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CAPMUL® MCM EP/NF

Ingredients: Caprylic/capric mono- & diglycerides

Chemical Name: Glyceryl caprylate/caprate

Description

Mixture of monoacylglycerols, obtained by direct esterification of glycerol with caprylic (octanoic) and capric (decanoic) acids.

Specifications

Specification	Limit	Reference Method
Acid Value (mg KOH/g)	<u><</u> 3.0	¹ EP/NF ²
Free Glycerol (%)	<u><</u> 3.0	EP/NF
Identification Tests	Pass	EP
Peroxide Value (mEq/kg)	<u><</u> 1	NF
Saponification Value (mg KOH/g)	250-280	NF
Total Ash (%)	<u><</u> 0.5	EP/NF
Water (%)	<u><</u> 0.5	EP/NF
Assay Monoacylglycerols (%)	45.0-75.0	EP/NF
Diacylglycerols (%)	20.0-50.0	EP/NF
Triacylglycerols (%)	<u><</u> 10.0	EP/NF
Fatty Acid Composition C6 (%)	<u><</u> 3.0	EP/NF
C8 (%)	50.0-90.0	EP/NF
C10 (%)	10.0-50.0	EP/NF
C12 (%)	<u><</u> 3.0	EP/NF
C14 (%)	<u><</u> 1.0	EP/NF

¹EP: European Pharmacopoeia

Typical Properties

Property	Range
Appearance/Form (@ 20°C)	Colorless or slightly yellow oily liquid or soft mass

Recommended Storage and Handling

- Store in tight, light-resistant containers in a dry location at ambient temperature.
- Retest/requalify 20 months after date of manufacture.
- Contents of package may need to be heated slightly with agitation to ensure uniformity prior to use (maximum of 6 heat cycles), details upon request.

Regulatory

- 1.2Meets the EP (European Pharmacopoeia) and USP/NF (United States Pharmacopeia / National Formulary) Monographs for "Glycerol (glyceryl) Monocaprylocaprate" Type I.
- If tested, expected to meet the USP/NF (United States Pharmacopeia / National Formulary) Monograph for "Mono- and Di-glycerides." Please contact the Business Manager for further details or advance requirements.
- Mono- and diglycerides are generally recognized as safe (GRAS) when used according to 21 CFR § 184.1505.

Applications

- Bioavailability enhancer
 Solubilizer
- Emulsifier / co-emulsifier
 Carrier (vehicle)
- Penetration enhancer (dermatological applications)

Standard Packaging

- 425 lb (192.8 kg) drum
- 50 lb (22.7 kg) HDPE jerrican

DISCLAIMER:

PLEASE NOTE: This specification is provided for information purposes only and should not be relied upon as a basis for product performance. It is suggested that you evaluate the product on at least a laboratory basis prior to its commercial usage. This specification may be superseded by a later issue. Please consult your sales representative to confirm that you have the correct specification. NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A SPECIFIC USE OR PURPOSE, EXPRESS OR IMPLIED, ARE MADE. These specifications are not intended to be, and shall not be construed to be, instructions or suggestions for use which may be in violation of valid patent rights.

²NF: United States Pharmacopeia/National Formulary