Pharmaceutical EXCIPIENTS
Breaking the Barrier of Drug Delivery

www.abiteccorp.com
ABITEC develops and manufactures lipid-based excipients to enhance the bioavailability of poorly water-soluble and poorly permeable Active Pharmaceutical Ingredients (APIs) for the pharmaceutical industry. These highly-functional, highly-reproducible, monograph compliant lipid excipients are produced in ISO certified facilities in accordance with cGMP and IPEC guidelines.
ABITEC is your expert in pharmaceutical lipid excipients.

ABITEC is a global leader in the development and manufacturing of speciality lipids and emulsifiers for the pharmaceutical, nutritional, and speciality chemical markets. Through our world-class technical, scientific, regulatory, and manufacturing expertise, we deliver high quality functional lipids that aid in solubilization, emulsification, and improved processing.

Pharmaceutical Health Offerings

ABITEC’s portfolio offers functional excipients for a wide range of dosage forms and applications

**Dosage Forms**
- ORAL
- TOPICAL
- TRANSDERMAL
- SUPPOSITORIES
- INJECTABLE
- OPHTHALMIC
- INHALED

**Applications**
- SOLUBILIZATION
- EMULSIFICATION
- DRY BINDING
- PERMEATION ENHANCEMENT
- ENCAPSULATION
- CONTROLLED RELEASE
- PROCESSING AIDS
- SOLID LIPID CARRIER SYSTEMS
Safe, High-Quality, Certified Ingredients.

- ISO 9001
- cGMP*
- HACCP**
- IPEC Member
- ISO 14001
- OHSAS 18001

*ABITEC follows requirements for United States 21 CFR § 110 Current Good Manufacturing Practice in the Manufacturing, Packing or Holding of Human Food or the Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2006, for applicable products.

**ABITEC follows HACCP for manufacturing of food products
DOSAGE VERSATILITY

ORAL
- Formulation of single lipid systems and self-emulsifying drug delivery systems (SEDDS)
- Manufacture of modified release systems, such as sustained release, controlled release, and extended release
- Readily employable as lubrication, dry-binding, and formulation processing aids

INJECTABLE
- Injectable lipids manufactured for the rigorous requirements of injectable formulations
- Increased solubilization of lipophilic actives
- Formulation of oil in water emulsions for injection
- Formulation of oleaginous solutions for intramuscular and subcutaneous injection

TOPICAL & TRANSDERMAL
- Increased solubilization of actives employed in creams and gels
- Penetration enhancers for transdermal delivery creams, gels, and delivery systems
- Formulation of emulsified creams and gels

SUPPOSITORIES
- Lipophilic bases for the formulation of suppositories
- Functional lipids for dissolving actives and incorporating them into suppositories

OPHTHALMIC
- Increased solubility of ophthalmic actives
- Formulation of oil in water emulsions for ophthalmic administration

INHALED
- Development of oil in water emulsions for carrying actives directly to the lungs or nasal mucosa
- Improved solubilization of hydrophobic actives for intranasal and pulmonary drug delivery
Excipients for Every Application

DRY BINDING
- Increase the hardness and reduce the friability of directly compressed tablets
- Plastically deforming lipids which decrease edge abrasion and increase tablet durability

STEROTEX® Powders

PERMEATION ENHANCEMENT
- Functional lipids which can increase the permeation of BCS Class III and BCS Class IV actives
- Increase permeation of polar molecules with functional groups which are ionized at biological pH
- Increase permeation of actives effected by PGP mediated efflux

CAPTEX®
CAPMUL®
ACCONON®

ENCAPSULATION
- Formulation of functional multi-particulates
- Use in both matrix and encapsulated multi-particulates
- Employ in both congealing and molten fluid bed unit operations

STEROTEX® Powders
ACCONON®
CAPMUL® Oils
CAPMUL® Powders
CAPTEX®

CONTROLLED RELEASE
- Formulation of both matrix and encapsulated controlled release
- Formulation of controlled release multi-particulates for use in tablet and capsule formulations
- Directly-compressed matrix controlled release tablet formulations

STEROTEX® Powders
CAPMUL® Oils
CAPMUL® Powders
HYDRO~KOTE®
BBS-C®

PROCESSING AIDS
- Direct-compression, free-fraction tablet lubricants which reduce ejection force but allow for faster disintegration times than surface spreading lubricants
- Soft gel lubricants which allow for less washing and ease of capsule printing
- Binder excipients for hot melt granulation and extrusion

STEROTEX® Powders
CAPMUL®
CAPTEX®

SOLUBILIZATION
- Increase the solubility of BCS Class II and BCS Class IV actives
- Increase the bioavailability of poorly water soluble actives
- Both single lipid and self-emulsifying drug delivery system (SEDDS) formulations of poorly water soluble APIs

CAPTEX®
CAPMUL®
ACCONON®

EMULSIFICATION
- Functional lipids for primary and secondary emulsification of actives
- Emulsifiers and surfactants for the formulation of self-emulsifying drug delivery systems (SEDDS)

CAPMUL®
ACCONON®

SOLID LIPID CARRIER SYSTEMS
- Functional lipids for the development of solid lipid nanoparticles and nanostructured lipids
- Provide for increased solubility, administration targeting, and adjustable release characteristics of hydrophobic actives in solid lipid matrices

CAPTEX®
CAPMUL®
ACCONON®

Featuring INJECTA™ parenteral-grade lipid excipients...

