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# Handbook of PHARMACEUTICAL EXCIPIENTS

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Second Edition

*Edited by*  
Ainley Wade and Paul J Weller



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# Carnauba Wax

## 1. Nonproprietary Names

BP: Carnauba wax  
PhEur: Cera carnauba  
USPNF: Carnauba wax

## 2. Synonyms

903; brazil wax; caranda wax.

## 3. Chemical Name and CAS Registry Number

Carnauba wax [8015-86-9]

## 4. Empirical Formula Molecular Weight

Carnauba wax consists primarily of a complex mixture of esters of acids and hydroxyacids. Also present are acids, oxypolyhydric alcohols, hydrocarbons, resinous matter and water.

## 5. Structural Formula

See Section 4.

## 6. Functional Category

Coating agent.

## 7. Applications in Pharmaceutical Formulation or Technology

Carnauba wax is widely used in cosmetics, certain foods and pharmaceutical formulations.

Carnauba wax is the hardest and highest melting of the waxes commonly used in pharmaceutical formulations and is used primarily as a 10% w/v aqueous emulsion to polish sugar-coated tablets. Aqueous emulsions may be prepared by mixing carnauba wax with an ethanolamine compound and oleic acid. The carnauba wax coating produces tablets of good luster without rubbing. Carnauba wax may also be used in powder form to polish sugar-coated tablets.

Carnauba wax (10-50% w/w) has also been used alone or with stearyl alcohol to produce sustained release solid dosage formulations.<sup>(1-4)</sup>

## 8. Description

Carnauba wax occurs as a light brown to pale yellow colored powder, flakes, or irregular lumps of a hard, brittle wax. It possesses a characteristic bland odor and practically no taste. It is free from rancidity. Commercially, various types and grades are available.

## 9. Pharmacopeial Specifications

Test	PhEur 1989	USPNF XVII
Identification	+	—
Appearance of solution	+	—
Melting range	80-88°C	81-86°C
Residue on ignition	—	≤ 0.25%
Total ash	≤ 0.25%	—
Heavy metals	—	≤ 0.004%
Acid value	2-7	2-7
Saponification value	78-95	78-95

## 10. Typical Properties

Flash point: 270-330°C

Refractive index:  $n_D^{90} = 1.450$

Solubility: soluble in warm chloroform, and warm toluene; slightly soluble in boiling ethanol (95%); practically insoluble in water.

Specific gravity: 0.990-0.999 at 25°C

Unsaponified matter: 50-55%

## 11. Stability and Storage Conditions

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

## 12. Incompatibilities

—

## 13. Method of Manufacture

Carnauba wax is obtained from the leaf buds and leaves of *Copernicia cerifera* Mart. (Fam. Palmae). The leaves are dried and shredded and the wax then removed by the addition of hot water.

## 14. Safety

Carnauba wax is widely used in oral pharmaceutical formulations, cosmetics, and certain food products and is generally regarded as an essentially nontoxic and nonirritant material.

## 15. Handling Precautions

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

## 16. Regulatory Status

GRAS listed, Accepted for use in certain foods in the UK. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets, also topical preparations). Included in nonparenteral medicines licensed in the UK.

## 17. Pharmacopeias

Br, Eur, Fr, Ger, Jpn, Neth, Swiss and USPNF.

## 18. Related Substances

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## 19. Comments

In cosmetics, carnauba wax is mainly used to increase the stiffness of formulations, e.g. lipsticks and mascaras.

## 20. Specific References

1. Wiseman EH, Federici NJ. Development of a sustained-release aspirin tablet. *J Pharm Sci* 1968; 51: 1535-1539.
2. Prasad CM, Srivastava GP. Study of some sustained release granulations of aspirin. *Indian J Hosp Pharm* 1971; 8: 21-28.
3. Dave SC, Chakrabarti T, Srivastava GP. Sustained release tablet formulation of diphenhydramine hydrochloride (Benadryl) - part II. *Indian J Pharm* 1974; 36: 94-96.
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## 21. General References

Briquet F, Brossard C, Ser J, Duchêne D. Optimization of a sustained release formulation containing spherical microgranules produced

by extrusion-spheronization [in French]. *STP Pharma* 1986; 2: 986-994.

**22. Authors**

USA: NH Kobayashi.

# White Wax

## 1. Nonproprietary Names

BP: White beeswax  
PhEur: Cera alba  
USPNF: White wax

## 2. Synonyms

Bleached wax; E901.

