

# Pharmaceutical **EXCIPIENTS**

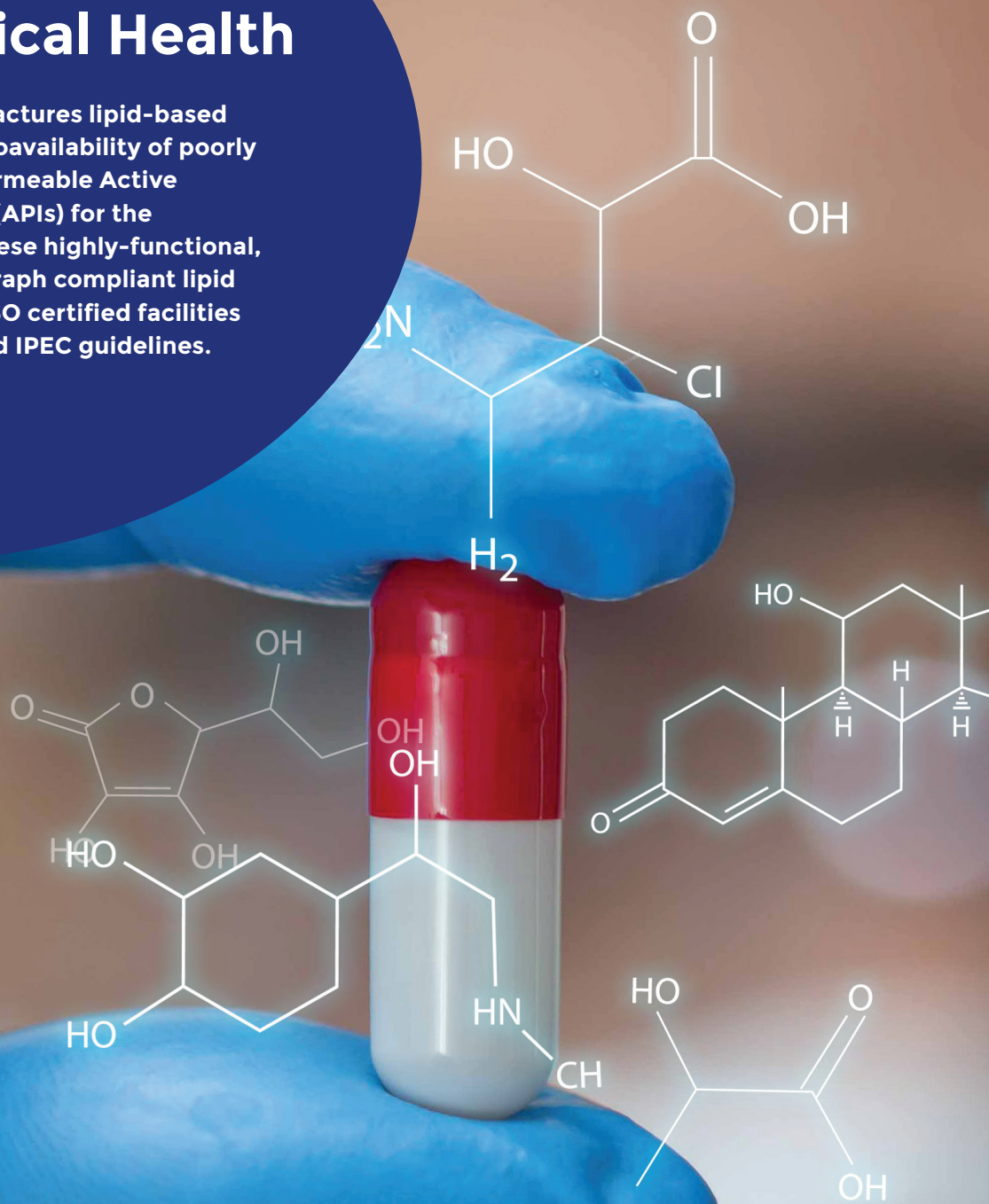
Breaking the Barrier of Drug Delivery

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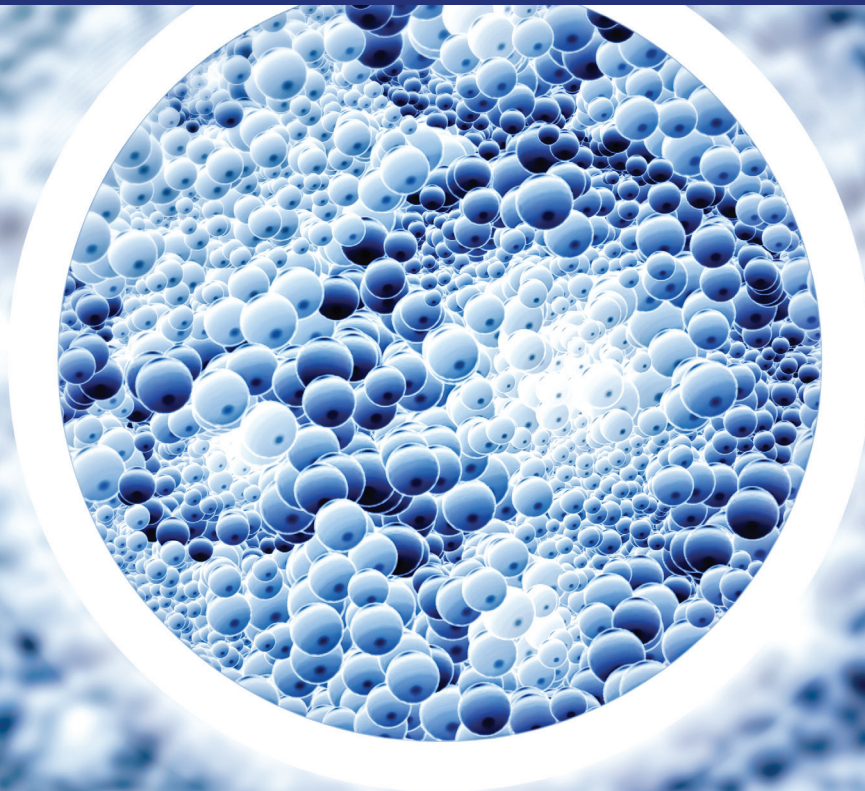
# Pharmaceutical Health

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*

# Functional Excipients for a range of dosage forms and applications.



## DOSAGE VERSATILITY

### ORAL

- Formulation of soft-gelatin capsules, liquid-filled, hard-gelatin capsules, tablets, and functional multi-particulates.
- 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®  
CAPROL®

## 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.



The background of the slide features a collection of laboratory glassware. At the top, a glass pipette with a black rubber bulb is shown dispensing a thin stream of yellow liquid. Below it, there are several other vessels: a beaker on the left containing a clear liquid, a small vial with a stopper in the center, and a large beaker on the right containing a yellow liquid with a scale marked from 100 to 300. In the foreground, a round-bottom flask is partially visible, containing a red liquid. A large, dark blue circle is superimposed over the center of the image, containing the title and bullet points.

