

# CGMP LIPIDS

Product	Part Number	Phase Supported <sup>1</sup>	DMF No. <sup>2</sup>
<b>Semi-Synthetic Phosphatidylcholine</b>			
DMPC	730345	C	25490
DPPC	730355	C	30760
DSPC	730365	C	25436
DEPC	730398	C	14604
DOPC	730375	C	23645
POPC	770557	C	16725
<b>Semi-Synthetic Phosphatidylglycerol</b>			
DMPG	730445	T	33600
DPPG	730455	T	9727
DSPG	730465	T	32215
<b>Semi-Synthetic Phosphatidylethanolamine</b>			
DOPE	770725	T	9192
<b>Synthetic Monophosphoryl Lipid A (MPLA) Adjuvants</b>			
PHAD <sup>®</sup>	770030	T	15738 <sup>‡</sup>
3D-PHAD <sup>®</sup>	770040	T	17259 <sup>‡</sup>
3D(6-acyl)-PHAD <sup>®</sup>	770050	T	18353 <sup>‡</sup>
<b>Detergents</b>			
DDM	770520	D	Pending
OGP	770511	D	Not Applicable
<b>PEG Lipids</b>			
DSPE-PEG(2K)-Mal	770126	T	19041
DSPE-mPEG(2000)	770120	T	33335
DMG-PEG 2000	770151	D	19710 <sup>‡</sup>
DSPE-PEG2000 Carboxy	770135	D	Pending
<b>Miscellaneous</b>			
Tricaprylin	730412	C	31820
Triolein	770110	C	12104
DOTAP	770890	T	16609
Cholesterol, plant	770100	T	23761

1 D – suitable for development and preclinical tox studies  
T – suitable for early clinical trial (Phase I/II) manufacturing  
C – suitable for Phase III and commercial manufacturing

2 Unless otherwise noted, the DMF is filed with CDER  
† – currently inactive  
‡ – DMF filed with CBER

## **cGMP Manufacturing API, Excipient, & Contract Manufacturing.**

- GMP manufacturing initiated in 1985
- FDA inspected since 1990; Drug, Animal Drug, and Pre-Approval Inspections; current EIR available upon request.
- Supplied the first semi-synthetic phospholipid for an approved drug product in 1990
  - Dipalmitoyl phosphatidylcholine (DPPC)
  - Exosurf<sup>®</sup> Neonatal, synthetic lung surfactant replacement for neonates with Respiratory Distress Syndrome (RDS)
- Currently support ~30 active drug master files for clinical trials and commercial products (see back for list of supported products)
- Manufacture cGMP quality materials from 50g to 25kg batches
- Maximum annual capacity: 2 MT per shift
- Contract manufacturing of proprietary lipid products available

# **More than Lipids**

**Solutions for the entire product cycle:  
Research to Commercialization.**