



宁夏太康药业有限公司
Ningxia Taikang Pharmaceutical Co.,Ltd.

地址：宁夏石嘴山市平罗工业园山水大道14号
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CERTIFICATE OF ANALYSIS

Date: Aug.15,2024

Product Name	Creatine Monohydrate 200 Mesh		
Manufacture Date	Aug.14,2024	Expiry Date	Aug.13,2027
Quantity	27000 KG	Number Of Packages	1080 Cartons
Batch No.	202408-015	Packing Spec	25kg/Carton
Item	Specification	Result	Analysis Method
Appearance	White Crystalline Powder	Conformed	USP43
Solubility	Slightly soluble in water	Conformed	USP43
Clarity & color of solution	Clear & colorless	Conformed	USP43
Odor & amp	Odorless & pale	Conformed	--
Melting point	292 °C	Conformed	USP43
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Conformed	USP43
Test of Sulfuric acid	No Carbonation	Conformed	USP43
Assay	99.5- 102% on the dried basis	99.97%	HPLC
Creatinine	≤100ppm	35ppm	USP43
Loss On Drying	10.5-12.0%	11.74%	USP43
Residue On Ignition	≤0.1%	0.02%	USP43
Iron	≤10ppm	<10ppm	USP43
Sulfate	≤0.03%	Conformed	USP43
Dicyandiamide	≤50ppm	30ppm	USP43
Dihydrotriazine	≤5ppm	Conformed	USP43
Cyanide	≤1ppm	Conformed	USP43
Any unspecified impurity	≤0.1%	Conformed	USP43
Total unspecified impurities	≤1.5%	Conformed	USP43
Total impurities	≤2.0%	Conformed	USP43
Heavy Metal	≤0.5ppm	<0.5ppm	USP43
Arsenic (As)	≤0.1ppm	<0.1ppm	USP43
Lead (Pb)	≤0.1ppm	<0.1ppm	USP43
Mercury (Hg)	≤0.1ppm	<0.1ppm	USP43
Cadmium (Cd)	≤0.1ppm	<0.1ppm	USP43
Bulk Density	≥430g/L	493g/L	--
Tapped Density	≥550g/L	859g/L	--
Total Bacterial Count	≤100cfu/g	<50cfu/g	USP43
Mould & Yeast	≤100cfu/g	<50cfu/g	USP43
E.Coli	Negative/10g	Negative	USP43
Salmonella	Negative/25g	Negative	USP43
S.aureus	Negative/10g	Negative	USP43
Conclusion: Qualified			
Country Of Origin: China			
Remark: Stored in cool, dry and ventilated warehouse, and keep away from Moisture.			
Person Responsible For Quality:	Ma Yan	Analyst	Yao Haiju

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