

台州市振宇生物科技有限公司

TAIZHOU ZHENYU BIOTECHNOLOGY CO., LTD

检 验 报 告 单

Certificate of Analysis

Product name	Acetaminophen (Paracetamol)		
Batch NO.	202305035A	Packing	25kg / bag
MFG. Date	May.06,2023	Quantity	5000Kg
EXP. Date	May.05,2027	Analysis Date	May. 10,2023
Standard	USP43		
Contents	Specification		Results
Characters	White, odorless, crystalline powder, having a slightly bitter taste.		Conforms
Solubility	Freely soluble in alcohol; soluble in boiling water and in 1 N sodium hydroxide.		Conforms
Identification	A: IR absorption	Conforms	Conforms
	B : The retention time of the major peak of the Sample solution corresponds to that of the standard solution, as obtained in the assay.	Conforms	Conforms
Loss on drying	≤0.5%		0.06%
Residue on ignition	≤0.1%		0.04%
Free p-aminophenol	≤0.005%		Below LOD
Related substances	Impurity B	≤0.05%	0.019%
	Impurity C	≤0.05%	Below LOD
	Impurity D	≤0.05%	Below LOD
	Impurity J	≤0.001%	Below LOD
	Individual unspecified impurity	≤0.05%	0.002%
	Total of impurities	≤0.1%	0.032%
Residual solvents	Residual content of acetic acid is limited by the test of loss on drying.	≤0.5%	0.06%
Assay(anhydrous basis)	98.0%- 101.0%		99.8%
Conclusion: It complies with the requirements of the USP43			
Packaging and storage-Preserve in tight, light-resistant containers, and store at room temperature. Protect from moisture and heat.			
Approved by	年艳	Checked by	伍晓梅
			张艳丽