# Handbook of PHARMACEUTICAL EXCIPIENTS



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**Second Edition** 

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## Corn Oil

### 1. Nonproprietary Names

USPNF: Corn oil

### 2. Synonyms

Calchem IVO-108; Lipex 104; maize oil.

### 3. Chemical Name and CAS Registry Number

Corn oil [8001-30-7]

### 4. Empirical Formula Molecular Weight

Corn oil is composed of fatty acid esters with glycerol, known commonly as triglycerides. Typical corn oil produced in the US contains five major fatty acids: linoleic 58.9%; oleic 25.8%; palmitic 11.0%; stearic 1.7% and linolenic 1.1%. Corn grown outside the US corn belt, including other countries, yields corn oil with lower linoleic, higher oleic and higher saturated fatty acid levels. Corn oil also contains small quantities of plant sterols.

### 5. Structural Formula

See Section 4.

### 6. Functional Category

Oleaginous vehicle; solvent.

# 7. Applications in Pharmaceutical Formulation or Technology

Corn oil is used primarily in pharmaceutical formulations as a solvent for intramuscular injections or as a vehicle for topical preparations. Emulsions containing up to 67% corn oil are also used as oral nutritional supplements, *see also* Section 19. Corn oil has a long history of use as an edible oil.

### 8. Description

Clear, light yellow colored, oily liquid with a faint characteristic odor and slightly nutty, sweet taste resembling cooked sweet corn.

### 9. Pharmacopeial Specifications

Test	USPNF XVII		
Specific gravity	0.914-0.921	-	
Heavy metals	≤ 0.001%		
Cottonseed oil	+		
Fatty acid composition	+		
Free fatty acids	+		
Iodine value	102-130		
Saponification value	187-193		
Unsaponifiable matter	≤ 1.5%		

### 10. Typical Properties

Acid value: 2-6

Autoignition temperature: 393°C

Density: see HPE Data. Flash point: 321°C Hydroxyl value: 8-12 Melting point: -18 to -10°C

Refractive index:

 $n_{\rm D}^{25} = 1.470 - 1.474;$  $n_{\rm D}^{40} = 1.464 - 1.468.$ 

Solubility: slightly soluble in ethanol (95%); miscible with

benzene, chloroform, ether and hexane. Viscosity (dynamic): see HPE Data.

	HPE Laboratory Project Data			
	Method	Lab #	Results	
Density	DE-5	30	0.918 g/cm <sup>3 (a)</sup>	
	DE-5	30	0.915 g/cm <sup>3 (b)</sup>	
Viscosity	VIS-2	30	38.83 mPa s (a)	
	VIS-2	30	37.36 mPa s (b)	

Supplier: a. Welch, Holme & Clark Co; b. Capital.

### 11. Stability and Storage Conditions

Corn oil is stable when protected with nitrogen in tightly sealed bottles. On prolonged exposure to air it thickens and becomes rancid. Corn oil may be sterilized by dry heat, maintaining it at 150°C for one hour. (1)

Corn oil should be stored in an airtight, light-resistant container in a cool, dry, place.

### 12. Incompatibilities

### 13. Method of Manufacture

Refined corn oil is obtained from the germ or embryo of Zea mays Linné (Fam. Gramineae) which contains nearly 50% of the fixed oil, compared with 3.0-6.5% in the whole kernel. The oil is obtained from the embryo by expression and/or solvent extraction. The crude oil is then refined to remove free fatty acids, phospholipids and impurities. It is bleached with solid adsorbents to lighten its color, dewaxed by chilling (which removes any solid waxy components) and deodorized at high temperature, under vacuum, to produce a bland, odorless, edible product.

### 14. Safety

Based upon its extensive history of food usage corn oil is generally regarded as a nontoxic and nonirritant material.

### 15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Spillages of this material are very slippery and should be covered with an inert absorbent material prior to disposal.

### 16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (IM injections, oral capsules, suspensions, tablets and topical emulsions).

### 17. Pharmacopeias

Cz, Egypt, Fr, Jpn, Mex and USPNF.

### 18. Related Substances

Canola Oil; Cottonseed Oil; Peanut Oil; Sesame Oil; Soybean Oil.



### 19. Comments

Corn oil contains a high content of unsaturated acids and has been used to replace fats and oils containing a high content of saturated acids in the diets of patients with hypercholesterolemia.

### 20. Specific References

 Pasquale D, Jaconia D, Eisman P, Lachman L. A study of sterilizing conditions for injectable oils. Bull Parenter Drug Assoc 1964; 18(3): 1-11.

### 21. General References

- Mann JI, Carter R, Eaton P. Re-heating corn oil does not saturate its double bonds [letter]. Lancet 1977; ii: 401.
- Strecker LR, Maza A, Winnie GF. Corn oil composition, processing and utilization. In: Erickson DR, editor. World conference proceedings. Edible fats and oils processing: basic principles and modern practices. American Oil Chemist's Society, 1990: 309-323.
- Watson SA, Ramstead PE, editors. Corn chemistry and technology. St. Paul: American Association of Cereal Chemists Inc, 1987: 53-78.

### 22. Authors

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