Phospholipon® 100 H

-Phosphatidylcholine , hydrogenated
for parenteral applications

-Fatty acid composition: approx. 85 % stearic acid,
approx. 15 % palmitic acid

-Raw material with enhanced chemical stability

- Drug Master File N° 15480, USA

Applications:
Preparation of liposomes for drugs, especially parenteral applications.

*Characteristics**:*

Phase transition temperature in hydrated form	approx.54°C
Properties	white,crystalline powder
Identity	conforms to reference spectra
Solubility (10% in CHCl 3 /Methanol =2/1 v/v)	clear solution
Iodine value	NMT 1
Fatty acids	
-Sum Stearic acid and Palmitic acid	NLT 98 %
Moisture (Karl Fisher)	NMT 2 %

Assay

-Hydrogenated Phosphatidylcholine	NLT 95%
-Hydrogenated Lysophosphatidylcholine	NMT 0.5%
Oil/triglycerides	NMT 1 %

*Residual solvents:

-*Ethanol	NMT 0.5 %
-*Acetone	NMT 50 ppm
-*Ethylmethylketone	NMT 50 ppm
-*Mesityl oxide	not detectable

Microbiological purity

-Aerobic total count	NMT 100 germs/1g
-Enterobacteria and certain other gram-neg. bacteria	absent in 1g
-Pseudomonas aeruginosa	absent in 1g
-Staphylococcus aureus	absent in 1g
-Endotoxins	NMT 10 IU/g

**Method descriptions are available on request

Packaging:
1kg welded in PE-coated aluminium foil
5kg welded in PE-coated aluminium foil

Storage:
Room temperature or below,dry condition,
sealed under inert gas

ALC
AMERICAN LECITHIN COMPANY
115 HURLEY ROAD, UNIT 2B • OXFORD, CT 06478 • (203) 262-7100 • (203) 262-7101 FAX