



一水肌酸(200目)质量标准		执行日期	2022.4.1
Specification of Creatine Monohydrat (200mesh)		Effective date	
Item	Specification	Method	
外观 Appearance	白色结晶性粉末 White crystalline powder	Visual	
鉴别 Identification	在含量项下, 样品溶液主峰的保留时间与标准溶液的保留时间一致。 The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.	USP<621>	
干燥失重 Loss on Drying	10.5%~12.0%	USP<731>	
炽灼残渣 Residue on Ignition	≤0.1%	USP<281>	
硫酸盐 Sulfate(SO ₄ ²⁻)	≤0.1%	USP<221>	
铁盐 Iron	≤10ppm	USP<241>	
重金属 Heavy Metals	≤10ppm	USP<231>	
铅 Lead (Pb)	≤1ppm	AAS	
镉 Cadmium (Cd)	≤1ppm	AAS	
汞 Mercury (Hg)	≤0.1ppm	AAS	
砷 Arsenic(As)	≤1ppm	AAS	
肌酸酐 Creatinine	≤100ppm	USP<621>	
双氰胺 Dicyandiamide	≤50ppm	USP<621>	
双氢三嗪 Dihydrotriazine	≤0.0005%	USP<621>	
其他未知杂质 Any Unspecified Impurity	≤0.1%	USP<621>	
其他未知总杂质 Total Unspecified Impurity	≤1.5%	USP<621>	
总杂质 Total Impurities	≤2.0%	USP<621>	
粒度 Particle Size	≥70% through 200mesh	USP<786>	
自然密度 Bulk Density	≥430g/L	USP<616>	
敲击密度 Tapped Density	≥550g/L	USP<616>	
含量(干基) Assay (dry basis)	99.5%~102.0%	USP<621>	
* 细菌总数 Total bacterial count	≤100cfu/g	USP<61>	
* 霉菌&酵母菌 Mould&Yeast	≤100cfu/g	USP<61>	
* 大肠埃希氏菌 E.Coli	Negative/g	USP<62>	
* 沙门氏菌 Salmonella	Negative/10g	USP<62>	
* 金黄色葡萄球菌 Staphylococcus	Negative/g	USP<62>	
Note: * External inspection once a year.			
Shelf life: 24 months/ Storage: Room temperature, dry and well ventilated.			