

3/26/2024

# ABISOL<sup>™</sup> Emulsion Preconcentrate Kit

- Ingredients: Medium Chain Triglycerides; Glyceryl Mono and Dicaprylocaprate; Linoleoyl Polyoxylglycerides; and Polyoxyl 35 Castor Oil
- Synonyms: Glycerol Tricaprylate/Caprate (Captex<sup>®</sup> 300 EP/NF); Glyceryl Monocaprylate Type I (Capmul<sup>®</sup> MCM EP/NF); Corn Oil PEG-6 Esters/ Linoleoyl Macrogolglycerides (Acconon<sup>®</sup> CMG-6 EP/NF); and Macgrogolglycerol Ricinoleate/Polyethoxylated Castor Oil

#### Description

The ABISOL Emulsion Preconcentrate Kit includes five emulsion preconcentrates, each with a different hydrophobicity profile. ABISOL Emulsion Preconcentrates have calculated Hydrophobic-Lipophilic Balance (HLB) values that range between 5 and 10.

Each preconcentrate is a uniform blend of CAPTEX<sup>®</sup> 300 EP/NF, CAPMUL<sup>®</sup> MCM EP/NF, polyethoxylated castor oil EP/NF, and, at times, contains ACCONON<sup>®</sup> CMG-6 EP/NF at predefined w/w ratios.

#### Specifications

	ABISOL Emulsion Preconcentrates							
Property		Ш	ш	IV	۷			
Appearance	Clear Yellow Liquid	Clear Yellow Liquid	Clear Yellow Liquid	Clear Yellow Liquid	Clear Yellow Liquid			
Density @ 25°C (g/mL)	0.874- 1.069	0.887- 1.084	0.897- 1.096	0.900- 1.101	0.926- 1.132			
Viscosity @ 25°C (cSt)	79.4- 97.0	101.2- 123.6	143.2- 175.0	185.6- 226.8	261.3- 319.3			

<sup>1</sup>EP/ Ph.Eur.: European Pharmacopoeia

<sup>2</sup>NF: United States Pharmacopeia/National Formulary

## **Typical Properties**

ABISOL Emulsion Preconcentrates								
Property		II	III	IV	V			
Calculated HLB	5.3	6.25	7.5	8.5	9.9			

## Applications

- Formulation Aid
- Solubility Enhancement
- Reduce Food Effect

#### **Recommended Storage and Handling**

- Retest/requalify 18 months from date of manufacture.
- Store in tightly closed containers below 35°C.

### Packaging

- . Kit containing five 8-ounce glass jars
- · 50 lb (22.7 kg) HDPE jerrican

### Regulatory

- · CAPTEX® 300 EP/NF
- <sup>1</sup> Ph.Eur & <sup>2</sup>USP/NF: *Medium-Chain Triglycerides* • CAPMUL<sup>®</sup> MCM EP/NF
- Ph.Eur: Glycerol Monocaprylocaprate Type I USP/NF: Glyceryl Mono and Dicaprylocaprate
- ACCONON<sup>®</sup> CMG-6 EP/NF Ph.Eur: Linoleoyl Macrogolglycerides USP/NF: Linoleoyl Polyoxylglycerides
- Polyethoxylated Castor Oil Ph.Eur: Macrogolglycerol Ricinoleate USP/NF: Polyoxyl 35 Castor Oil

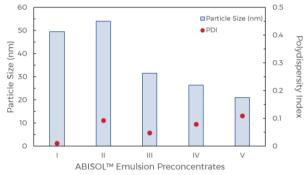
### DISCLAIMER:

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.



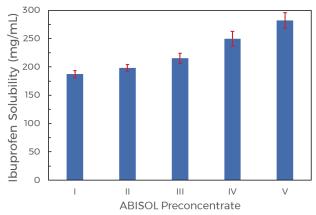
#### **Application Data**

Particle size of 1% w/w emulsions in deionized water.



**Fig. 1. Emulsions made with ABISOL preconcentrates.** Representative data composed of 1% w/w emulsions of each ABISOL preconcentrate prepared by adding 1 g of preconcentrate to 99 grams of deionized water and mixing for 5 minutes with a magnetic stir bar and magnetic stir plate. Emulsion particle size and polydispersity indexes were obtained using a Malvern Zetasizer.

Comparison of Ibuprofen (IBU) solubility in ABISOL Emulsion Preconcentrates.

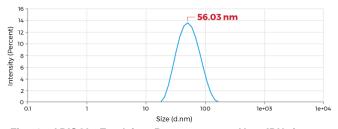


**Fig. 2. IBU has the highest solubility in ABISOL Preconcentrate V.** Excess IBU (1.6 g) was added to each preconcentrate (4 g) and allowed to mix for 24 hours. IBU concentration was determined by measuring the absorbance at 265 nm and comparing it to a standard curve. Each experiment was repeated in triplicate (n=3).

#### **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.

Particle size of the ABISOL Preconcentrate V + IBU emulsion.



**Fig. 3. ABISOL Emulsion Preconcentrate V + IBU forms a nanoemulsion.** IBU dissolved in ABISOL Emulsion Preconcentrate V was diluted 100-fold by placing 1 g into 99 g of deionized water and mixed for 2 minutes with a magnetic stir bar and a magnetic stir plate. Particle size was measured on a Malvern Zetasizer.

#### Version: 6