croscarmellose sodium may be milled to break the polymer fibers into shorter lengths and hence improve its flow properties.

14 Safety

Croscarmellose sodium is mainly used as a disintegrant in oral pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material. However, oral consumption of large amounts of croscarmellose sodium may have a laxative effect, although the quantities used in solid dosage formulations are unlikely to cause such problems.

In the UK, croscarmellose sodium is accepted for use in dietary supplements.

The WHO has not specified an acceptable daily intake for the related substance carboxymethylcellulose sodium, used as a food additive, since the levels necessary to achieve a desired effect were not considered sufficient to be a hazard to health.[14]

See also Carboxymethylcellulose Sodium.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Croscarmellose sodium may be irritant to the eyes; eye protection is recommended.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral capsules, granules, sublingual tablets, and tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Carboxymethylcellulose calcium; carboxymethylcellulose sodium.

18 Comments

Croscarmellose sodium is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Typically, the degree of substitution (DS) for croscarmellose sodium is 0.7.

The EINECs number for croscarmellose sodium is 232-674-9.

19 Specific References

1 Botzolakis JE, Augsburger LL. Disintegrating agents in hard gelatin capsules. Part I: mechanism of action. *Drug Dev Ind Pharm* 1988; **14**(1): 29–41.
2 Dahl TC *et al.* The influence of disintegrant level and capsule size on dissolution of hard gelatin capsules stored in high humidity conditions. *Drug Dev Ind Pharm* 1991; **17**(7): 1001–1016.
3 Gissinger D, Stamm A. A comparative evaluation of the properties of some tablet disintegrants. *Drug Dev Ind Pharm* 1980; **6**(5): 511–536.

4 Shangraw R *et al*. A new era of tablet disintegrants. *Pharm Technol* 1980; **4**(10): 49–57.
5 Zhao N, Augsburger LI. The influence of product brand-to-brand variability on superdisintegrant performance. A case study with croscarmellose sodium. *Pharm Dev Technol* 2006; **11**(2): 179–185.
6 Zhao N, Augsburger LI. The influence of swelling capacity of superdisintegrants in different pH media on the dissolution of hydrochlorthiazide from directly compressed tablets. *AAPS Pharm Sci Tech* 2005; **6**(1): E120–E126.
7 Battu SK *et al*. Formulation and evaluation of rapidly disintegrating fenoverine tablets: effects of superdisintegrants. *Drug Dev Ind Pharm* 2007; **33**(11): 1225–1232.
8 Gordon MS, Chowhan ZT. Effect of tablet solubility and hygroscopicity on disintegrant efficiency in direct compression tablets in terms of dissolution. *J Pharm Sci* 1987; **76**: 907–909.
9 Gordon MS, Chowhan ZT. The effect of aging on disintegrant efficiency in direct compression tablets with varied solubility and hygroscopicity, in terms of dissolution. *Drug Dev Ind Pharm* 1990; **16**: 437–447.
10 Johnson JR *et al*. Effect of formulation solubility and hygroscopicity on disintegrant efficiency in tablets prepared by wet granulation, in terms of dissolution. *J Pharm Sci* 1991; **80**: 469–471.
11 Gordon MS *et al*. Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; **82**(2): 220–226.
12 Khattab I *et al*. Effect of mode of incorporation of disintegrants on the characteristics of fluid-bed wet-granulated tablets. *J Pharm Pharmacol* 1993; **45**(8): 687–691.
13 Ferrero C *et al*. Disintegrating efficiency of croscarmellose sodium in a direct compression formulation. *Int J Pharm* 1997; **147**: 11–21.
14 FAO/WHO. Evaluation of certain food additives and contaminants. Thirty-fifth report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1990; No. 789.

20 General References

DMV-Frontera Excipients. Product literature: *Primellose and Primojel*, August 2008.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 6 February 2009).
FMC Biopolymer. Material Safety Datasheet: *Ac-Di-Sol*, May 2008.
JRS Pharma. Product literature: *Vivasol*. http://www.jrspharma.de/Pharma/wEnglisch/produktinfo/productinfo_vivasol.shtml (accessed 6 February 2009).

21 Author

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22 Date of Revision

6 February 2009.

Crospovidone

1 Nonproprietary Names

BP: Crospovidone
PhEur: Crospovidone
USP-NF: Crospovidone

2 Synonyms

Crospovidonum; *Crospopharm*; crosslinked povidone; E1202; *Kollidon CL*; *Kollidon CL-M*; *Polyplasdone XL*; *Polyplasdone XL-10*; polyvinylpolypyrrolidone; PVPP; 1-vinyl-2-pyrrolidinone homopolymer.

3 Chemical Name and CAS Registry Number

1-Ethenyl-2-pyrrolidinone homopolymer [9003-39-8]

4 Empirical Formula and Molecular Weight

$(C_6H_9NO)_n$ >1 000 000

The USP32–NF27 describes crospovidone as a water-insoluble synthetic crosslinked homopolymer of *N*-vinyl-2-pyrrolidinone. An exact determination of the molecular weight has not been established because of the insolubility of the material.

5 Structural Formula

See Povidone.

6 Functional Category

Tablet disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Crospovidone is a water-insoluble tablet disintegrant and dissolution agent used at 2–5% concentration in tablets prepared by direct-compression or wet- and dry-granulation methods.[1–6] It rapidly exhibits high capillary activity and pronounced hydration capacity, with little tendency to form gels. Studies suggest that the particle size of crospovidone strongly influences disintegration of analgesic tablets.[7] Larger particles provide a faster disintegration than smaller particles. Crospovidone can also be used as a solubility enhancer. With the technique of co-evaporation, crospovidone can be used to enhance the solubility of poorly soluble drugs. The drug is adsorbed on to crospovidone in the presence of a suitable solvent and the solvent is then evaporated. This technique results in faster dissolution rate.

8 Description

Crospovidone is a white to creamy-white, finely divided, free-flowing, practically tasteless, odorless or nearly odorless, hygroscopic powder.

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–8.0 (1% w/v aqueous slurry)
Density 1.22 g/cm^3
Density (bulk) *see* Table II.
Density (tapped) *see* Table II.

Magnesium Stearate

1 Nonproprietary Names

BP: Magnesium Stearate
JP: Magnesium Stearate
PhEur: Magnesium Stearate
USP-NF: Magnesium Stearate

2 Synonyms

Dibasic magnesium stearate; magnesium distearate; magnesii stearas; magnesium octadecanoate; octadecanoic acid, magnesium salt; stearic acid, magnesium salt; *Synpro 90*.

3 Chemical Name and CAS Registry Number

Octadecanoic acid magnesium salt [557-04-0]

4 Empirical Formula and Molecular Weight

$C_{36}H_{70}MgO_4$ 591.24

The USP32–NF27 describes magnesium stearate as a compound of magnesium with a mixture of solid organic acids that consists chiefly of variable proportions of magnesium stearate and magnesium palmitate ($C_{32}H_{62}MgO_4$). The PhEur 6.5 describes magnesium stearate as a mixture of solid organic acids consisting mainly of variable proportions of magnesium stearate and magnesium palmitate obtained from sources of vegetable or animal origin.

M

5 Structural Formula

$[CH_3(CH_2)_{16}COO]_2Mg$

6 Functional Category

Tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium stearate is widely used in cosmetics, foods, and pharmaceutical formulations. It is primarily used as a lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5.0% w/w. It is also used in barrier creams. *See also* Section 18.

8 Description

Magnesium stearate is a very fine, light white, precipitated or milled, impalpable powder of low bulk density, having a faint odor of stearic acid and a characteristic taste. The powder is greasy to the touch and readily adheres to the skin.

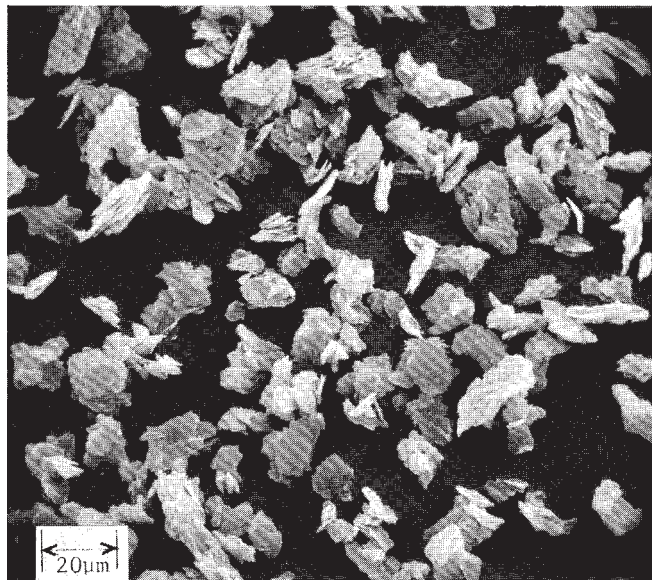
9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

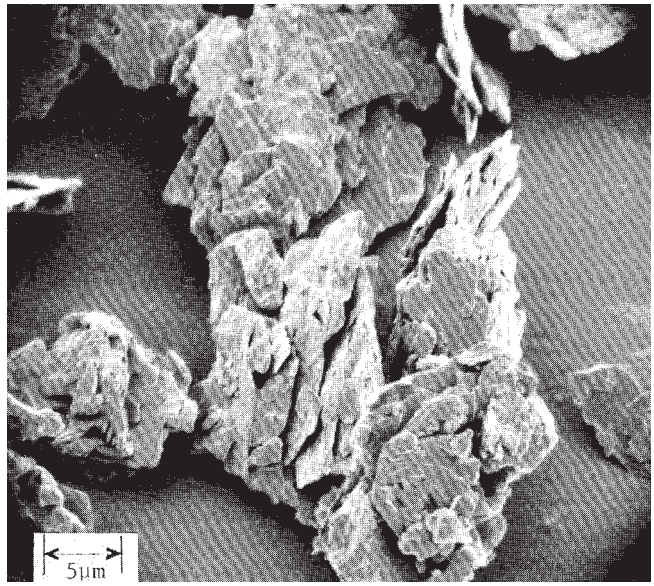
10 Typical Properties

Crystalline forms High-purity magnesium stearate has been isolated as a trihydrate, a dihydrate, and an anhydrate.
Density (bulk) 0.159 g/cm^3
Density (tapped) 0.286 g/cm^3
Density (true) 1.092 g/cm^3
Flash point 250°C
Flowability Poorly flowing, cohesive powder.
Melting range
117–150°C (commercial samples);
126–130°C (high purity magnesium stearate).
NIR spectra *see* Figure 1.
Solubility Practically insoluble in ethanol, ethanol (95%), ether and water; slightly soluble in warm benzene and warm ethanol (95%).
Specific surface area 1.6–14.8 m^2/g

SEM 1: Excipient: magnesium stearate; magnification: 600×.