## 3. Chemical Name and CAS Registry Number

White beeswax [8012-89-3]

## 4. Empirical Formula Molecular Weight

White wax is the chemically bleached form of natural beeswax, see Section 13.

Beeswax consists of 70-75% of a mixture of various esters of straight chain monohydric alcohols with even number carbon chains from C<sub>24</sub>-C<sub>36</sub> esterified with straight chain acids which also have even numbers of carbon atoms up to C<sub>36</sub> together with some C<sub>18</sub> hydroxy acids. The chief ester is myricyl palmitate. Also present are free acids (about 14%) and carbohydrates (about 12%) as well as approximately 1% free wax alcohols and stearic esters of fatty acids.

## 5. Structural Formula

See Section 4.

## 6. Functional Category

Emulsion stabilizer; stiffening agent.

## 7. Applications in Pharmaceutical Formulation or Technology

White wax is a chemically bleached form of yellow wax and is used in similar applications, such as to increase the consistency of creams and ointments, and to stabilize water-in-oil emulsions. White wax is also used to polish sugar-coated tablets and to adjust the melting point of suppositories. See also Yellow Wax.

## 8. Description

White wax consists of tasteless, white or slightly yellow-colored sheets or fine granules with some translucence. Odor is similar to yellow wax although it is less intense.

## 9. Pharmacopeial Specifications

Test	PhEur 1981	USPNF XVII
Melting range	61-65°C	62-65°C
Saponification cloud test	—	+
Saponification value	87-104	—
Fats, or fatty acids, Japan wax, rosin and soap	—	+
Acid value	17-24	17-24
Ester value	70-80	72-79
Ratio number	3.3-4.3	—
Ceresin, paraffin and certain other waxes	+	—
Glycerin and other polyhydric alcohols	≤ 0.5%	—

## 10. Typical Properties

Arsenic: ≤ 3 ppm  
Density: 0.95-0.96 g/cm<sup>3</sup>  
Flash point: 245-258°C  
Heavy metals: ≤ 0.004%  
Iodine number: 8-11  
Lead: ≤ 10 ppm  
Melting point: 61-65°C  
Peroxide value: ≤ 8  
Solubility: soluble in chloroform, ether, fixed oils, volatile oils and warm carbon disulfide; sparingly soluble in ethanol (95%); practically insoluble in water.  
Unsaponified matter: 52-55%

### HPE Laboratory Project Data

Method	Lab #	Results
Density	DE-1	7
		0.958 ± 0.006 g/cm <sup>3</sup>

## 11. Stability and Storage Conditions

When heated above 150°C esterification occurs with a consequent lowering of acid value and elevation of melting point. White wax is stable when stored in a well-closed container, protected from light.

## 12. Incompatibilities

Incompatible with oxidizing agents.

## 13. Method of Manufacture

Beeswax (yellow wax) is obtained from the honeycomb of the bee [*Apis mellifera* Linné (Fam. Apidae)], see Yellow Wax. Subsequent treatment with oxidizing agents bleaches the wax to yield white wax.

## 14. Safety

Used in both topical and oral formulations, white wax is generally regarded as being an essentially nontoxic and nonirritant material. However, although rare, hypersensitivity reactions to beeswax, attributed to contaminants in the wax, have been reported.<sup>(1,2)</sup>

## 15. Handling Precautions

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

## 16. Regulatory Status

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets, rectal, topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

## 17. Pharmacopeias

Aust, Belg, Br, Cz, Egypt, Eur, Fr, Ger, Gr, Hung, Ind, It, Jpn, Mex, Neth, Nord, Port, Rom, Swiss, USPNF and Yug. Also in BP Vet.

## 18. Related Substances

Yellow Wax.

## 19. Comments

—

**20. Specific References**

1. Cronin E. Contact dermatitis from cosmetics. *J Soc Cosmet Chem* 1967; 18: 681-691.
2. Rothenborg HW. Occupational dermatitis in beekeeper due to poplar resins in beeswax. *Arch Dermatol* 1967; 95: 381-384.

**21. General References**

Puleo SL. Beeswax. *Cosmet Toilet* 1987; 102(6): 57-58.

**22. Authors**

USA: LD Bighley.

# Yellow Wax

## 1. Nonproprietary Names

BP: Yellow beeswax  
PhEur: Cera flava  
USPNF: Yellow wax

## 2. Synonyms

E901; refined wax.