## 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.



# Product Versatility



## **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.

# Excipient Classification

Product	Form	Chemical Name	Description
CAPTEX® 170 EP	Liquid	Coco-Caprylate/Caprata	Cocoyl Caprylocaprate EP
CAPTEX 200P	Liquid	Propylene Glycol Dicaprylocaprate	Propylene Glycol Dicaprylocaprate EP; Propylene Glycol Dicaprylate/Dicaprate USP
CAPTEX 300 EP/NF	Liquid	Glyceryl Tricaprylate/Tricaprate	Medium-Chain Triglycerides EP; Medium-Chain Triglycerides USP/NF;
CAPTEX INJ 300 LOW C6 EP/ NF/JPE	Liquid	Glyceryl Tricaprylate/Tricaprate	Medium-Chain Triglycerides EP; Medium-Chain Tri USP/NF; Medium-Chain Fatty Acid Triglycerid
CAPTEX 355 EP/NF/JPE	Liquid	Glyceryl Tricaprylate/Tricaprate	Medium-Chain Triglycerides EP; Medium-Chain Tri USP/NF; Medium-Chain Fatty Acid Triglycerid
CAPTEX INJ 355 EP/NF/JPE	Liquid	Glyceryl Tricaprylate/Tricaprate	Medium-Chain Triglycerides EP; Medium-Chain Tri USP/NF; Medium-Chain Fatty Acid Triglycerid
CAPTEX 8000	Liquid	Glyceryl Tricaprylate, Tricaprylin	Medium-Chain (Fatty Acid) Triglyceride JP Glycerol Esters of Fatty Acids JSFA; Tricapr
CAPTEX INJ 8000	Liquid	Glyceryl Tricaprylate, Tricaprylin	Medium-Chain (Fatty Acid) Triglyceride JP Glycerol Esters of Fatty Acids JSFA; Tricapr
CAPMUL® 808G EP/NF	Solid	Glyceryl Monocaprylate	Glycerol Monoaprylate Type II EP, Glyceryl Monocaprylate Type II USP/NF
CAPMUL GDB EP/NF	Powder	Glyceryl Dibehenate	Glyceryl Dibehenate USP/NF and Glycerol Dibeh
CAPMUL GMO-50 EP/NF	Semi-Solid	Glyceryl Monooleate	Glycerol Monooleate EP; Glyceryl Monooleate U
CAPMUL MCM C8 EP/NF	Liquid/Solid or Mix	Glyceryl Monocaprylate	Glycerol Monocaprylate Type I EP, Glyceryl Monocaprylate Type I USP/NF
CAPMUL MCM NF	Liquid/Solid or Mix	Glyceryl Caprylate/Caprata	Mono- and Di-Glycerides USP/NF
CAPMUL MCM EP/NF	Liquid/Solid or Mix	Glyceryl Caprylate/Caprata	Glycerol Monocaprylocaprate, Type I EP; Glyceryl Mono Type I USP/NF; (Mono- and Di-Glycerides USP/NF;
CAPMUL INJ MCM EP/NF	Liquid/Solid or Mix	Glyceryl Caprylate/Caprata	Glycerol Monocaprylocaprate, Type I EP; Glyceryl Mono Type I USP/NF; (Mono- and Di-Glycerides USP/NF;
CAPMUL INJ MCM EP	Liquid/Solid or Mix	Glyceryl Caprylate/Caprata	Glycerol Monocaprylocaprate Type I EP
CAPMUL PG-2L EP/NF	Liquid	Propylene Glycol Dilaurate	Propylene Glycol Dilaurate EP; Propylene Glycol Dilaurate USP/NF
CAPMUL PG-8 NF	Liquid	Propylene Glycol Monocaprylate	Propylene Glycol Monocaprylate Type II USP
CAPMUL PG-8-70 NF	Liquid	Propylene Glycol Monocaprylate	Propylene Glycol Monocaprylate Type I USP
CAPMUL PG-12 EP/NF	Liquid	Propylene Glycol Monolaurate	Propylene Glycol Monolaurate Type II EP Propylene Glycol Monolaurate Type II USP/
CAPROL® PGE 860	Liquid	Polyglycerol (10) Oleate, Polyglycerol Oleate	Polyglycerol esters of fatty acids
ACCONON® AKG-6 EP/NF	Liquid	PEG-6 Oleic Glycerides	Oleoyl Macrogolglycerides EP; Oleoyl Polyoxylglycerides USP/NF
ACCONON C-44 EP/NF	Solid	PEG-32 Lauric Glycerides	Lauroyl Macrogolglycerides EP; Lauroyl Polyoxylglycerides USP/NF
ACCONON C-50 EP/NF	Solid	PEG-32 Hydrogenated Palm Glycerides	Stearoyl Macrogolglycerides EP; Stearoyl Polyoxylglyc
ACCONON CMG-6 EP/NF	Liquid	Linoleoyl Polyoxylglycerides (Corn Oil PEG-6 Esters)	Linoleoyl Polyoxylglycerides USP/NF; Linoleoyl Macrogolglycerides EP
ACCONON MC8-2 EP/NF	Liquid	PEG-8 Caprylic/Capric Glycerides	Caprylocaproyl Macrogolglycerides EP; Caprylocaproyl Polyoxylglycerides USP/N
ACCONON INJ MC8-2 EP/NF	Liquid	PEG-8 Caprylic/Capric Glycerides	Caprylocaproyl Macrogolglycerides EP; Caprylocaproyl Polyoxylglycerides USP/N
STEROTEX® K, NF	Powder	Hydrogenated Soybean Oil and Castor Wax	Hydrogenated Vegetable Oil Type I USP/N
STEROTEX NF	Powder	Hydrogenated Cottonseed Oil	Hydrogenated Vegetable Oil Type I USP/N
BBS-C	Semi-Solid	Partially Hydrogenated Soybean Oil/ Cottonseed Oil	Hydrogenated Vegetable Oil Type II USP/N
HYDRO-KOTE® C	Solid/Flakes	Hydrogenated Cottonseed Oil	Hydrogenated Cottenseed Oil
HYDRO-KOTE 112	Solid/Flakes	Hydrogenated PKO/Soy Lecithin	Hydrogenated Palm Kernel Oil w/soy lecith
HYDRO-KOTE M	Solid/Flakes	Hydrogenated PKO/Soy Lecithin	Hydrogenated Palm Kernel Oil w/soy lecith



