



Capmul[®] GMO-50, EP / NF

CAS Number: 25496-72-4

Meets current European Pharmacopoeia / United States Pharmacopoeia / National Formulary
Monographs for *Glycerol Monooleates, 60%*.

Synonyms:

Glycerol Mono-oleate

Product Type:

Capmul[®] GMO-50, EP / NF (Glycerol Monooleate) is a mixture of monoglycerides, mainly glycerol monooleate, together with variable quantities of diglycerides and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of oleic acid, or by esterification of glycerol with oleic acid of vegetable origin. A suitable antioxidant may be added. **Capmul[®] GMO-50, EP / NF** is a multi-functional emulsifier useful in the production of pharmaceutical and food products. **Capmul[®] GMO-50, EP / NF** conforms to the specific citations in the U.S. Code of Federal Regulations (21 CFR § 184.1505 and 21 CFR § 184.1323).

Specifications:

Specification	Limit	Test Method
Characters	Pass	¹ EP
Identification A, B	Pass	EP / ² NF
Identification C	Pass	EP
Acid Value	6.0 max.	EP / NF
Iodine Value	65.0-95.0	EP / NF
Peroxide Value	12.0 max.	EP / NF
Saponification Value	150-170	EP / NF
Free Glycerol (%)	6.0 max.	EP / NF
Fatty Acid Composition		EP / NF
Palmitic Acid (16:0)	12.0% max.	
Stearic Acid (18:0)	6.0% max.	
Oleic Acid (18:1)	60.0% min.	
Linoleic Acid (18:2)	35.0% max.	
Linolenic Acid (18:3)	2.0% max.	
Arachidic Acid (20:0)	2.0% max.	
Eicosenoic Acid (20:1)	2.0% max.	
Water (%)	1.0% max.	EP / NF
Total Ash (%)	0.1 max.	EP / NF
Assay		EP / NF
Monoacylglycerols	55.0-65.0%	
Diacylglycerols	15.0-35.0%	
Triacylglycerols	2.0-10.0%	

¹EP: Current European Pharmacopoeia

²NF: Current United States Pharmacopoeia / National Formulary



Capmul[®] GMO-50, EP / NF

Regulatory:

- Meets current European Pharmacopoeia monograph for “Glycerol Mono-Oleates.”
- Meets current USP / National Formulary monograph for “Glyceryl Monooleates.”
- Generally recognized as safe (GRAS) according to 21 CFR § 184.1505 and 21 CFR § 184.1323.

Functions:

- Emulsifier
- Solubilizer
- Bioavailability Enhancer
- Emollient

Pharmaceutical Applications:

- Suppository
- Transdermal delivery Systems
- Self-emulsifying drug delivery systems
- Micro emulsions

Shelf-Life:

- Retest and re-qualify 12 months from the date of manufacture.

Storage:

- Store in a dry location at 68-77 °F.
- Preserve in tight containers.
- Protect from light.

Standard Package:

- Tank car
- Tank wagon
- 400 lb. (182 kg) drums
- 50 lb. (22.7 kg) pails

The information contained in this bulletin to the best of our knowledge is currently true and accurate. Any recommendations or suggestions are made without warranty or guarantee since, among other reasons, the conditions of storage and use are beyond our control.