

PURASORB[®] PDLG 5505G

Product specification data sheet

Rev. No. 3/ March 2021

Description PURASORB PDLG 5505G is a GMP grade copolymer of DL-lactide and Glycolide in a 55/45 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 5505G is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

| | |
|-----------------------------|--|
| Chemical composition | 55/45 DL-lactide/Glycolide copolymer |
| Material numbers | 1001012905 / 1001012916 / (1840431) |
| 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 | 52 - 58 mol % |
| Monomer ratio, G | NMR spectroscopy | 42 - 48 mol % |
| Inherent viscosity | Viscometry Chloroform, 25 °C, c = 0.5 g/dl | 0.40 - 0.60 dl/g |
| Specific rotation | Polarimetry Chloroform, 20 °C | (-2.0) - (+2.0) ° |
| Tg | DSC, 10°C/min | 42.0 – 52.0 °C |
| Mw | GPC, Chloroform | For information purpose only |
| Mn | GPC, Chloroform | For information purpose only |
| Mw/Mn | GPC, Chloroform | For information purpose only |
| Water | Coulometric titration | max. 0.50 % |
| Tin | ICP | max. 50 ppm |
| Residual solvent, total | GC, headspace | max. 0.50 % |
| Residual solvent, acetone | GC, headspace | max. 5000 ppm |
| Residual solvent, toluene | GC, headspace | max. 890 ppm |

| Test | Method | Specification |
|------------------------------|----------------|----------------------------|
| Residual monomer, total | GC | max. 0.50 % |
| Residual monomer, DL-lactide | GC | max. 0.50 % |
| Residual monomer, Glycolide | GC | max. 0.50 % |
| Elemental impurities | USP method 232 | max. 10 ppm |
| Acid number | Titration | max. 3.5 mg KOH/g |
| Total microbial count | TAMC | max. 2×10^3 CFU/g |
| Yeast and moulds | TYMC | max. 2×10^2 CFU/g |
| Bacterial endotoxins | USP method 85 | max. 6.00 EU/g |

Packaging PURASORB PDLG 5505G 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 5505G keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PDLG 5505G 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 5505G is best stored in an inert atmosphere and at low temperatures (-15°C).