## 3. Chemical Name and CAS Registry Number

Yellow beeswax [8012-89-3]

## 4. Empirical Formula Molecular Weight

Yellow wax is naturally obtained beeswax, *see* Section 13. Beeswax consists of 70-75% of a mixture of various esters of straight chain monohydric alcohols with even number carbon chains from C<sub>24</sub>-C<sub>36</sub> esterified with straight chain acids which also have even numbers of carbon atoms up to C<sub>36</sub> together with some C<sub>18</sub> hydroxy acids. The chief ester is myricyl palmitate. Also present are free acids (about 14%) and carbohydrates (about 12%) as well as approximately 1% free wax alcohols and stearic esters of fatty acids.

## 5. Structural Formula

*See* Section 4.

## 6. Functional Category

Emulsion stabilizer; stiffening agent.

## 7. Applications in Pharmaceutical Formulation or Technology

Yellow wax is used in food, cosmetics and confectionery products. However, its main use is in topical pharmaceutical formulations, where it is used at a concentration of 5-20%, as a stiffening agent in ointments and creams. Yellow wax is also employed in emulsions since it enables water to be incorporated into water-in-oil emulsions.

In some oral formulations, yellow wax is used as a polishing agent for sugar-coated tablets; it is also used in sustained release formulations.

Yellow wax forms a soap with borax.

## 8. Description

Yellow or light brown pieces or plates with a fine-grained matt, noncrystalline fracture and a faint characteristic odor. The wax becomes soft and pliable when warmed.

## 9. Pharmacopeial Specifications

Test	PhEur 1981	USPNF XVII
Melting range	61-65°C	62-65°C
Saponification cloud test	—	+
Saponification value	87-102	—
Fats, or fatty acids, Japan wax, rosin and soap	—	+
Acid value	17-22	17-24
Ester value	70-80	72-79

## Continued

Test	PhEur 1981	USPNF XVII
Ratio number	3.3-4.3	—
Ceresin, paraffin and certain other waxes	+	—
Glycerin and other polyhydric alcohols	≤ 0.5%	—

## 10. Typical Properties

Acid value: 20

Arsenic: ≤ 3 ppm

Density: 0.950-0.960 g/cm<sup>3</sup>

Flash point: 245-258°C

Heavy metals: ≤ 0.004%

Iodine number: 8-11

Lead: ≤ 10 ppm

Melting point: 61-65°C

Peroxide value: ≤ 8

Refractive index: 1.440-1.445

Solubility: soluble in chloroform, ether, fixed oils, volatile oils, and warm carbon disulfide; sparingly soluble in ethanol (95%); practically insoluble in water.

Unaponified matter: 52-55%

Viscosity (kinematic):

1470 mm<sup>2</sup>/s (1470 cSt) at 99°C

## 11. Stability and Storage Conditions

When heated above 150°C esterification occurs with a consequent lowering of acid value and elevation of melting point. Yellow wax is stable when stored in a well-closed container, protected from light.

## 12. Incompatibilities

Incompatible with oxidizing agents.

## 13. Method of Manufacture

Yellow wax is a natural secretion of bees [*Apis mellifera* Linné (Fam. Apidae)] and is obtained commercially from honeycombs. Honey is abstracted from combs either by draining or centrifugation and water added to the remaining wax to remove soluble impurities. Hot water is then added to form a floating melt which is strained to remove foreign matter. The wax is then poured into flat dishes or molds to cool and harden.

## 14. Safety

Used in both topical and oral formulations, yellow wax is generally regarded as being an essentially nontoxic and nonirritant material. However, hypersensitivity reactions attributed to contaminants in the wax, although rare, have been reported.<sup>(1,2)</sup>

## 15. Handling Precautions

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

## 16. Regulatory Status

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets, and topical preparations). Included in nonparenteral medicines licensed in the UK.

**17. Pharmacopeias**

Aust, Belg, Br, Chin, Egypt, Eur, Fr, Ger, Ind, It, Jpn, Neth, Nord, Port, Rom, Swiss, USPNF and Yug.

**18. Related Substances**

White Wax.

**19. Comments**

-

**20. Specific References**

1. Cronin E. Contact dermatitis from cosmetics. *J Soc Cosmet Chem* 1967; 18: 681-691.
2. Rothenborg HW. Occupational dermatitis in beekeeper due to poplar resins in beeswax. *Arch Dermatol* 1967; 95: 381-384.

**21. General References**

Puleo SL. Beeswax. *Cosmet Toilet* 1987; 102(6): 57-58.

**22. Authors**

USA: LD Bighley.