INJECTA lipid excipients undergo secondary sterile filtration and aseptic processing in state-of-the-art facilities to ensure products are of the highest quality. The entire INJECTA product line is tested for pyrogens, microbial contaminants, elemental impurities, and particulate matter by validated testing protocols.
Self-Emulsifying Drug Delivery Systems (SEDDS)

- Ever increasing numbers of Active Pharmaceutical Ingredients (APIs) are poorly water soluble and lipophilic in structure, creating challenges for the pharmaceutical market.

- Bioavailability Enhancement through the means of a SEDDS system is an effective way of delivering actives to their destination in the body.

- ABITEC Functional Excipients can be used alone or in conjunction with one another to formulate a SEDDS and improve solubility.
CAPMUL® Mono- and diglycerides
These functional lipid excipients act as solubilizers and emulsifiers in oral drug delivery systems. CAPMUL excipients are recognized as the ideal starting point when formulating BCS Class II & IV (poorly water soluble) and BCS Class III & IV (poorly permeable) molecules. Lipid based drug delivery systems may be formulated as liquid or semi-solid formulations for oral dosage forms.
CAPMUL® GDB EP/NF powders now available.

CAPTEX® Medium-Chain Triglycerides
CAPTEX medium-chain esters are preferred lipophilic vehicles and solvents, used alone or in combination with other excipients, in the development of solution, suspension, emulsion, and microemulsion formulations.

CAPROL® Polyglycerol Esters
Used as emulsifiers and solubilizers in an array of pharmaceutical applications because they offer a wide range of Hydrophilic-Lipophilic Balances (HLBs) meeting the needs of many formulation requirements.

ACCONON® Surfactants
Improve the bioavailability of poorly water soluble drugs by direct solubilization or by acting as a stabilizing surfactant in active carrying emulsions.

STEROTEX® Vegetable Oils
STEROTEX can be blended into powders for direct-compression in order to provide both lubrication and dry binding for tableting unit operations. Sterotex can also be melt processed to manufacture functional multi-particulates for use in sustained release, taste-masking, and abuse-deterrent applications.

HYDRO-KOTE®
HYDRO-KOTE hydrogenated vegetable oils are refined, bleached, and deodorized. Their unique properties make them very useful in a variety of applications for the pharmaceutical industry including, topical creams and ointments, suppositories, controlled release, and as a replacement to cocoa butter.

