

Phospholipon® 100 H

-Phosphatidylcholine , hydrogenated for parenteral applications		Oil/triglycerides	NMT 1 %
-Fatty acid composition: approx. 85 % stearic acid, approx. 15 % palmitic acid		*Residual solvents:	
		-*Ethanol	NMT 0.5 %
		-*Acetone	NMT 50 ppm
		-*Ethylmethylketone	NMT 50 ppm
		-*Mesityl oxide	not detectable
-Raw material with enhanced chemical stability		Microbiological purity	
- Drug Master File N° 15480, USA		-Aerobic total count	NMT 100 germs/1g
<i>Applications:</i> Preparation of liposomes for drugs, especially parenteral applications.		-Enterobacteria and certain other gram-neg. bacteria	absent in 1g
<i>Characteristics**:</i> Phase transition temperature in hydrated form	approx. 54°C	-Pseudomonas aeruginosa	absent in 1g
Properties	white, crystalline powder	-Staphylococcus aureus	absent in 1g
Identity	conforms to reference spectra	-Endotoxins	NMT 10 IU/g
Solubility (10% in CHCl ₃ /Methanol =2/1 v/v)	clear solution	**Method descriptions are available on request	
Iodine value	NMT 1	<i>Packaging:</i> 1kg welded in PE-coated aluminium foil 5kg welded in PE-coated aluminium foil	
Fatty acids		<i>Storage:</i> Room temperature or below, dry condition, sealed under inert gas	
-Sum Stearic acid and Palmitic acid	NLT 98 %		
Moisture (Karl Fisher)	NMT 2 %		
Assay			
-Hydrogenated Phosphatidylcholine	NLT 95%		
-Hydrogenated Lysophosphatidylcholine	NMT 0.5%		