

#### **OUR SOLUTIONS PORTFOLIO**

ABITEC products are specifically designed for meeting the solubility challenges of the pharmaceutical industry. Our products can be used alone or in conjunction with one another to formulate a Self-Emulsifying Drug Delivery System (SEDDS).

#### **CAPMUL® Where Formulation Begins™**

This line is a highly-functional, highly reproducible medium and long chain monoglycerides (MCM). The CAPMUL line can be used alone as a primary solubilizer or in conjunction, as an emulsifier, with other ABITEC ingredients.

#### **CAPTEX®**

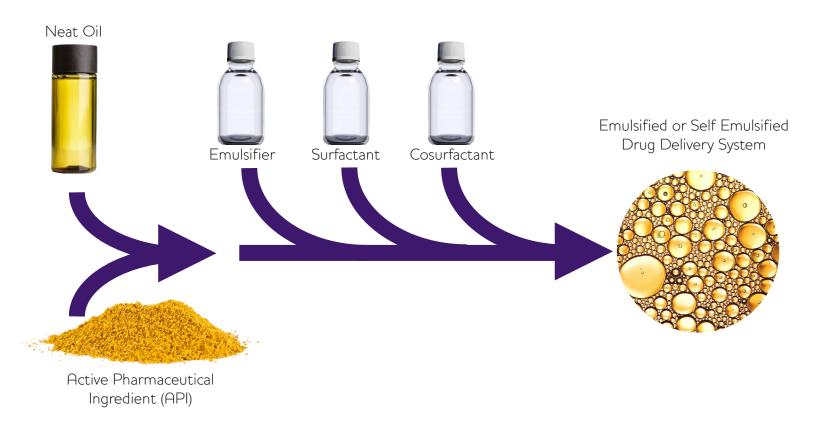
This line of highly-functional, highly reproducible medium chain triglycerides is manufactured by the complete esterification of glycerol or propylene glycol with select fatty acids.

#### **ACCONON®**

This line of highly-functional, highly reproducible pegylated esters is manufactured by the esterification of polyethylene glycol with selected fatty acids

All grades are designed to simultaneously meet both the application needs of respective individual pharmaceutical formulations, as well as regulatory monographs.

### **CAPMUL + CAPTEX + ACCONON = SEDDS**



#### **MORE APPLICATIONS**

The **STEROTEX** line is a high-functional, high-reproducible line of hydrogenated vegetable oil, which has numerous applications in the pharmaceutical industry including:

- Lubrication for direct compression tableting
- Sustained-release multi-particulate formulations
- Taste masking
- Abuse deterrence
- Moisture barrier

## ORAL APPLICATIONS

## UNLOCKING BIOAVAILABILITY™

The majority of NCE's being considered for therapeutic applications are BCS Class II, Class III, or Class IV, indicating that these potential API's will exhibit solubility and/or permeability challenges. Functional lipids are one of the most widely employed excipient classes utilized in overcoming both solubility and permeability challenges. Many API's which are insoluble in aqueous media can be dissolved in functional lipids improving their solubility by means of generating an oil/water emulsion carrier system for the API. The lipid excipients that ABITEC produces are critical components across a multitude of drug formulations and are used for various dosage forms, one of which is oral.

#### Focused on Formulation

ABITEC is a developer and manufacturer of functional lipids for the application challenges of the pharmaceutical industry. Our products improve the bioavailability of API's, provide for sustained release, abuse deterrence, taste masking, moisture barrier and lubrication applications.

#### Improves solubility

- Neat lipid solubilization where the drug is dissolved in one functional lipid
- SEDDS formulation employing combinations of functional lipids, surfactants and co-surfactants to generate a micellar transport carrier for API's



#### **Enhances permeability**

- API's effected by PGP Mediated Efflux
- Polar API's transported by paracellular mechanism

#### **Quality & Regulatory Standards**

A commitment to create high quality monograph excipients with precedence of use.

#### Technical Support & Expertise

Our diverse group of formulators, application scientists and material experts are here to provide you extensive product, regulatory and technical support.





#### **Production Capabilities**

Extensive synthesis and manufacturing capabilities that are highly focused on cGMP, IPEC and ISO standards. ABITEC products are manufactured in the US and are highly reproducible.









