

C16 PEG2000 Ceramide

N-palmitoyl-sphingosine-1-{succinyl[methoxy(polyethylene glycol)2000]}

880180P-200mg

Molecular Weight	2634.365 (average MW due to polydispersity of PEG)
Physical State	Powder
Storage	-20°C
Expiration Date	One year from date of receipt
M Lot Number	6300PND033
Lot Number	880180P-200MG-D-033

ANALYSIS	SPECIFICATION	RESULTS
Physical Examination	White to off white powder which contains no foreign matter	Pass
TLC (Mobile Phase 90:10 [v/v] Chloroform: Methanol)	Ninhydrin: negative Iodine: one major spot Phosphorus: negative Charring: positive Water dip: one major spot	Ninhydrin: negative Iodine: one major spot Phosphorus: negative Charring: positive Water dip: one major spot
UHPLC-CAD	NLT 97% (wt/wt%) C16 PEG2k Ceramide NMT 3% (wt/wt%) total all impurities	99% wt/wt% C16PEG2k Ceramide 1% wt/wt% total impurities
Ratio of Constitutional Isomers by Carbon NMR	Run and Report	85 mol% sn-1 PEG 15 mol% sn-3 PEG
Proton NMR	NMR spectrum consistent with structure	Consistent with structure
FTIR	Conforms to reference standard	Conforms to reference standard
PDI by TOF-MS	Run and Report	1.004
Weight Average Molecular Weight (M_w) by TOF-MS	Run and Report	2512.464
Residual Solvents (GC/FID)	NMT 100 ppm diethyl ether NMT 100 ppm dimethylformamide NMT 20 ppm chloroform NMT 100 ppm toluene NMT 100 ppm methanol NMT 100 ppm ethanol NMT 100 ppm isopropanol NMT 100 ppm ethyl acetate NMT 100 ppm cyclohexane NMT 250 ppm total residual solvents	None Detected None Detected None Detected None Detected None Detected None Detected None Detected None Detected 68 ppm None Detected 68 ppm total
Karl Fischer Water Titration	NMT 2.0% water / weight product	0.3%
IC-Anion	Cl ⁻ Run and Report	0.127 wt% Cl ⁻
IC-Cation	Na ⁺ Run and Report	0.004 wt% Na ⁺
Elemental Impurities by ICP-MS	NMT 0.2 ppm Cd	0.01 ppm

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Elemental Impurities by ICP-MS	NMT 0.5 ppm Pb	0.05 ppm
	NMT 1.5 ppm As	0.01 ppm
	NMT 0.3 ppm Hg	BLOQ
	NMT 0.5 ppm Co	BLOQ
	NMT 1 ppm V	BLOQ
	NMT 2 ppm Ni	0.24 ppm
	NMT 25 ppm Li	0.12 ppm
	NMT 9 ppm Sb	0.05 ppm
	NMT 30 ppm Cu	1.16 ppm
Solubility in Ethanol	NLT 150 mg/ml	Pass

Approved by:



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