	Regulatory Status	Production Status	Oral	Topical & Transdermal	Parenteral	Suppositories	Ophthalmic	Permeation Enhancement	Solubilization	Emulsification	Encapsulation	Processing Aid	Dry Binding	Controlled Release
			Dosage Form					Application						
	EP, cosmetic, No oral use	Commercial		X					X					
EP; USP/NF	EP, USP/NF, E477*, USFA, JSFA*	Commercial		X					X					
EP; NF;	IIG, EP, USP/NF, USFA, JSFA*	Commercial	X	X					X					
in Triglycerides ceride JPE	EP, USP/NF, JPE, USFA, JSFA	Commercial			X		X							
in Triglycerides ceride JPE	IIG, EP, USP/NF, JPE, USFA, JSFA	Commercial	X	X					X					
in Triglycerides ceride JPE	EP, USP/NF, JPE, USFA, JSFA	Commercial			X		X							
de JPE; caprylin	JPE*, USFA, JSFA	Commercial	X	X					X					
de JPE; caprylin	JPE*, USFA, JSFA	Commercial			X		X							
P, P/NF	EP, USP/NF	Commercial	X	X				X	X	X				
ibehenate EP	EP, USP/NF	Developmental	X											X
ate USP/NF	IIG, EP, USP/NF, USFA, JSFA, JPE*, E471	Commercial	X	X					X	X				
P, P/NF	IIG, EP, GRAS, USFA, JSFA*	Commercial	X	X				X	X	X				
NF	IIG, USP/NF, GRAS, USFA, JSFA*	Commercial	X	X				X	X	X				
Monocaprylocaprate, P/NF, if tested).	IIG, EP, USP/NF, GRAS, USFA, JSFA*	Commercial	X					X	X	X				
Monocaprylocaprate, P/NF, if tested).	EP, USP/NF, GRAS, USFA, JSFA*	Developmental	X				X	X	X	X				
I EP	USP/NF, GRAS, USFA, JSFA*	Developmental			X		X		X					
NF	EP, USP/NF, USFA, JSFA*, E477*	Commercial	X						X	X				
I USP/NF	USP/NF, FCC, USFA, JSFA*, E477*	Commercial	X	X					X	X				
USP/NF	USP/NF, FCC, USFA, JSFA*, E477*	Commercial	X	X					X	X				
II EP; USP/NF	EP, USP/NF, E477*, USFA, JSFA*	Commercial	X	X				X	X	X				
s	USFA	Commercial	X	X					X	X				
NF	EP, USP/NF	Developmental	X	X					X	X				
; NF	IIG, EP, USP/NF	Developmental	X	X					X	X	X			
glycerides USP/NF	EP, USP/NF	Developmental	X	X					X	X	X			
NF; P	EP, USP/NF	Developmental	X	X					X	X	X			
s EP; SP/NF	IIG, EP, USP/NF	Commercial	X	X					X	X	X			
s EP; SP/NF	IIG, EP, USP/NF	Developmental	X	X			X		X	X	X			
SP/NF	USP/NF	Commercial	X			X					X	X	X	X
SP/NF	USP/NF, BP	Commercial	X			X					X	X	X	X
SP/NF	USP/NF	Commercial	X			X								X
		Commercial		X		X								X
lecithin		Commercial		X		X								X
lecithin		Commercial		X		X								X

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.

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