SEM 2: Excipient: magnesium stearate; magnification: 2400×.



11 Stability and Storage Conditions

Magnesium stearate is stable and should be stored in a well-closed container in a cool, dry place.

Table I: Pharmacopeial specifications for magnesium stearate.

Test	JP XV	PhEur 6.5	USP32–NF27
Identification	+	+	+
Characters	—	+	—
Microbial limits	+	+	+
Aerobic microbes	⩽1000 cfu/g	⩽10^3 cfu/g	⩽1000 cfu/g
Fungi and yeasts	⩽500 cfu/g	⩽10^2 cfu/g	⩽500 cfu/g
Acidity or alkalinity	+	+	+
Acid value of the fatty acid	—	195–210	—
Freezing point	—	⩾53°C	—
Nickel	—	⩽5 ppm	—
Cadmium	—	⩽3 ppm	—
Specific surface area	—	—	+
Loss on drying	⩽6.0%	⩽6.0%	⩽6.0%
Chloride	⩽0.1%	⩽0.1%	⩽0.1%
Sulfate	⩽1.0%	⩽1.0%	⩽1.0%
Lead	—	⩽10 ppm	⩽0.001%
Heavy metals	⩽20 ppm	—	—
Relative stearic/palmitic content	+	+	+
Assay (dried, as Mg)	4.0–5.0%	4.0–5.0%	4.0–5.0%

12 Incompatibilities

Incompatible with strong acids, alkalis, and iron salts. Avoid mixing with strong oxidizing materials. Magnesium stearate cannot be used in products containing aspirin, some vitamins, and most alkaloidal salts.

13 Method of Manufacture

Magnesium stearate is prepared either by the interaction of aqueous solutions of magnesium chloride with sodium stearate or by the interaction of magnesium oxide, hydroxide, or carbonate with stearic acid at elevated temperatures.

14 Safety

Magnesium stearate is widely used as a pharmaceutical excipient and is generally regarded as being nontoxic following oral administration. However, oral consumption of large quantities may produce a laxative effect or mucosal irritation.

No toxicity information is available relating to normal routes of occupational exposure. Limits for heavy metals in magnesium stearate have been evaluated in terms of magnesium stearate worst-case daily intake and heavy metal composition.[1]

Toxicity assessments of magnesium stearate in rats have indicated that it is not irritating to the skin, and is nontoxic when administered orally or inhaled.[2,3]

Magnesium stearate has not been shown to be carcinogenic when implanted into the bladder of mice.[4]

LD_{50} (rat, inhalation): >2 mg/L[2]

LD_{50} (rat, oral): >10 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Excessive inhalation of magnesium stearate dust may cause upper respiratory tract discomfort, coughing, and choking. Magnesium stearate should be handled in a well-ventilated environment; a respirator is recommended. In the USA, the OSHA limit is 10 mg/m^3 TWA for magnesium stearate.

16 Regulatory Acceptance

GRAS listed. Accepted as a food additive in the USA and UK. Included in the FDA Inactive Ingredients Database (oral capsules, powders, and tablets; buccal and vaginal tablets; topical preparations; intravitreal implants and injections). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients. Listed on the US TSCA inventory.

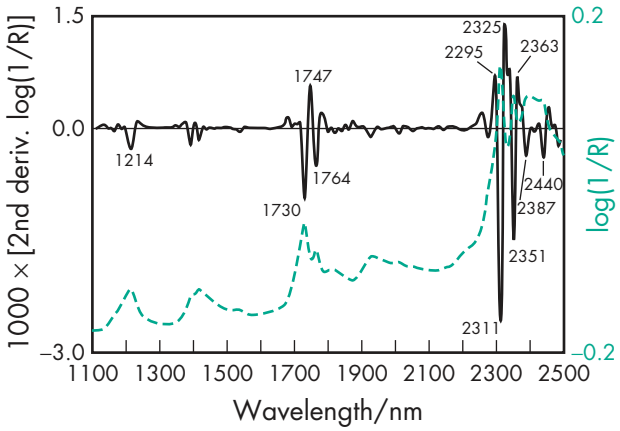


Figure 1: Near-infrared spectrum of magnesium stearate measured by reflectance.

17 Related Substances

Calcium stearate; magnesium aluminum silicate; stearic acid; zinc stearate.

18 Comments

Magnesium stearate is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Magnesium stearate is hydrophobic and may retard the dissolution of a drug from a solid dosage form; the lowest possible concentration is therefore used in such formulations.[5–10] Capsule dissolution is also sensitive to both the amount of magnesium stearate in the formulation and the mixing time; higher levels of magnesium stearate and long mixing times can result in the formation of hydrophobic powder beds that do not disperse after the capsule shell dissolves.[11,12]

An increase in the coefficient of variation of mixing and a decrease in the dissolution rate have been observed following blending of magnesium stearate with a tablet granulation. Tablet dissolution rate and crushing strength decreased as the time of blending increased; and magnesium stearate may also increase tablet friability. Blending times with magnesium stearate should therefore be carefully controlled.[13–29] A variety of online analytical techniques have been investigated to monitor magnesium stearate in powder blends and tablets.[30–32] Inverse gas chromatography has been used to examine the surface coverage of magnesium stearate on powder blends.[33] Magnesium stearate also affects the flow properties of blends.[34]

The existence of various crystalline forms of magnesium stearate has been established.[35–39] A trihydrate, a dihydrate, and an anhydrate have been isolated,[5,37,38,40] and an amorphous form has been observed.[41] While the hydrated forms are stable in the presence of moisture, the anhydrous form adsorbs moisture at relative humidity up to 50%, and at higher humidities rehydrates to form the trihydrate. The anhydrate can be formed by drying either of the hydrates at 105°C.[38]

It has not been conclusively established which form of pure magnesium stearate possesses the best lubricating properties.[36,37,41–43] Commercial lots of magnesium stearate generally

consist of mixtures of crystalline forms.[37,39,41,42,44–46] Because of the possibility of conversion of crystalline forms during heating, consideration should be given to the pretreatment conditions employed when determining physical properties of magnesium stearate powders such as surface area.[47,48]

Physical properties of magnesium stearate can vary among batches from different manufacturers[46] because the solid-state characteristics of the powder are influenced by manufacturing variables.[36] Variations in the physical properties of different lots of magnesium stearate from the same vendor have also been observed.[46] Presumably because of these variations, it has not been possible to conclusively correlate the dissolution rate retardation with observed lubricity.[49]

However, various physical properties of different batches of magnesium stearate, such as specific surface area, particle size, crystalline structure, moisture content, and fatty acid composition, have been correlated with lubricant efficacy.[37,41,45,46,50–55] Due to variations in the specific surface area, the labeling states that specific surface area and the method specified for its determination should be listed on the label. Reduction in dissolution caused by the effects of magnesium stearate in some cases can be overcome by including a highly swelling disintegrant in the formulation.[56]

The impact of magnesium stearate levels on tablet compaction properties and performance of roller compacted granulations has been examined.[57–59] In other compaction studies performed with granules, magnesium stearate has been shown to exert an influence on granule relaxation and may help to prevent capping.[60]

There is evidence to suggest that the hydrophobic nature of magnesium stearate can vary from batch to batch owing to the presence of water-soluble, surface-active impurities such as sodium stearate. Batches containing very low concentrations of these impurities have been shown to retard the dissolution of a drug to a greater extent than when using batches that contain higher levels of impurities.[49] One study related lubricity to the fatty acid composition (stearate : palmitate) of lubricant lots for tablet formulations based on compaction data and tablet material properties.[54] However, other studies have indicated that fatty acid composition has no influence on lubricant activity[37] and high-purity magnesium stearate was as effective a lubricant as the commercial material.[10] Moisture sorption at different relative humidities can result in morphological changes in the magnesium stearate.[61,62]

Magnesium stearate has been investigated for use in inhalation powders to control their performance.[63]

A specification for magnesium stearate is included in the Food Chemicals Codex (FCC).[64] The EINECS number for magnesium stearate is 209-150-3.