# Stearic Acid

## 1. Nonproprietary Names

BP: Stearic acid  
USPNF: Stearic acid

## 2. Synonyms

570; *Crodacid*; *Crosterene*; *Glycon S-90*; *Hystrene*; *Industrene*; *Kortacid 1895*; *Pristerene*.

## 3. Chemical Name and CAS Registry Number

Octadecanoic acid [57-11-4]

## 4. Empirical Formula Molecular Weight

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

The BP 1993 and the USPNF XVII describe stearic acid as a mixture of stearic acid ( $C_{18}H_{36}O_2$ ) and palmitic acid ( $C_{16}H_{32}O_2$ ). 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 USPNF XVII also contains a monograph for purified stearic acid, *see* Section 18.

## 5. Structural Formula

$CH_3(CH_2)_{16}COOH$

## 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<sup>(1-3)</sup> although it may also be used as a binder,<sup>(4)</sup> or in combination with shellac as a tablet coating. 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.<sup>(5,6)</sup> 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 also widely used in cosmetics and food products.

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 and taste suggesting tallow. *See also* Section 13.

### SEM: 1

Excipient: Stearic acid, 95% (*Emersol 153*)

Manufacturer: Emery Industries

Lot No.: 18895

Magnification: 120x

Voltage: 10 kV



### SEM: 2

Excipient: Stearic acid, food grade (*Emersol 6332*)

Manufacturer: Emery Industries

Lot No.: 18895

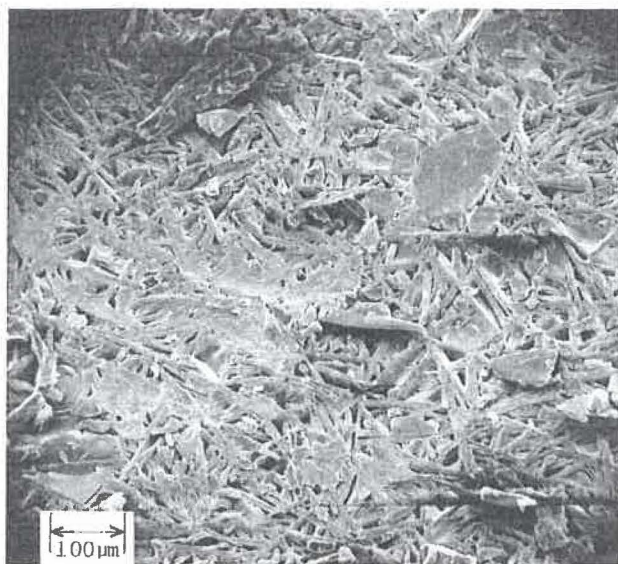
Magnification: 120x

Voltage: 10kV

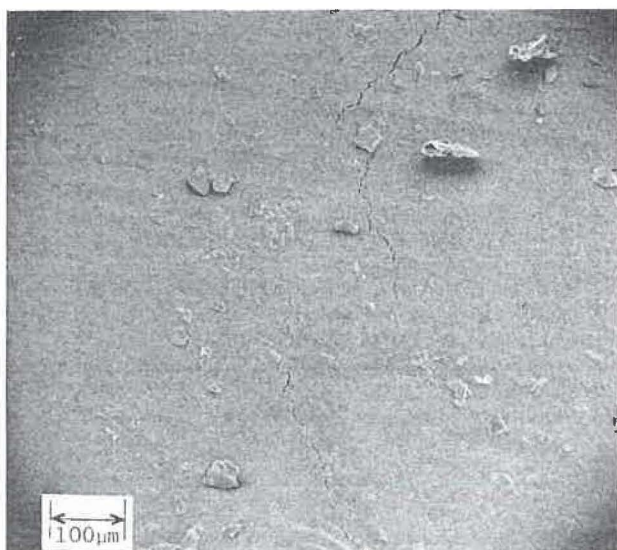


**SEM: 3**

Excipient: Stearic acid USP (*Hydrofol Acid 1655*)  
 Manufacturer: Sherex Chemical Company Inc  
 Lot No.: 9303-M639-521  
 Magnification: 120x  
 Voltage: 10kV

**SEM: 4**

Excipient: Stearic acid (*Hydrofol Acid 1870*)  
 Manufacturer: Sherex Chemical Company Inc  
 Lot No.: 9227-M635-421  
 Magnification: 120x  
 Voltage: 10kV

