

ESUNMED PLLA porous Microspheres

Product Name	Poly(L-lactic acid) porous microspheres
CAS No.	33135-50-1
Batch No.	MP-PLLA porous -260107-171
Production Date	260107
Test Date	260126

Item	Unit	Standard	Reference standard	Method	Result
Appearance	/	/	/	Optical microscopy	Spherical particle
Median size (D50)	μm	30-50	/	Laser particle analyzer	35.26
Intrinsic viscosity [η]	dL/g	/	/	Refer to ASTM D 2857 in Chloroform 30 °C	0.97
Moisture	%	≤ 0.5	YY/T 0661-2017	Karl Fischer coulometric titration	0.25
Monomer residue	%	≤ 2.0	YY/T 0661-2017	GC	Below the LOQ
Solvent residue (Total)	ppm	ICH limit value	YY/T 0661-2017	GC	Qualified
PVA residue	%	< 0.2	/	UV	Qualified
Sodium ion residue	ppm	/	/	IC	Qualified
Residual pore forming agent	ppm	/	/	IC	Qualified
Heavy metal residue (Pb)	μg/g	≤ 10	YY/T 0661-2017	Colorimetric method of Chinese Pharmacopoeia	Qualified
Sn Residue	μg/g	≤ 150	YY/T 0661-2017	ICP	Qualified
Specific optical rotation	°	-155 ~ -160	YY/T 0661-2017	Polarimetric test of Chinese Pharmacopoeia in dichloromethane, 20 °C	-155.88

Storage Conditions: Store in a low-temperature refrigerator at 2-8°C.