19 Specific References

1 Chowhan ZT. Harmonization of excipient standards. Weiner ML, Kotkoskie LA, eds. *Excipient Toxicity and Safety*. New York: Marcel Dekker, 2000; 321–354.
2 Anonymous. Final report of the safety assessment of lithium stearate, aluminum distearate, aluminum stearate, aluminum tristearate, ammonium stearate, calcium stearate, magnesium stearate, potassium stearate, sodium stearate, and zinc stearate. *J Am Coll Toxicol* 1982; **1**: 143–177.
3 Sondergaard D *et al*. Magnesium stearate given perorally to rats: a short term study. *Toxicology* 1980; **17**: 51–55.
4 Boyland E *et al*. Further experiments on implantation of materials into the urinary bladder of mice. *Br J Cancer* 1964; **18**: 575–581.
5 Levy G, Gumtow RH. Effect of certain formulation factors on dissolution rate of the active ingredient III: tablet lubricants. *J Pharm Sci* 1963; **52**: 1139–1144.
6 Ganderton D. The effect of distribution of magnesium stearate on the penetration of a tablet by water. *J Pharm Pharmacol* 1969; **21**(Suppl.): 9S–18S.
7 Caldwell HC. Dissolution of lithium and magnesium from lithium carbonate capsules containing magnesium stearate. *J Pharm Sci* 1974; **63**: 770–773.
8 Chowhan ZT *et al*. Tablet-to-tablet dissolution variability and its relationship to the homogeneity of a water-soluble drug. *Drug Dev Ind Pharm* 1982; **8**: 145–168.
9 Lerk CF *et al*. Interaction of tablet disintegrants and magnesium stearate during mixing II: effect on dissolution rate. *Pharm Acta Helv* 1982; **57**: 282–286.
10 Hussain MSH *et al*. Effect of commercial and high purity magnesium stearates on in-vitro dissolution of paracetamol DC tablets. *Int J Pharm* 1992; **78**: 203–207.
11 Samyn JC, Jung WY. *In vitro* dissolution from several experimental capsule formulations. *J Pharm Sci* 1970; **59**: 169–175.
12 Murthy KS, Samyn JC. Effect of shear mixing on *in vitro* drug release of capsule formulations containing lubricants. *J Pharm Sci* 1977; **66**: 1215–1219.
13 Ragnarsson G *et al*. The influence of mixing time and colloidal silica on the lubricating properties of magnesium stearate. *Int J Pharm* 1979; **3**: 127–131.
14 Bolhuis GK *et al*. Mixing action and evaluation of tablet lubricants in direct compression. *Drug Dev Ind Pharm* 1980; **6**: 573–589.
15 Bossert J, Stamm A. Effect of mixing on the lubrication of crystalline lactose by magnesium stearate. *Drug Dev Ind Pharm* 1980; **6**: 573–589.
16 Bolhuis GK *et al*. Interaction of tablet disintegrants and magnesium stearate during mixing I: effect on tablet disintegration. *J Pharm Sci* 1981; **70**: 1328–1330.
17 Sheikh-Salem M, Fell JT. The influence of magnesium stearate on time dependent strength changes in tablets. *Drug Dev Ind Pharm* 1981; **7**: 669–674.
18 Stewart PJ. Influence of magnesium stearate on the homogeneity of a prednisone granule ordered mix. *Drug Dev Ind Pharm* 1981; **7**: 485–495.
19 Jarosz PJ, Parrott EL. Effect of tablet lubricants on axial and radial work of failure. *Drug Dev Ind Pharm* 1982; **8**: 445–453.
20 Mitrevej KT, Augsburger LL. Adhesion of tablets in a rotary tablet press II: effects of blending time, running time, and lubricant concentration. *Drug Dev Ind Pharm* 1982; **8**: 237–282.
21 Khan KA *et al*. The effect of mixing time of magnesium stearate on the tableting properties of dried microcrystalline cellulose. *Pharm Acta Helv* 1983; **58**: 109–111.
22 Johansson ME. Investigations of the mixing time dependence of the lubricating properties of granular and powdered magnesium stearate. *Acta Pharm Suec* 1985; **22**: 343–350.
23 Johansson ME. Influence of the granulation technique and starting material properties on the lubricating effect of granular magnesium stearate. *J Pharm Pharmacol* 1985; **37**: 681–685.
24 Chowhan ZT, Chi LH. Drug–excipient interactions resulting from powder mixing III: solid state properties and their effect on drug dissolution. *J Pharm Sci* 1986; **75**: 534–541.
25 Chowhan ZT, Chi LH. Drug–excipient interactions resulting from powder mixing IV: role of lubricants and their effect on *in vitro* dissolution. *J Pharm Sci* 1986; **75**: 542–545.
26 Johansson ME, Nicklasson M. Influence of mixing time, particle size and colloidal silica on the surface coverage and lubrication of magnesium stearate. Rubinstein MH, ed. *Pharmaceutical Technology: Tableting Technology*. Chichester: Ellis Horwood, 1987; 43–50.
27 Wang LH, Chowhan ZT. Drug–excipient interactions resulting from powder mixing V: role of sodium lauryl sulfate. *Int J Pharm* 1990; **60**: 61–78.
28 Muzikova J, Horacek J. The dry binders, *Vivapur 102*, *Vivapur 12* and the effect of magnesium stearate on the strength of tablets containing these substances. *Ceske Slov Farm* 2003; **52**(4): 176–180.
29 Muzikova J. Effect of magnesium stearate on the tensile strength of tablets made with the binder *Prosolv SMCC 90*. *Ceska Slow Farm* 2002; **51**(1): 41–43.
30 Aguirre-Mendez C, Romanach RJ. A Raman spectroscopic method to monitor magnesium stearate in blends and tablets. *Pharmaceut Tech Eur* 2007; **19**(9): 53–61.
31 St-Onge L *et al*. Rapid quantitative analysis of magnesium stearate in tablets using laser-induced breakdown spectroscopy. *J Pharm Pharmaceut Sci* 2005; **8**(2): 272–288.
32 Duong N-H *et al*. A homogeneity study using NIR spectroscopy: tracking magnesium stearate in Bohle bin-blender. *Drug Dev Ind Pharm* 2003; **29**(6): 679–687.
33 Swaminathan V *et al*. Measurement of the surface energy of lubricated pharmaceutical powders by inverse gas chromatography. *Int. J. Pharm* 2006; **312**(1–2): 158–165.

34 Faqih AM *et al*. Effect of moisture and magnesium stearate concentration on flow properties of cohesive granular materials. *Int J Pharm* 2007; **336**(2): 338–345.
35 Muller BW. The pseudo-polymorphism of magnesium stearate. *Zbl Pharm* 1977; **116**(12): 1261–1266.
36 Miller TA, York P. Physical and chemical characteristics of some high purity magnesium stearate and palmitate powders. *Int J Pharm* 1985; **23**: 55–67.
37 Ertel KD, Carstensen JT. Chemical, physical, and lubricant properties of magnesium stearate. *J Pharm Sci* 1988; **77**: 625–629.
38 Ertel KD, Carstensen JT. An examination of the physical properties of pure magnesium stearate. *Int J Pharm* 1988; **42**: 171–180.
39 Wada Y, Matsubara T. Pseudo-polymorphism and crystalline transition of magnesium stearate. *Thermochim Acta* 1992; **196**: 63–84.
40 Sharpe SA *et al*. Physical characterization of the polymorphic variations of magensium stearate and magnesium palmitate hydrate species. *Struct Chem* 1997; **8**(1): 73–84.
41 Leinonen UI *et al*. Physical and lubrication properties of magnesium stearate. *J Pharm Sci* 1992; **81**(12): 1194–1198.
42 Muller BW. Polymorphism of magnesium stearate and the influence of the crystal structure on the lubricating behavior of excipients. *Acta Pharm Suec* 1981; **18**: 74–75.
43 Okoye P, Wu S.H. Lubrication of direct-compressible blends with magnesium stearate monohydrate and dihydrate. *Pharm Technol* 2007; **31**(9): 116–129.
44 Brittain HG. Raw materials. *Drug Dev Ind Pharm* 1989; **15**(13): 2083–2103.
45 Dansereau R, Peck GE. The effect of the variability in the physical and chemical properties of magnesium stearate on the properties of compressed tablets. *Drug Dev Ind Pharm* 1987; **13**: 975–999.
46 Barra J, Somma R. Influence of the physicochemical variability of magnesium stearate on its lubricant properties: possible solutions. *Drug Dev Ind Pharm* 1996; **22**(11): 1105–1120.
47 Phadke DS, Collier JL. Effect of degassing temperature on the specific surface area and other physical properties of magnesium stearate. *Drug Dev Ind Pharm* 1994; **20**(5): 853–858.
48 Koivisto M *et al*. Effect of temperature and humidity on vegetable grade magnesium stearate. *Powder Technol* 2004; **147**(1–3): 79–85.
49 Billany MR, Richards JH. Batch variation of magnesium stearate and its effect on the dissolution rate of salicylic acid from solid dosage forms. *Drug Dev Ind Pharm* 1982; **8**: 497–511.
50 Frattini C, Simioni L. Should magnesium stearate be assessed in the formulation of solid dosage forms by weight or by surface area? *Drug Dev Ind Pharm* 1984; **10**: 1117–1130.
51 Bos CE *et al*. Lubricant sensitivity in relation to bulk density for granulations based on starch or cellulose. *Int J Pharm* 1991; **67**: 39–49.
52 Phadke DS, Eichorst JL. Evaluation of particle size distribution and specific surface area of magnesium stearate. *Drug Dev Ind Pharm* 1991; **17**: 901–906.
53 Steffens KJ, Koglin J. The magnesium stearate problem. *Manuf Chem* 1993; **64**(12): 16–19.
54 Marwaha SB, Rubinstein MH. Structure-lubricity evaluation of magnesium stearate. *Int J Pharm* 1988; **43**(3): 249–255.
55 Rao KP *et al*. Impact of solid-state properties on lubrication efficacy of magnesium stearate. *Pharm Dev Technol* 2005; **10**(3): 423–437.
56 Desai DS *et al*. Physical interactions of magnesium stearate with starch-derived disintegrants and their effects on capsule and tablet dissolution. *Int J Pharm* 1993; **91**(2–3): 217–226.
57 Wurster DE *et al*. The influence of magnesium stearate on the hiestand tableting indices and other related mechanical properties of maltodextrins. *Pharm Dev Technol* 2005; **10**(4): 461–466.
58 Likitlersuang S *et al*. The effect of binary mixture composition and magnesium stearate concentration on the hiestand tableting indices and other related mechanical properties. *Pharm Dev Technol* 2007; **12**(5): 533–541.
59 He X *et al*. Mechanistic study of the effect of roller compaction and lubricant on tablet mechanical strength. *J Pharm Sci* 2007; **96**(5): 1342–1355.
60 Ebba F *et al*. Stress relaxation studies of granules as a function of different lubricants. *Eur J Pharm Biopharm* 2001; **52**(2): 211–220.
61 Swaminathan V, Kildisig DO. An examination of the moisture sorption characteristics of commercial magnesium stearate. *AAPS Pharm Sci Tech* 2001; **2**(4): 28.
62 Bracconi P *et al*. Structural properties of magnesium stearate pseudopolymorphs: effect of temperature. *Int J Pharm* 2003; **262**(1–2): 109–124.
63 Guchardi R *et al*. Influence of fine lactose and magnesium stearate on low dose dry powder inhaler formulations. *Int J Pharm* 2008; **348**(1–2): 10–17.
64 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 568.

