

Cixi Xinyu Pastics Factory

Certificate of Analysis

Product name:	PVC Granules for IV Set Drip Chamber							
Test standards:	GB15593-2020, REACH, ROHS2.0							
Batch No.	2025101354							
Expiry Date:	2030/10/13			Manufacturing Date:			2025/10/14	
Test item		Unit	Test Method		Standards		Test Results	
Physical performance	Shore Hardness		HA	GB/T2411		≥ 80		84
	Elongation at Break		%	GB/T5836		≥ 300		356.73
	Tensile Strength		Mpa	GB/T1040		≥ 15		16.05
	Density		g/cm ³	GB/T1033		1.25 ± 0.05		1.25
	Max Force		N	GB/T13525-1922		≥ 500		634.18
	Appearance		No color or nearly colorless transparent granular substance, uniform plasticizing and free of impurities				Qualified	
	Color		Transparent colorless				Transparent colorles	
Water dissolution chemical performance	pH value		≤ 1.0				0.10	
	Nonvolatile matter		≤ 2.0				0.40	
	Zinc(ug/ml)		≤ 0.4				0.11	
	Reducing substances (consumption of 0.02mol/LKMnO4)		≤ 0.3				0.08	
	Heavy metal (ug/ml)		≤ 0.3				≤ 0.22	
	Ultraviolet absorption (230-260nm)		≤ 0.3				0.1	
	Ash(mg/B)		≤ 1				Qualified	
	Vinyl chloride monomer (ug/g)		≤ 1				Qualified	
Biological performance	Pyrogen		No pyrogen				Qualified	
	Hemolysis		Hemolysis rate $\leq 5\%$				Qualified	
	Acute systemic toxicity		No cause acute systemic toxicity				Qualified	
Conclusion:	Qualified							
Suggested Processing Temperature	Area1	165-180℃	Area2	165-180℃	Area3	165-180℃	Area4	165-180℃
Tested by:HUANG Jiaqi		Approved by: PAN Xiaohong						
Date: 2025.10.31		Date: 2025.10.31						