**9. Pharmacopeial Specifications**

Test	BP 1993	USPNF XVII (Suppl 6)
Identification	+	+
Congealing temperature	≥ 54°C	≥ 54°C
Residue on ignition	—	≤ 0.1%
Sulfated ash	≤ 0.1%	—
Heavy metals	≤ 20 ppm	≤ 0.001%
Mineral acid	+	+
Neutral fat or paraffin	—	+
Acid value	200-212	—
Iodine value	≤ 4.0	≤ 4.0
Organic volatile impurities	—	+
Assay of stearic acid	≥ 40.0%	≥ 40.0%
Assay of both acids	≥ 90.0%	≥ 90.0%

**10. Typical Properties**

*Acid value:* 200-212

*Density (bulk):* ≈ 0.8 g/cm<sup>3</sup>

*Melting point:* ≥ 54°C

*Moisture content:* contains practically no water.

*Saponification value:* 200-220

*Solubility:* freely soluble in benzene, carbon tetrachloride, chloroform and ether; soluble in ethanol, hexane and propylene glycol; practically insoluble in water.

See also Section 18.

**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 oxidizing agents.

Insoluble stearates are formed with many metals; 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 that have suggested incompatibilities, e.g. naproxen,<sup>(7)</sup> may not necessarily be applicable to formulated products.

Stearic acid has been reported to cause pitting in the film-coating of tablets coated using an aqueous film-coating technique; the pitting was found to be a function of the melting point of the stearic acid.<sup>(8)</sup>

**13. Method of Manufacture**

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

Stearic acid may also be manufactured by 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

Table I: Specifications of different stearic acid grades (Witco Corporation).

Product	Stearic acid content (%)	Titer (°C)	Acid value	Iodine value	Saponification value	Unsapoifiable 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	58-62	200-207	≤ 1.5	200-208	≤ 0.5
Industrene 8718	87	64.5-67.5	196-201	≤ 2.0	196-202	≤ 1.5

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. 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<sub>50</sub> (mouse, IV): 23 mg/kg<sup>(9)</sup>

LD<sub>50</sub> (rabbit, skin): > 5 g/kg

LD<sub>50</sub> (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.

#### 16. Regulatory Status

GRAS listed. Accepted as a food additive in the UK. Included in the FDA Inactive Ingredients Guide (buccal tablets, oral capsules, solutions, suspensions and tablets, topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

#### 17. Pharmacopeias

Aust, Belg, Br, Braz, Chin, Cz, Egypt, Fr, Hung, Ind, It, Jpn, Mex, Nord, Rom, Swiss, USPNF and Yug.

#### 18. Related Substances

Calcium Stearate; Magnesium Stearate; palmitic acid; purified stearic acid; Zinc Stearate.

#### Palmitic acid: C<sub>16</sub>H<sub>32</sub>O<sub>2</sub>

Molecular weight: 256.42

CAS number: [57-10-3]

Synonyms: cetylic acid; hexadecanoic acid; hexadecylic acid.

Appearance: the pure material is a white, crystalline powder.

Boiling point: 215°C

Density: 0.853 g/cm<sup>3</sup> at 62°C

Melting point: 63-64°C

Refractive index: n<sub>D</sub><sup>80</sup> = 1.4273

Solubility: freely soluble in chloroform; ether, propan-2-ol and hot ethanol (95%); sparingly soluble in ethanol (95%); practically insoluble in water.

#### Purified stearic acid: C<sub>18</sub>H<sub>36</sub>O<sub>2</sub>

Molecular weight: 284.47

CAS number: [57-11-4]

Synonyms: octadecanoic acid.

Pharmacopeias: USPNF.

Acid value: 195-200

Boiling point: 361°C

Density: 0.847 g/cm<sup>3</sup> at 70°C

Flash point: 196°C

Iodine number: ≤ 1.5

Melting point: 66-69°C

Refractive index: n<sub>D</sub><sup>80</sup> = 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: purified stearic acid contains not less than 96.0% of stearic and palmitic acid, of which, stearic acid constitutes not less than 90.0% of the total.

#### 19. Comments

A wide range of different grades of stearic acid are commercially available which have varying chemical compositions and hence different physical and chemical properties, see Table I.<sup>(10)</sup>

#### 20. Specific References

- Iranloye TA, Parrott EL. Effects of compression force, particle size, and lubricants on dissolution rate. *J Pharm Sci* 1978; 67: 535-539.
- Jarosz PJ, Parrott EL. Effect of tablet lubricants on axial and radial work of failure. *Drug Dev Ind Pharm* 1982; 8: 445-453.
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**21. General References**

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

**22. Authors**

USA; LV Allen.

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*Entonox*, 324  
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