20 General References

Bohidar NR *et al*. Selecting key pharmaceutical formulation factors by regression anaysis. *Drug Dev Ind Pharm* 1979; **5**: 175–216.

Butcher AE, Jones TM. Some physical characteristics of magnesium stearate. *J Pharm Pharmacol* 1972; **24**: 1P–9P.

European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 3 February 2009).

Ford JL, Rubinstein MH. An investigation into some pharmaceutical interactions by differential scanning calorimetry. *Drug Dev Ind Pharm* 1981; **7**: 675–682.

Johansson ME. Granular magnesium stearate as a lubricant in tablet formulations. *Int J Pharm* 1984; **21**: 307–315.

Jones TM. The effect of glidant addition on the flowability of bulk particulate solids. *J Soc Cosmet Chem* 1970; **21**: 483–500.

Pilpel N. Metal stearates in pharmaceuticals and cosmetics. *Manuf Chem Aerosol News* 1971; **42**(10): 37–40.

York P. Tablet lubricants. Florence AT, ed. *Materials Used in Pharmaceutical Formulation*. London: Society of Chemical Industry, 1984; 37–70.

Zanowiak P. Lubrication in solid dosage form design and manufacture. Swarbick J, Boylan JC, eds. *Encyclopedia of Pharmaceutical Technology.*, vol. **9**: New York: Marcel Dekker, 1990; 87–112.

21 Authors

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22 Date of Revision

3 February 2009.

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The therapeutic use of sodium propionate in topical antifungal preparations has largely been superseded by a new generation of antifungal drugs.

A specification for sodium propionate is contained in the Food Chemicals Codex (FCC).[6]

The EINECS number for sodium propionate is 205-290-4. The PubChem Compound ID (CID) for sodium propionate is 23663426.

19 Specific References

1 Bishop Y, ed. *The Veterinary Formulary*, 6th edn. London: Pharmaceutical Press, 2005; 419–420.
2 Heseltine WW. A note on sodium propionate. *J Pharm Pharmacol* 1952; **4**: 120–122.
3 Graham WD *et al*. Chronic toxicity of bread additives to rats. *J Pharm Pharmacol* 1954; **6**: 534–545.
4 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3276.
5 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). http://www.hse.gov.uk/coshh/table1.pdf (accessed 5 February 2009).
6 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 906.

20 General References

Doores S. Organic acids. Branen AL, Davidson PM, eds. *Antimicrobials in Foods*. New York: Marcel Dekker, 1983; 85–87.
Furia TE, ed. *CRC Handbook of Food Additives*. Cleveland, OH: CRC Press, 1972; 137–141.

21 Author

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22 Date of Revision

5 February 2009.

Sodium Starch Glycolate

1 Nonproprietary Names

BP: Sodium Starch Glycolate
PhEur: Sodium Starch Glycolate
USP-NF: Sodium Starch Glycolate

2 Synonyms

Carboxymethyl starch, sodium salt; carboxymethylamylum natricum; *Explosol*; *Explotab*; *Glycolys*; *Primojel*; starch carboxymethyl ether, sodium salt; *Tablo*; *Vivastar P*.

3 Chemical Name and CAS Registry Number

Sodium carboxymethyl starch [9063-38-1]

4 Empirical Formula and Molecular Weight

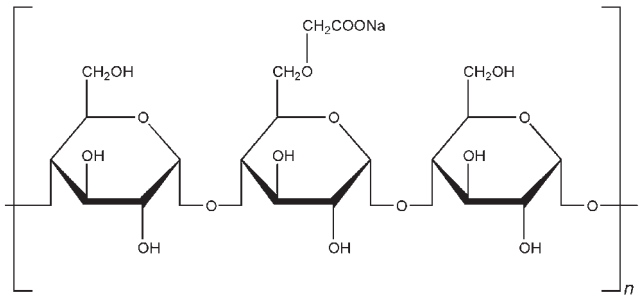
The USP32–NF27 describes two types of sodium starch glycolate, Type A and Type B, and states that sodium starch glycolate is the sodium salt of a carboxymethyl ether of starch or of a crosslinked carboxymethyl ether of starch.

The PhEur 6.0 describes three types of material: Type A and Type B are described as the sodium salt of a crosslinked partly *O*-carboxymethylated potato starch. Type C is described as the sodium salt of a partly *O*-carboxymethylated starch, crosslinked by physical dehydration. Types A, B, and C are differentiated by their pH, sodium, and sodium chloride content.

The PhEur and USP–NF monographs have been harmonized for Type A and Type B variants.

Sodium starch glycolate may be characterized by the degree of substitution and crosslinking. The molecular weight is typically 5×10^5–1×10^6.

5 Structural Formula



6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule[1–6] and tablet formulations.[7–10] It is commonly used in tablets prepared by either direct-compression[11–13] or wet-granulation processes.[14–16] The usual concentration employed in a formulation is between 2% and 8%, with the optimum concentration about 4%, although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling.[17–20]

Although the effectiveness of many disintegrants is affected by the presence of hydrophobic excipients such as lubricants, the disintegrant efficiency of sodium starch glycolate is unimpaired. Increasing the tablet compression pressure also appears to have no effect on disintegration time.[10–12]

Sodium starch glycolate has also been investigated for use as a suspending vehicle.[21]

8 Description

Sodium starch glycolate is a white or almost white free-flowing very hygroscopic powder. The PhEur 6.0 states that when examined under a microscope it is seen to consist of: granules, irregularly shaped, ovoid or pear-shaped, 30–100 µm in size, or rounded, 10–35 µm in size; compound granules consisting of 2–4 components occur occasionally; the granules have an eccentric hilum and clearly visible concentric striations. Between crossed nicol prisms, the granules show a distinct black cross intersecting at the hilum; small crystals are visible at the surface of the granules. The granules show considerable swelling in contact with water.

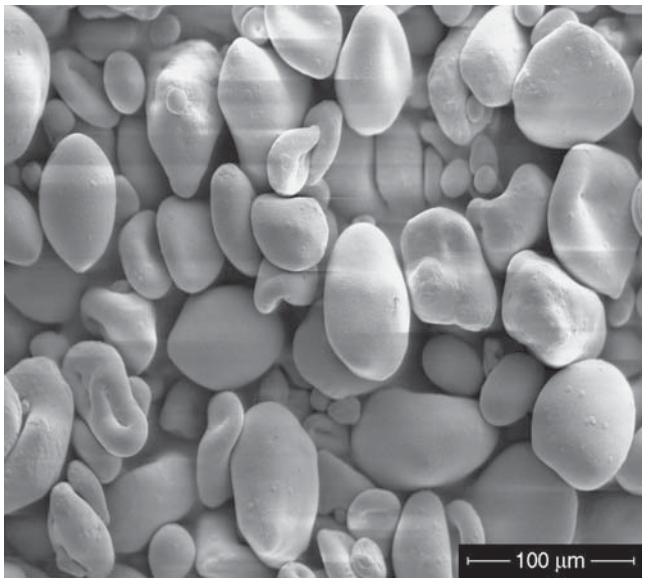
9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