BBS-C Vegetable Oils
BBS-C is a partially hydrogenated vegetable oil (soybean & cottonseed) with superior creaming properties and resistance to oxidation. It is excellent for use in suspension formulations for softgels and syrups.
<table>
<thead>
<tr>
<th>Product</th>
<th>Form</th>
<th>Chemical Name</th>
<th>Description</th>
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<tbody>
<tr>
<td>CAPTEX® 170 EP</td>
<td>Liquid</td>
<td>Coco-Caprylate/Caprate</td>
<td>Cocoyl Caprylocaprate EP</td>
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<tr>
<td>CAPTEX 200P</td>
<td>Liquid</td>
<td>Propylene Glycol Dicaprylocaprate</td>
<td>Propylene Glycol Dicaprylocaprate EP, Propylene Glycol Dicaprylocaprate USP</td>
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<td>CAPTEX 300 EP/NF</td>
<td>Liquid</td>
<td>Glyceril Tricaprylate/Tricaprate</td>
<td>Medium-Chain Triglycerides EP; Medium-Chain Triglycerides USP/NF, JPE</td>
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<td>CAPTEX INJ 300 LOW C6 EP/NF/JPE</td>
<td>Liquid</td>
<td>Glyceril Tricaprylate/Tricaprate</td>
<td>Medium-Chain Triglycerides EP; Medium-Chain Triglycerides USP/NF, JPE</td>
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<td>CAPTEX 355 EP/NF/JPE</td>
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<td>Glyceril Tricaprylate/Tricaprate</td>
<td>Medium-Chain Triglycerides EP; Medium-Chain Triglycerides USP/NF, JPE</td>
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<td>CAPTEX INJ 355 EP/NF/JPE</td>
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<td>Medium-Chain Triglycerides EP; Medium-Chain Triglycerides USP/NF, JPE</td>
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<td>Liquid</td>
<td>Glyceril Tricaprylate, Tricaprylin</td>
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<td>CAPMUL® 808G EP/NF</td>
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<tr>
<td>CAPMUL GDB EP/NF</td>
<td>Powder</td>
<td>Glyceril Dibehenate</td>
<td>Glyceril Dibehenate USP/NF and Glycerol Dibehenate</td>
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<tr>
<td>CAPMUL GMO-50 EP/NF</td>
<td>Semi-Solid</td>
<td>Glyceril Monoooleate</td>
<td>Glycerol Monoooleate EP; Glycerol Monoooleate USP/NF, JPE</td>
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<tr>
<td>CAPMUL MCM C8 EP/NF</td>
<td>Liquid/Solid or Mix</td>
<td>Glyceril Monocaprylate</td>
<td>Glycerol Monocaprylate Type I EP, Glycerol Monocaprylate Type I USP/NF</td>
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<td>CAPMUL MCM NF</td>
<td>Liquid/Solid or Mix</td>
<td>Glyceril Caprylate/Caprate</td>
<td>Mono- and Di-Glycerides USP/NF</td>
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<td>CAPMUL MCM EP/NF</td>
<td>Liquid/Solid or Mix</td>
<td>Glyceril Caprylate/Caprate</td>
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<td>Liquid/Solid or Mix</td>
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<td>CAPMUL PG-8-70 NF</td>
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<td>Propylene Glycol Monocaprylate</td>
<td>Propylene Glycol Monocaprylate EP, Propylene Glycol Monocaprylate Type II USP</td>
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<td>CAPMUL PG-12 EP/NF</td>
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<td>Propylene Glycol Monolaurate</td>
<td>Propylene Glycol Monolaurate EP, Propylene Glycol Monolaurate Type II USP</td>
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<td>CAPROL® PGE 860</td>
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<td>Polyglycerol (10) Oleate, Polyglycerol Oleate</td>
<td>Polglycerol esters of fatty acids</td>
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<tr>
<td>ACCONON® AKG-6 EP/NF</td>
<td>Liquid</td>
<td>PEG-6 Oleic Glycerides</td>
<td>Oleyl Macroglycerides EP, Oleyl Polyoxyglycerides USP/NF, USP</td>
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<tr>
<td>ACCONON C-44 EP/NF</td>
<td>Solid</td>
<td>PEG-32 Lauric Glycerides</td>
<td>Lauroyl Macroglycerides EP, Lauroyl Polyoxyglycerides USP/NF, USP</td>
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<td>ACCONON C-50 EP/NF</td>
<td>Solid</td>
<td>PEG-32 Hydrogenated Palm Glycerides</td>
<td>Stearoyl Macroglycerides EP, Stearoyl Polyoxyglycerides USP/NF, USP</td>
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<tr>
<td>ACCONON CMG-6 EP/NF</td>
<td>Liquid</td>
<td>Linoleoyl Polyoxyglycerides (Corn Oil PEG-6 Esters)</td>
<td>Linoleoyl Polyoxyglycerides USP/NF, Linoleoyl Polyoxyglycerides EP</td>
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<tr>
<td>ACCONON MC8-2 EP/NF</td>
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<td>PEG-8 Caprylocaproyl/Capric Glycerides</td>
<td>Caprylocaproyl Macroglycerides EP, Caprylocaproyl Polyoxyglycerides USP/NF</td>
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<td>PEG-8 Caprylocaproyl/Capric Glycerides</td>
<td>Caprylocaproyl Macroglycerides EP, Caprylocaproyl Polyoxyglycerides USP/NF</td>
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<td>Hydrogenated Vegetable Oil Type I USP/N F</td>
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<td>STEROTEX NF</td>
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<td>Hydrogenated Vegetable Oil Type I USP/N F</td>
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<td>BBS-C</td>
<td>Semi-Solid</td>
<td>Partially Hydrogenated Soybean Oil/Cottonseed Oil</td>
<td>Hydrogenated Vegetable Oil Type II USP/N F</td>
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<td>HYDRO-KOTE® C</td>
<td>Solid/Flakes</td>
<td>Hydrogenated Cottonseed Oil</td>
<td>Hydrogenated Cottonseed Oil</td>
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<td>HYDRO-KOTE 112</td>
<td>Solid/Flakes</td>
<td>Hydrogenated PKO/Soy Lecithin</td>
<td>Hydrogenated Palm Kernel Oil w/soy lecithin</td>
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<td>Hydrogenated Palm Kernel Oil w/soy lecithin</td>
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Ask us about our non-monographed customized excipient grades to meet the specific needs of your API formulation.
ABITEC is a US-based company with first-class ISO certified cGMP facilities in Janesville, WI and Paris, IL, along with our corporate location in Columbus, OH. Since our founding in the 1960s, ABITEC continues to take pride in its dedication to its customers.