PURASORB ® PDLG 8505A

Product specification data sheet Rev. No. 1 / June 2019

Description PURASORB PDLG 8505A is an acid terminated GMP grade copolymer of DL-lactide and Glycolide in a 85/15 molar ratio and with an inherent viscosity midpoint of 0.5 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDLG 8505A is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

Chemical composition	85/15 DL-lactide/Glycolide copolymer
Item	1840446
Molecular formula	$[(C_6H_8O_4)_x(C_4H_4O_4)_y]_n$
Chemical name	3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with 1,4-dioxane-2,5-dione
CAS Registry number	26780-50-7

Test	Method	Specification
Appearance	Visual test	White to light tan granules
Identity	FTIR spectroscopy	Conforms to reference
Monomer ratio, DL	NMR spectroscopy	82 - 88 mol %
Monomer ratio, G	NMR spectroscopy	12 - 18 mol %
Inherent viscosity	Viscometry Chloroform, 25 °C, c = 0.5 g/dl	0.45 - 0.55 dl/g
Specific rotation	Polarimetry Chloroform, 20 °C	(-2) - (+2) °
Tg, second run	DSC, 10 °C/min	Report result
Water	Coulometric titration	max. 0.5 %
Mw	GPC, Chloroform	For information purpose only
Mn	GPC, Chloroform	For information purpose only
Mw/Mn	GPC, Chloroform	For information purpose only
Tin	ICP	max. 50 ppm
Residual solvent, total	GC, headspace	max. 0.1 %
Residual solvent, toluene	GC, headspace	max. 890 ppm

Test	Method	Specification
Residual monomer, total	GC	max. 2 %
Residual monomer, DL-lactide	GC	max. 2 %
Residual monomer, Glycolide	GC	max. 2 %
Acid number	Titration	Report result
Elemental impurities	USP method 232	max. 10 ppm
Total microbial count	TAMC	max. 2 x 10^3 CFU/g
Yeast and moulds	TYMC	max. 2 x 10^2 CFU/g
Bacterial endotoxins	USP method 85	max. 6 EU/g

Packaging

PURASORB PDLG 8505A can be supplied in 1 kg packages. Our standardized packaging consists out of four protective layers, an inner layer of clean room grade PE bag, an outer bag of aluminum coated polyester-PE laminate, inserted in the additional bag of PE for extra protection and shipped in sealed PE containers.

Storage & Handling

When stored in the original packaging at low temperatures (-15°C), PURASORB PDLG 8505A keeps its initial properties for at least three years (retest date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PDLG 8505A keeps its initial properties for at least one year.

Please refer to our current stability statement for most up to date information on storage stability.

Allow the material to reach room temperature before opening the packaging. After opening the original packaging PURASORB PDLG 8505A is best stored in an inert atmosphere and at low temperatures (-15°C).