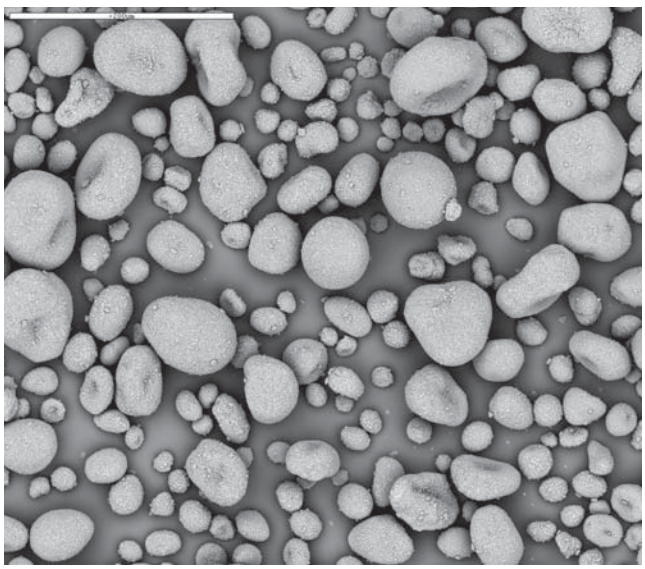
10 Typical Properties

Acidity/alkalinity *See* Section 9.
Density (bulk)
0.756 g/cm^3 for *Glycolys*;
0.81 g/cm^3 for *Primojel*;
0.67 g/cm^3 for *Tablo*.
Density (tapped)
0.945 g/cm^3 for *Glycolys*;
0.98 g/cm^3 for *Primojel*;
0.83 g/cm^3 for *Tablo*.
Density (true)
1.56 g/cm^3 for *Primojel*;
1.49 g/cm^3 for *Tablo*.
Melting point Does not melt, but chars at approximately 200°C.
NIR spectra *see* Figure 1.
Particle size distribution 100% of particles less than 106 µm in size. Average particle size (d_{50}) is 38 µm and 42 µm for *Primojel* by microscopy and sieving, respectively.
Solubility Practically insoluble in methylene chloride. It gives a translucent suspension in water.
Specific surface area
0.24 m^2/g for *Glycolys*;
0.185 m^2/g for *Primojel*;
0.335 m^2/g for *Tablo*.

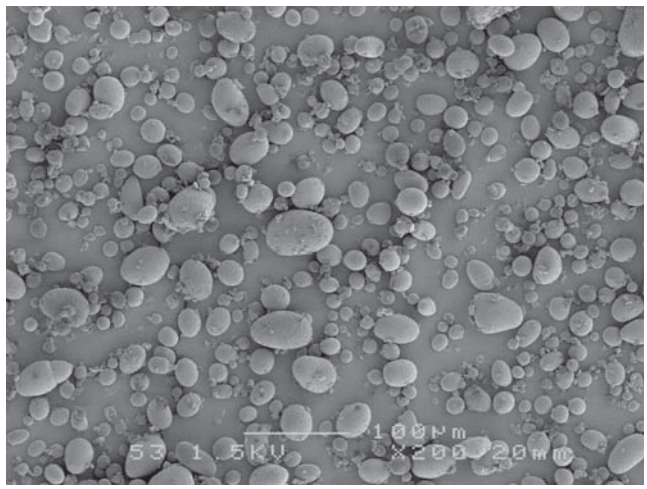
SEM 1: Excipient: sodium starch glycolate (*Explotab*); manufacturer: JRS Pharma; magnification: 300×; voltage: 5 kV.



SEM 2: Excipient: sodium starch glycolate (*Glycolys*); manufacturer: Roquettes Frères.



SEM 3: Excipient: sodium starch glycolate (*Primojel*); manufacturer: DMV-Fonterra Excipients; magnification: 200×; voltage: 1.5 kV.



SEM 4: Excipient: sodium starch glycolate (*Vivastar P*); manufacturer: JRS Pharma; magnification: 300×; voltage: 5 kV.

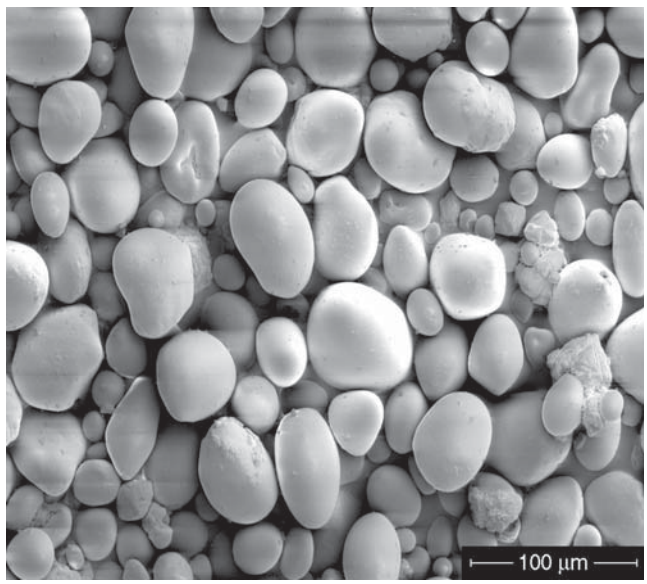


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Table I: Pharmacopeial specifications for sodium starch glycolate.

Test	PhEur 6.0	USP32–NF27
Identification	+	+
Characters	+	—
Appearance of solution	+	—
pH	+	+
Type A	5.5–7.5	5.5–7.5
Type B	3.0–5.0	3.0–5.0
Type C	5.5–7.5	—
Heavy metals	⩽20 ppm	⩽0.002%
Iron	⩽20 ppm	⩽0.002%
Loss on drying	+	⩽10%
Type A	⩽10.0%	—
Type B	⩽10.0%	—
Type C	⩽7.0%	—
Microbial limits	+[a]	+[a]
Sodium chloride	+	⩽7.0%
Type A	⩽7.0%	—
Type B	⩽7.0%	—
Type C	⩽1.0%	—
Sodium glycolate	+	⩽2.0%
Type A	⩽2.0%	—
Type B	⩽2.0%	—
Type C	⩽2.0%	—
Assay (of Na)	+	+
Type A	2.8–4.2%	2.8–4.2%
Type B	2.0–3.4%	2.0–3.4%
Type C	2.8–5.0%	—

(a) Complies with tests for *Salmonella* and *Escherichia coli*.

Swelling capacity In water, sodium starch glycolate swells to up to 300 times its volume.

Viscosity (dynamic) ⩽200 mPa s (200 cP) for a 4% w/v aqueous dispersion; viscosity is 4.26 mPa s for a 2% w/v aqueous dispersion (depending on source and grade).

11 Stability and Storage Conditions

Tablets prepared with sodium starch glycolate have good storage properties.[22–24] Sodium starch glycolate is stable although very hygroscopic, and should be stored in a well-closed container in order to protect it from wide variations of humidity and temperature, which may cause caking.

The physical properties of sodium starch glycolate remain unchanged for up to 3 years if it is stored at moderate temperatures and humidity.

12 Incompatibilities

Sodium starch glycolate is incompatible with ascorbic acid.[25]

13 Method of Manufacture

Sodium starch glycolate is a substituted derivative of potato starch. Typically, commercial products are also crosslinked using either sodium trimetaphosphate (Types A and B) or dehydration (Type C).[26]

Starch is carboxymethylated by reacting it with sodium chloroacetate in an alkaline, nonaqueous medium, typically denatured ethanol or methanol, followed by neutralization with citric acid, acetic acid, or some other acid. *Vivastar P* is manufactured in methanolic medium, and *Explotab* in ethanolic medium.

14 Safety

Sodium starch glycolate is widely used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. However, oral ingestion of large quantities may be harmful.

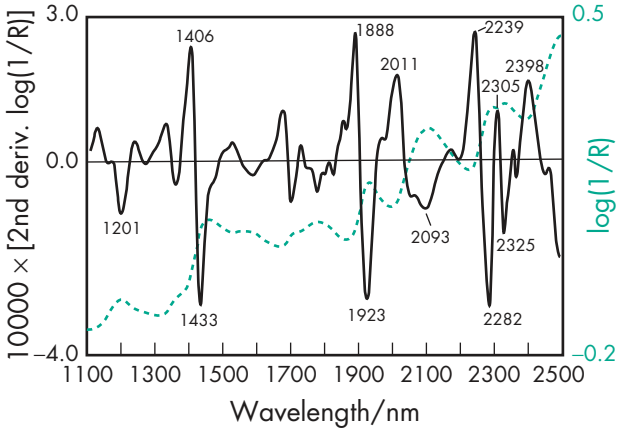

Figure 1: Near-infrared spectrum of sodium starch glycolate measured by reflectance.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Sodium starch glycolate may be irritant to the eyes; eye protection and gloves are recommended. A dust mask or respirator is recommended for processes that generate a large quantity of dust.

16 Regulatory Acceptance

Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Pregelatinized starch; starch.

18 Comments

Sodium starch glycolate is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

The physical properties of sodium starch glycolate, and hence its effectiveness as a disintegrant, are affected by the degree of crosslinkage, extent of carboxymethylation, and purity.[27,28]

Sodium starch glycolate has been reported to interact with glycopeptide antibiotics,[29,30] basic drugs, and increase the photostability of norfloxacin.[31] The solubility of the formulation matrix and mode of incorporation in wet granulation can affect the disintegration time; disintegration times can be slower in tablets containing high levels of soluble excipients.[32]

Commercially, sodium starch glycolate is available in a number of speciality grades, e.g. low pH (*Explotab Low pH*, *Glycolys Low pH*); low viscosity (*Explotab CLV*, *Glycolys LV*); low solvent (*Vivastar PSF*); and low moisture *Glycolys LM*.

A specification for sodium starch glycolate is included in the *Japanese Pharmaceutical Excipients* (JPE).[33]

19 Specific References

1 Newton JM, Razzo FN. Interaction of formulation factors and dissolution fluid and the *in vitro* release of drug from hard gelatin capsules. *J Pharm Pharmacol* 1975; **27**: 78P.

