常州市阳光药业有限公司 CHANGZHOU SUNLIGHT PHARMACEUTICAL CO.;LTD 检验报告单

Certificate of Analysis

产品名称:对氨基 Package: 25kg/	基苯甲酸乙酯				
Package: 25kg/		生产日期:Oct.03,2021		有效期至:Oct.02,2023	
Package: 25kg/Fiber drum		Batch number:		Batch Quantity:	
包装: 25kg/纸板桶		批号:C5892110011	批量:1000kg		
Testing method		Refer to USP36 testing method			
检验方法		参照 USP36 检测方法			
Items tested		Specification Result		Result	
检测项目	规格标准		检测结果		
Characters	White crystals or crystalline powder		White crystalline powder		
性状	白色结晶或结晶性粉末		白色结晶性粉末		
Identification 鉴定	IR should comply with the reference standard spectrum. 红外光谱应与对照品图谱一致 Absorptivities at 278 nm, calculated on the dried basis, do not differ by more than 3.0%.紫外光谱在 278nm 处的吸收值与对照品差值应不得大于 3.0% An orange-red precipitate is performed. 重氮化-偶合反应生成橙红色沉淀		IR complies with the reference standard spectrum. 红外光谱与对照品图谱一致 Absorptivities at 278 nm, calculated on the dried basis, do not differ by more than3.0%.紫外光谱在 278nm 处的吸收值与对照品差值不大于 3.0% An orange-red precipitate is performed. 重氮化-偶合反应生成橙红色沉淀		
Melting point 熔点	88 -92°C		88.0-88.5℃		
Melting range 熔程	Not more than 2°C				
	不得超过 2℃		0.5℃		
Loss on drying	Not more than 0.5%		0.35%		
干燥失重	不得超过 0.5%				
Readily carbonizable Substances 易碳化物质	The resolution has no more color than matching fluid A. 溶液颜色不深于对照液颜色		Conform 符合规定		
Residue on ignition 炽灼残渣	Not more than 0.1% 不得超过 0.1%		0.04%		
Heavy metals	Not more than 0.001%		Conform		
重金属	不得超过 0.001%		符合规定		
Chloride	Conform		Conform		
氯化物	符合规定		符合规定		
Assay (HPLC) 含量	98.0%-102.0%		99.64%		
Ordinary impurities	1/1	-10 /		Conform	
一般杂质	≤1%		符合规定		
Reaction	Conform		Conform		
化学反应		符合规定		符合规定	
Conclusion 结论		W. M. W. Qualiti	d		
放行人/日期(Approval	by/Date):	13	1	2021-11-03	