



常州市阳光药业有限公司  
CHANGZHOU SUNLIGHT PHARMACEUTICAL CO.,LTD

检验报告单

Certificate of Analysis

R10144 R20556



Product name 产品名称		Date of manufacture 生产日期	Date of expiry 有效期至
P-Aminobenzoic acid 对氨基苯甲酸		Aug.30.2023	Aug.29.2025
Batch number 批号	Batch Quantity 批量	Package 包装	Testing method 检验方法
C5012309007	1001kg	25kg/Paper drum 25kg/全纸桶	Refer to USP 43 testing method 参照 USP 43 检测方法
Items tested 检测项目	Specification 规格标准		Result 检测结果
Characters 性状	White or light yellow crystal or crystalline powder without smell 白色或淡黄色无气味结晶或结晶性粉末		White crystalline powder without smell 白色无气味结晶性粉末
Identification 鉴定	IR should comply with the reference standard spectrum. 红外光谱应与对照品图谱一致 Solution main peak retention time should be consist with standard solution main peak retention time 溶液主峰保留时间和标准品溶液主峰保留时间一致		IR complies with the reference standard spectrum. 红外光谱与对照品图谱一致 Solution main peak retention time should be consist with standard solution main peak retention time 溶液主峰保留时间和标准品溶液主峰保留时间一致
Loss on drying 干燥失重	Not more than 0.2% 不得超过 0.2%		0.18%
Residue on ignition 炽灼残渣	Not more than 0.1% 不得超过 0.1%		0.06%
Assay 含量	98.0~102.0%		99.75%
Organic impurities (HPLC) 有机杂质	Nitrobenzoic acid 对硝基苯甲酸≤0.2%		Not detected 未检出
	Benzocaine≤0.2% 苯佐卡因≤0.2%		Not detected 未检出
	Any unspecified impurity≤0.1% 任何其他杂质≤0.1%		0.01%
	Total impurities≤0.5% 总杂质≤0.5%		0.01%
Aniline and P-toluidine 苯胺和对甲苯胺 (GC)	Aniline≤10ppm 苯胺≤10ppm		Not detected 未检出
	P-toluidine≤10ppm 对甲苯胺≤10ppm		Not detected 未检出
Pb 铅	≤3ppm		Not detected 未检出
Cd 镉	≤1ppm		Not detected 未检出
Hg 汞	≤0.1ppm		Not detected 未检出
As 砷	<1ppm		0.00014ppm
Acrobic plate count 菌落总数	Not more than 10 <sup>5</sup> cfu/g 不得超过 10 <sup>5</sup> cfu/g		<100 cfu/g
Yeasts & Molds 酵母菌和霉菌	Not more than 10 <sup>2</sup> cfu/g 不得超过 10 <sup>2</sup> cfu/g		<10 cfu/g
E.Coli 大肠埃希菌	Negative 不得检出		Not detected 未检出
Coliforms 大肠菌群	Not more than 10cfu/g 不得超过 10cfu/g		Not detected 未检出
Salmonelia 沙门氏菌	Negative 不得检出		Not detected 未检出
Conclusion 结论	Qualified 合格		
放行人/日期 (Approval by/Date):			

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