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2 Stewart AG *et al*. The release of a model low-dose drug (riboflavine) from hard gelatin capsule formulations. *J Pharm Pharmacol* 1979; **31**: 1–6.
3 Chowhan ZT, Chi L-H. Drug–excipient interactions resulting from powder mixing III: solid state properties and their effect on drug dissolution. *J Pharm Sci* 1986; **75**: 534–541.
4 Botzolakis JE, Augsburger LL. Disintegrating agents in hard gelatin capsules part 1: mechanism of action. *Drug Dev Ind Pharm* 1988; **14**(1): 29–41.
5 Hannula A-M *et al*. Release of ibuprofen from hard gelatin capsule formulations: effect of modern disintegrants. *Acta Pharm Fenn* 1989; **98**: 189–196.
6 Marvola M *et al*. Effect of sodium bicarbonate and sodium starch glycolate on the *in vivo* disintegration of hard gelatin capsules – a radiological study in the dog. *Acta Pharm Nord* 1989; **1**: 355–362.
7 Khan KA, Rooke DJ. Effect of disintegrant type upon the relationship between compressional pressure and dissolution efficiency. *J Pharm Pharmacol* 1976; **28**: 633–636.
8 Rubinstein MH, Price EJ. *In vivo* evaluation of the effect of five disintegrants on the bioavailability of frusemide from 40 mg tablets. *J Pharm Pharmacol* 1977; **29**: 5P.
9 Caramella C *et al*. The influence of disintegrants on the characteristics of coated acetylsalicylic acid tablets. *Farmaco (Prat)* 1978; **33**: 498–507.
10 Gebre Mariam T *et al*. Evaluation of the disintegration efficiency of a sodium starch glycolate prepared from enset starch in compressed tablets. *Eur J Pharm Biopharm* 1996; **42**(2): 124–132.
11 Cid E, Jaminet F. [Influence of adjuvants on the dissolution rate and stability of acetylsalicylic acid in compressed tablets.] *J Pharm Belg* 1971; **26**: 38–48[in French].
12 Gordon MS, Chowhan ZT. Effect of tablet solubility and hygroscopicity on disintegrant efficiency in direct compression tablets in terms of dissolution. *J Pharm Sci* 1987; **76**: 907–909.
13 Cordoba-Diaz M *et al*. Influence of pharmacotechnical design on the interaction and availability of norfloxacin in directly compressed tablets with certain antacids. *Drug Dev Ind Pharm* 2000; **26**: 159–166.
14 Sekulović D *et al*. The investigation of the influence of Explotab on the disintegration of tablets. *Pharmazie* 1986; **41**: 153–154.
15 Bolhius GK *et al*. Improvement of dissolution of poorly soluble drugs by solid deposition on a super disintegrant. Part 2. Choice of super disintegrants and effect of granulation. *Eur J Pharm Sci* 1997; **5**(2): 63–69.
16 Gordon MS *et al*. Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; **82**: 220–226.
17 Khan KA, Rhodes CT. Disintegration properties of calcium phosphate dibasic dihydrate tablets. *J Pharm Sci* 1975; **64**: 166–168.
18 Khan KA, Rhodes CT. Water-sorption properties of tablet disintegrants. *J Pharm Sci* 1975; **64**: 447–451.
19 Wan LSC, Prasad KPP. Uptake of water by excipients in tablets. *Int J Pharm* 1989; **50**: 147–153.
20 Thibert R, Hancock BC. Direct visualization of superdisintegrant hydration using environmental scanning electron microscopy. *J Pharm Sci* 1996; **85**: 1255–1258.
21 Danckwerts MP *et al*. Pharmaceutical formulation of a fixed-dose anti-tuberculosis combination. *Int J Tuberc Lung D* 2003; **7**: 289–297.
22 Horhota ST *et al*. Effect of storage at specified temperature and humidity on properties of three directly compressible tablet formulations. *J Pharm Sci* 1976; **65**: 1746–1749.
23 Sheen P-C, Kim S-I. Comparative study of disintegrating agents in tiaramide hydrochloride tablets. *Drug Dev Ind Pharm* 1989; **15**(3): 401–414.
24 Gordon MS, Chowhan ZT. The effect of aging on disintegrant efficiency in direct compression tablets with varied solubility and hygroscopicity, in terms of dissolution. *Drug Dev Ind Pharm* 1990; **16**(3): 437–447.
25 Botha SA *et al*. DSC screening for drug–excipient and excipient–excipient interactions in polypharmaceuticals intended for the alleviation of the symptoms of colds and flu. III. *Drug Dev Ind Pharm* 1987; **13**(7): 1197–1215.
26 Bolhuis GK *et al*. On the similarity of sodium starch glycolate from different sources. *Drug Dev Ind Pharm* 1986; **12**(4): 621–630.
27 Rudnic EM *et al*. Effect of molecular structure variation on the disintegrant action of sodium starch glycolate. *J Pharm Sci* 1985; **74**: 647–650.
28 Bolhuis GK *et al*. Effect of variation of degree of substitution, crosslinking and purity on the disintegrant efficiency of sodium starch glycolate. *Acta Pharm Technol* 1984; **30**: 24–32.
29 Claudius JS, Neau SH. Kinetic and equilibrium characterization of interactions between glycopeptide antibiotics and sodium carboxymethyl starch. *Int J Pharm* 1996; **144**: 71–79.
30 Claudius JS, Neau SH. The solution stability of vancomycin in the presence and absence of sodium carboxymethyl starch. *Int J Pharm* 1998; **168**: 41–48.
31 Cordoba-Borrego M *et al*. Validation of a high performance liquid chromatographic method for the determination of norfloxacin and its application to stability studies (photostability study of norfloxacin). *J Pharm Biomed Anal* 1999; **18**: 919–926.
32 Gordon MS *et al*. Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; **82**: 220–226.
33 Japanese Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients 2004*. Tokyo: Yakuji Nippo, 2004; 774.

20 General References

Augsburger LL *et al*. Superdisintegrants: characterisation and function. Swarbrick J, ed. *Encyclopedia of Pharmaceutical Technology*, 3rd edn. London: Informa Healthcare, 2007; 2553–2567.
Blanver. Technical literature: *Tablo*, *Explosol*, 2008.
DMV-Fonterra Excipients. Technical literature: *Primojel*, 2008.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 3 February 2009).
Edge S *et al*. Chemical characterisation of sodium starch glycolate particles. *Int J Pharm* 2002; **240**: 67–78.
Edge S *et al*. Powder compaction properties of sodium starch glycolate disintegrants. *Drug Dev Ind Pharm* 2002; **28**(8): 989–999.
JRS Pharma. Technical literature: *Explotab, Vivastar P*, 2004.
Khan KA, Rhodes CT. Further studies of the effect of compaction pressure on the dissolution efficiency of direct compression systems. *Pharm Acta Helv* 1974; **49**: 258–261.
Mantovani F *et al*. A combination of vapor sorption and dynamic laser light scattering methods for the determination of the Flory parameter chi and the crosslink density of a powdered polymeric gel. *Fluid Phase Equilib* 2000; **167**(1): 63–81.
Mendell E. An evaluation of carboxymethyl starch as a tablet disintegrant. *Pharm Acta Helv* 1974; **49**: 248–250.
Roquette Frères. Technical literature: *Glycolys*, 2008.
Shah U, Augsburger L. Multiple sources of sodium starch glycolate NF: evaluation of functional equivalence and development of standard performance tests. *Pharm Dev Tech* 2002; **7**(3): 345–359.
Young PM *et al*. Interaction of moisture with sodium starch glycolate. *Pharm Dev Tech* 2007; **12**: 211–216.
Young PM *et al*. The effect of moisture on the compressibility and compactability of sodium starch glycolates. *Pharm Dev Tech* 2007; **12**: 217–222.

21 Author

PM Young.

22 Date of Revision

3 February 2009.

S

Stearic Acid

1 Nonproprietary Names

BP: Stearic Acid
JP: Stearic Acid
PhEur: Stearic Acid
USP-NF: Stearic Acid

2 Synonyms

Acidum stearicum; cetylacetic acid; *Crodacid*; *Cristal G*; *Cristal S*; *Dervacid*; E570; *Edenor*; *Emersol*; *Extra AS*; *Extra P*; *Extra S*; *Extra ST*; 1-heptadecanecarboxylic acid; *Hystrene*; *Industrene*; *Kortacid 1895*; *Pearl Steric*; *Pristerene*; stereophanic acid; *Tegostearic*.

3 Chemical Name and CAS Registry Number

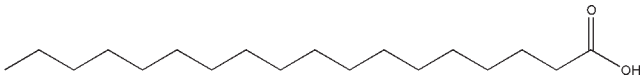
Octadecanoic acid [57-11-4]

4 Empirical Formula and Molecular Weight

$C_{18}H_{36}O_2$ 284.47 (for pure material)

The USP32–NF27 describes stearic acid as a mixture of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$). In the USP32–NF27, the content of stearic acid is not less than 40.0% and the sum of the two acids is not less than 90.0%. The USP32–NF27 also contains a monograph for purified stearic acid; *see* Section 17. The PhEur 6.5 contains a single monograph for stearic acid but defines stearic acid 50, stearic acid 70, and stearic acid 95 as containing specific amounts of stearic acid ($C_{18}H_{36}O_2$); *see* Section 9.