## **EXCIPIENT CLASSIFICATION**

Trade Name	Chemical Name	Monograph	
Captex® 300 EP/NF	Caprylic/Capric Triglyceride	Medium Chain Triglyceride (EP, NF)	
Captex® 300 Low C6 EP/NF/JPE	Caprylic/Capric Triglyceride	Medium Chain Triglyceride (EP/NF/JPE)	
Captex® 355 EP/NF	Caprylic/Capric Triglyceride	Medium Chain Triglyceride (EP, NF)	
Capmul® MCM EP/NF	Glyceryl Caprylate/Caprate	Glyceryl Monocaprylocaprate Type I (EP) Glyceryl Monocaprylocaprate Type I (NF)	
Capmul® MCM C8 EP	Glyceryl Monocaprylate Glycerol Monocaprylate Type		
Capmul® GMO-50 EP/NF	Glyceryl Monooleate	Glyceryl Monooleate Glyceryl Monooleate (EP) Glyceryl Monooleate (NF)	
Capmul® 808G EP/NF	Glyceryl Monocaprylate	nocaprylate Glycerol Monocaprylate Type II (EP, NF)	
Capmul® PG-2L EP/NF	Propylene Glycol Dilaurate	Propylene Glycol Dilaurate (EP, NF)	
Capmul® PG-8 NF	Propylene Glycol Monocaprylate	Propylene Glycol Monocaprylate Type II	
Capmul® PG-8-70 NF	Propylene Glycol Monocaprylate	Proplylene Glycol Monocaprylate Type I	
Capmul® PG-12 EP/NF	Propylene Glycol Monolaurate Proplylene Glycol Monolaurate Type		
Acconon® MC8-2 EP/NF	PEG-8 Carpylic/Capric Glycerides Caprylocaproyl Macrogolglycerides (EP Caprylocaproyl Polyoxyglycerides (NF)		
Acconon® C-44 EP/NF	PEG-32 Lauric Glycerides  Lauroyl Macrogolglycerides (EP)  Lauroyl Polyoxyglycerides (NF)		
Acconon® C-50 EP/NF	Stearoyl Macrogolglycerides Stearoyl Polyoxylglycerides	Stearoyl Macrogolglycerides (EP) Stearoyl Polyoxyglycerides (NF)	
Acconon® AKG-6 EP/NF	Oleoyl Macrogolglycerides, Oleoyl Polyoxylglycerides	Oleoyl Macrogolglycerides (EP) Stearoyl Polyoxyglycerides (NF)	
Sterotex® NF	Hydrogenated Cottonseed Oil Hydrogenated Vegetable Oil Type I (NF), Hydrogenated Vegetable Oil (BP)		
Sterotex® HM NF	Hydrogenated Soybean Oil Hydrogenated Vegetable Oil Type I (NF), Hydrogenated Vegetable Oil (BP)		
Sterotex <sup>®</sup> K NF	Hydrogenated Soybean Oil and Castor Wax	HVaroaenatea Veaetanie ( )ii IVDE L(IVIE)	

Ask us about our non-monographed customized excipient

Fatty Acid Distribution (%)	Melting Point	Composition (%)	Appearance
Capric (C10) 25 - 35 Caprylic (C8) ≈70		Triglyceride (100)	Clear colorless liquid
Capric (C10) 25 - 35 Caprylic (C8) ≈70		Triglyceride (100)	Clear colorless liquid
Capric (C10) 35 - 45 Caprylic (C8) ≈55		Triglyceride (100)	Clear colorless liquid
Capric (C10) 10-50 Caprylic (C8) 50-90		Monoglyceride (45-75) Diglyceride (20-50) Triglyceride (<10)	Colorless or slightly yellow liquid or soft mass
Caprylic (C8) ≥90		Monoglyceride (45-75) Diglyceride (20-50) Triglyceride (<10)	Colorless or slightly yellow liquid or soft mass
Oleic (C18:1) ≥60 Linoleic (C18:2) ≤35		Monoglyceride (55-65) Diglyceride (15-35) Triglyceride (2-10)	Amber liquid or semi-solid
Caprylic (C8) ≥90		Monoglyceride (≥80) Diglyceride (≤20) Triglyceride (≤5)	Colorless or slightly yellow solid
Lauric (C12) ≥95		Propylene Glycol Diesters (≥70) Propylene Glycol (≤30)	Colorless or slightly yellow liquid
Caprylic (C8) ≥90		Propylene Glycol Monoesters (≥90)	Colorless liquid
Caprylic (C8) ≥90		Propylene Glycol Monoesters (55-80) Propylene Glycol Diesters (20-45)	Colorless or slightly yellow liquid
Lauric (C12) ≥95		Propylene Glycol Monoesters (≥90)	Colorless or slightly yellow liquid
Capric (C10) 30-40 Caprylic (C8) 60-70			Clear colorless liquid
Lauric (C12) 40-50			Pale yellow solid
Palmitic (C16) 40-50 Stearic (C18) 48-58			Pale yellow solid
Oleic Acid (C18:1) 58-80 Linoleic Acid (C18:2) 15-35			Light amber liquid
	≈63 °C		Fine white powder
	≈69 °C		Fine white powder
	≈83 °C		Fine white powder



# Start Formulating Today Let us Help!



#### Need formulation assistance?

Let our technical team assist you in your formulation needs, email Amanda Coulter at acoulter@abiteccorp.com



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