5 Structural Formula



6 Functional Category

Emulsifying agent; solubilizing agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Stearic acid is widely used in oral and topical pharmaceutical formulations. It is mainly used in oral formulations as a tablet and capsule lubricant;[1–3] *see* Table I, although it may also be used as a binder[4] or in combination with shellac as a tablet coating. It has also been suggested that stearic acid may be used in enteric tablet coatings and as a sustained-release drug carrier.[5]

In topical formulations, stearic acid is used as an emulsifying and solubilizing agent. When partially neutralized with alkalis or triethanolamine, stearic acid is used in the preparation of creams.[6,7] The partially neutralized stearic acid forms a creamy base when mixed with 5–15 times its own weight of aqueous liquid, the appearance and plasticity of the cream being determined by the proportion of alkali used.

Stearic acid is used as the hardening agent in glycerin suppositories.

Stearic acid is also widely used in cosmetics and food products.

Table I: Uses of stearic acid.

Use	Concentration (%)
Ointments and creams	1–20
Tablet lubricant	1–3

8 Description

Stearic acid is a hard, white or faintly yellow-colored, somewhat glossy, crystalline solid or a white or yellowish white powder. It has a slight odor (with an odor threshold of 20 ppm) and taste suggesting tallow.

See also Section 13.

9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

10 Typical Properties

Acid value 195–212
Boiling point 383°C
Density (bulk) ≈0.537 g/cm^3
Density (tapped) 0.571 g/cm^3
Density (true) 0.980 g/cm^3
Flash point 113°C (closed cup)
Melting point 69–70°C
Moisture content Contains practically no water.
NIR spectra *see* Figure 1.
Partition coefficient Log (oil : water) = 8.2
Refractive index 1.43 at 80°C
Saponification value 200–220
Solubility Freely soluble in benzene, carbon tetrachloride, chloroform, and ether; soluble in ethanol (95%), hexane, and propylene glycol; practically insoluble in water.[8]
Specific surface area
0.51–0.53 m^2/g

SEM 1: Excipient: stearic acid, 95% (*Emersol 153*); manufacturer: Emery Industries; lot no.: 18895; magnification: 120×; voltage: 10 kV.

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SEM 2: Excipient: stearic acid, food grade (*Emersol 6332*); manufacturer: Emery Industries; lot no.: 18895; magnification: 120×; voltage: 10 kV.

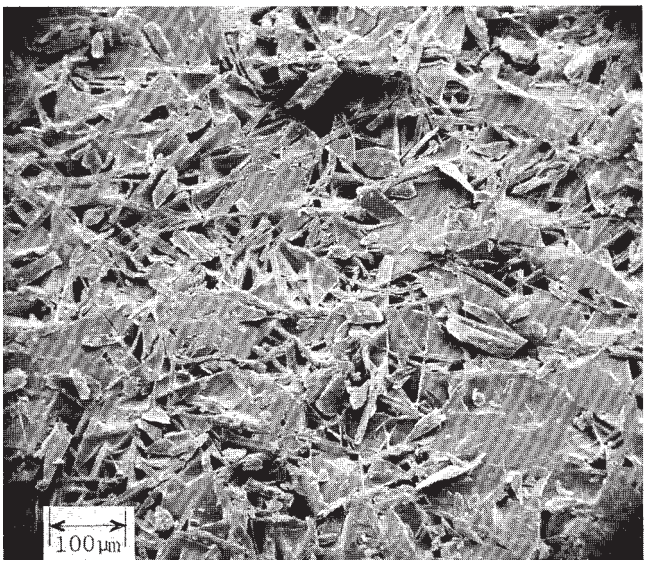

Table II: Pharmacopeial specifications for stearic acid.

Test	JP XV	PhEur 6.5	USP32–NF27
Identification	—	+	—
Characters	—	+	—
Acidity	—	+	—
Acid value	194–210	194–212	—
Appearance	—	+	—
Content of stearic acid	—	+	⩾40.0%
Stearic acid 50	—	40–60%	—
Stearic acid 70	—	60–80%	—
Stearic acid 95	—	⩾90.0%	—
Content of stearic and palmitic acids	—	+	⩾90.0%
Stearic acid 50	—	⩾90.0%	—
Stearic acid 70	—	⩾90.0%	—
Stearic acid 95	—	⩾96.0%	—
Congealing temperature	56.0–72.0°C	—	⩾54°C
Freezing point	—	+	—
Stearic acid 50	—	53–59°C	—
Stearic acid 70	—	57–64°C	—
Stearic acid 95	—	64–69°C	—
Iodine value	⩽4.0	+	⩽4.0
Stearic acid 50	—	⩽4.0%	—
Stearic acid 70	—	⩽4.0%	—
Stearic acid 95	—	⩽1.5%	—
Nickel	—	⩽1 ppm	—
Residue on ignition	⩽0.1%	—	⩽0.1%
Heavy metals	⩽20 ppm	—	⩽0.001%
Neutral fat or paraffin	+	—	+
Mineral acid	+	—	+

See also Section 17 and Table III.

11 Stability and Storage Conditions

Stearic acid is a stable material; an antioxidant may also be added to it; *see* Section 13. The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Stearic acid is incompatible with most metal hydroxides and may be incompatible with bases, reducing agents, and oxidizing agents.

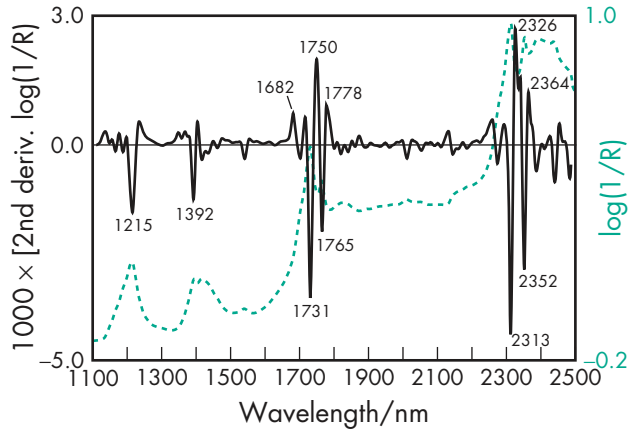

Figure 1: Near-infrared spectrum of stearic acid measured by reflectance.

Ointment bases made with stearic acid may show evidence of drying out or lumpiness due to such a reaction when compounded with zinc or calcium salts.

A number of differential scanning calorimetry studies have investigated the compatibility of stearic acid with drugs. Although such laboratory studies have suggested incompatibilities, e.g. with naproxen,[9] they may not necessarily be applicable to formulated products.

Stearic acid has been reported to cause pitting in the film coating of tablets applied using an aqueous film-coating technique; the pitting was found to be a function of the melting point of the stearic acid.[10]

13 Method of Manufacture

Stearic acid is manufactured by hydrolysis of fat by continuous exposure to a countercurrent stream of high-temperature water and fat in a high-pressure chamber. The resultant mixture is purified by vacuum steam distillation and the distillates are then separated using selective solvents.

Stearic acid may also be manufactured by the hydrogenation of cottonseed and other vegetable oils; by the hydrogenation and subsequent saponification of olein followed by recrystallization from alcohol; and from edible fats and oils by boiling with sodium hydroxide, separating any glycerin, and decomposing the resulting soap with sulfuric or hydrochloric acid. The stearic acid is then subsequently separated from any oleic acid by cold expression.

Stearic acid is derived from edible fat sources unless it is intended for external use, in which case nonedible fat sources may be used. The USP32–NF27 states that stearic acid labeled solely for external use is exempt from the requirement that it be prepared from edible sources. Stearic acid may contain a suitable antioxidant such as 0.005% w/w butylated hydroxytoluene.

14 Safety

Stearic acid is widely used in oral and topical pharmaceutical formulations; it is also used in cosmetics and food products. Stearic acid is generally regarded as a nontoxic and nonirritant material. However, consumption of excessive amounts may be harmful.

LD_{50} (mouse, IV): 23 mg/kg[11]
LD_{50} (rat, IV): 21.5 mg/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Stearic acid dust may be irritant to the skin, eyes, and mucous membranes. Eye protection, gloves, and a dust respirator are recommended. Stearic acid is combustible.

Table III: Specifications of different stearic acid grades.

Product	Stearic acid content (%)	Melting range (°C)	Acid value	Iodine value	Saponification value	Unsaponifiable matter (%)
Hystrene 5016	44	54.5–56.5	206–210	⩽0.5	206–211	⩽0.2
Hystrene 7018	68.5	61.0–62.5	200–205	⩽0.5	200–206	⩽0.2
Hystrene 9718	90	66.5–68.0	196–201	⩽0.8	196–202	⩽0.3
Industrene 7018	65	58.0–62.0	200–207	⩽1.5	200–208	⩽0.5
Industrene 8718	87	64.5–67.5	196–201	⩽2.0	196–202	⩽1.5

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe (fatty acids). Included in the FDA Inactive Ingredients Database (sublingual tablets; oral capsules, solutions, suspensions, and tablets; topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Calcium stearate; magnesium stearate; polyoxyethylene stearates; purified stearic acid; zinc stearate.

Purified stearic acid

Empirical formula $C_{18}H_{36}O_2$
Molecular weight 284.47
CAS number [57-11-4]
Synonyms Octadecanoic acid
Acid value 195–200
Boiling point 361°C
Density 0.847 g/cm^3 at 70°C
Flash point 196°C
Iodine number ⩽1.5
Melting point 66–69°C
Refractive index n_D^{80} = 1.4299
Solubility Soluble 1 in 5 parts benzene, 1 in 6 parts carbon tetrachloride, 1 in 2 parts chloroform, 1 in 15 parts ethanol, 1 in 3 parts ether; practically insoluble in water.
Vapor density (relative) 9.80 (air = 1)
Comments The USP32–NF27 describes purified stearic acid as a mixture of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$), which together constitute not less than 96.0% of the total content. The content of $C_{18}H_{36}O_2$ is no less than 90.0% of the total.

18 Comments

Stearic acid is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

A wide range of different grades of stearic acid are commercially available that have varying chemical compositions and hence different physical and chemical properties; *see* Table III.[12] Stearic acid is highly soluble in structurally diverse solvents. Stearic acid/solvent packing within a 24.8 ?^{3} cubic volume explains the stoichiometry of stearic acid solubility at multiple temperatures in multiple solvents.[13]

In one study the release of an active drug in a formulation containing stearic acid was independent of compression pressure in the range 1–7 tons; the particle size of the stearic acid did have a significant influence on the drug release.[14]

A potential application of stearic acid is in the preparation of 'cushioning pellets', composed of stearic acid : microcrystalline cellulose (4 : 1 w/w). The use of these pellets may avoid rupture of the coating of pellets during the compression step of manufacturing.[15]

A specification for stearic acid is contained in the Food Chemicals Codex (FCC).[16]

The EINECS number for stearic acid is 200-313-4.

19 Specific References

1 Iranloye TA, Parrott EL. Effects of compression force, particle size, and lubricants on dissolution rate. *J Pharm Sci* 1978; **67**: 535–539.
2 Jarosz PJ, Parrott EL. Effect of tablet lubricants on axial and radial work of failure. *Drug Dev Ind Pharm* 1982; **8**: 445–453.
3 Mitrevej KT, Augsburger LL. Adhesion of tablets in a rotary tablet press II: effects of blending time, running time, and lubricant concentration. *Drug Dev Ind Pharm* 1982; **8**: 237–282.
4 Musikabhumma P *et al*. Evaluation of stearic acid and polyethylene glycol as binders for tabletting potassium phenethicillin. *Drug Dev Ind Pharm* 1982; **8**: 169–188.
5 Zhang Q *et al*. Studies on the cyclosporin A loaded stearic acid nanoparticles. *Int J Pharm* 2000; **200**: 153–159.
6 Suzuki K. Rheological study of vanishing cream. *Cosmet Toilet* 1976; **91**(6): 23–31.
7 Mores LR. Application of stearates in cosmetic creams and lotions. *Cosmet Toilet* 1980; **95**(3): 79, 81–84.
8 Yalkowsky SH, He Y, eds. *Handbook of Solubility Data*. Boca Raton, FL: CRC Press, 2003; 1119–1120.
9 Botha SA, Lötter AP. Compatibility study between naproxen and tablet excipients using differential scanning calorimetry. *Drug Dev Ind Pharm* 1990; **16**: 673–683.
10 Rowe RC, Forse SF. Pitting: a defect on film-coated tablets. *Int J Pharm* 1983; **17**: 347–349.
11 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3229–3300.
12 Phadke DS *et al*. Evaluation of batch-to-batch and manufacturer-to-manufacturer variability in the physical properties of talc and stearic acid. *Drug Dev Ind Pharm* 1994; **20**: 859–871.
13 Schmidt WF *et al*. Stearic acid solubility and cubic phase volume. *Chem Phys Lipids* 2006; **142**(1–2): 23–32.
14 Killen BU, Corrigon OI. Factors influencing drug release from stearic acid based compacts. *Int J Pharm* 2001; **228**(1–2): 189–198.
15 Qi XL *et al*. Preparation of tablets containing enteric-coated diclofenac sodium pellets. *Yao Xue Xue Bao* 2008; **43**(1): 97–101.
16 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 927.

20 General References

Allen LV. Featured excipient: capsule and tablet lubricants. *Int J Pharm Compound* 2000; **4**(5): 390–392404–405.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. http://www.edqm.eu/site/-614.html (accessed 25 February 2009).
Pilpel N. Metal stearates in pharmaceuticals and cosmetics. *Manuf Chem Aerosol News* 1971; **42**(10): 37–40.
Oxford University. Material safety data sheet: Stearic acid, 2009. http://msds.chem.ox.ac.uk/ST/stearic_acid.html (accessed 25 February 2009).
ScienceLab.com, Inc. Material safety data sheet: Stearic acid, .2005.

21 Author

LV Allen Jr.

22 Date of Revision

25 February 2009.

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recommended. Stearyl alcohol is not a fire hazard, although it will burn and may give off noxious fumes containing carbon monoxide.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral tablets, rectal topical, and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Cetostearyl alcohol; cetyl alcohol.

18 Comments

The EINECS number for stearyl alcohol is 204-017-6. The PubChem Compound ID (CID) for stearyl alcohol is 8221.

19 Specific References

1 Egan RR, Portwood O. Higher alcohols in skin lotions. *Cosmet Perfum* 1974; **89**(3): 39–42.
2 Alexander P. Organic rheological additives. *Manuf Chem* 1986; **57**(9): 49, 52.
3 Cao DY *et al*. Preparation of tetramethylpyrazine phosphate pulsed-release tablets. *Chin J New Drugs* 2005; **14**(6): 723–726.
4 Cao QR *et al*. Photoimages and the release characteristics of lipophilic matrix tablets containing highly water-soluble potassium citrate with high drug loadings. *Int J Pharm* 2007; **339**(1–2): 19–24.
5 Kaiho F *et al*. Application of fatty alcohols to pharmaceutical dosage forms. *Yakuzaigaku* 1984; **44**: 99–102.
6 Tanabe K *et al*. Effect of additives on release of ibuprofen from suppositories. *Yakuzaigaku* 1988; **48**: 262–269.
7 Passerini N *et al*. Controlled release of verapamil hydrochloride from waxy microparticles prepared by spray congealing. *J Control Release* 2003; **88**(2): 263–275.
8 Liggins RT, Burt HM. Paclitaxel loaded poly(L-lactic acid) microspheres: properties of microspheres made with low molecular weight polymers. *Int J Pharm* 2001; **222**(1): 19–33.
9 Takahashi Y *et al*. Trial for transdermal administration of sulfonylureas. *J Pharm Soc Japan* 1997; **117**: 1022–1027.
10 Weller PJ. Stearyl alcohol. Kibbe AH, ed. *Handbook of Pharmaceutical Excipients*, 3rd edn. London and Washington, DC: Pharmaceutical Press and American Pharmaceutical Association, 2000; 537–538.
11 Gaul LE. Dermatitis from cetyl and stearyl alcohols. *Arch Dermatol* 1969; **99**: 593.
12 Fisher AA. Contact dermatitis from stearyl alcohol and propylene glycol. *Arch Dermatol* 1974; **110**: 636.
13 Black H. Contact dermatitis from stearyl alcohol in Metosyn (flucinonide) cream. *Contact Dermatitis* 1975; **1**: 125.
14 Cronin E. *Contact Dermatitis*. Edinburgh: Churchill Livingstone, 1980; 808.
15 Yesudian PD, King CM. Allergic contact dermatitis from stearyl alcohol in Efudix cream. *Contact Dermatitis* 2001; **45**: 313–314.
16 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 2758.

20 General References

Barry BW. Continuous shear, viscoelastic and spreading properties of a new topical vehicle, FAPG base. *J Pharm Pharmacol* 1973; **25**: 131–137.
Cognis. Product literature: *Speziol C18 Pharma,* 2004.
Cognis. Product literature: *Drug-Delivery Agents* – Pharmaline, 2008.
Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory 1996*. Tokyo: Yakuji Nippo, 1996; 527.
Madan PL *et al*. Microencapsulation of a waxy solid: wall thickness and surface appearance studies. *J Pharm Sci* 1974; **63**: 280–284.
Rowe RC. A quantitative assessment of the reactivity of the fatty alcohols with cetrimide using immersion calorimetry. *J Pharm Pharmacol* 1987; **39**: 50–52.
Sasol. *Product literature: Sasol olefins and surfactants,* 2005.
Schott H, Han SK. Effect of inorganic additives on solutions of nonionic surfactants II. *J Pharm Sci* 1975; **64**: 658–664.
Wan LSC, Poon PKC. The interfacial activity of sodium lauryl sulfate in the presence of alcohols. *Can J Pharm Sci* 1970; **5**: 104–107.

21 Author

RT Guest.

22 Date of Revision

12 February 2009.

S

Sucralose

1 Nonproprietary Names

USP-NF: Sucralose

2 Synonyms

Splenda; sucralosa; sucralosum; *SucraPlus*; TGS; 1′,4′,6′-trichloro-galactosucrose; 4,1′,6′-trichloro-4,1′,6′-trideoxy-*galacto*-sucrose.

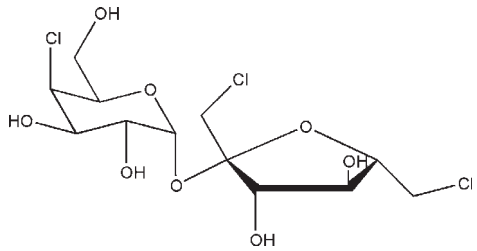
3 Chemical Name and CAS Registry Number

1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside [56038-13-2]

4 Empirical Formula and Molecular Weight

$C_{12}H_{19}Cl_3O_8$ 397.64

5 Structural Formula



6 Functional Category

Sweetening agent.

Index

Greek characters (α, β, γ etc.), numerical prefixes (50-, 1,2- etc.) and prefixes such as *para*, *ortho*, *O*-, *N*-, D-, L- etc. are excluded from alphabetization; page numbers in **bold** refer to monograph titles.

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