KAIFENG MINGREN PHARMACEUTICAL CO.,LTD.

开封明仁药业有限公司

Add.:Kaifeng Mingren Pharmaceutical Co.,Ltd,

Bianjing Road East of embankment, Kaifeng City, Henan Province.475000

Tel: 86-371-65741762 Fax: 86-371-65706158

CERTIFICATE OF ANALYSIS

检验报告单

REGISTER No. 记录编码: RP-S-YC05001-00 REPORT No.:报告单编号: YC05001202210005

Product: Phloroglucinol Anhydrous 产品名称: 无水间苯三酚	Batch No.:SB221001 批号:
Manufacturing date:Sep.29,2022 生产日期:	Quantity:500.00kg 数量:
Retest Date:Aug.2025 复验期:	Package:25kg/DRUM 包装规格:
Sample Receiving Date:Oct.03,2022 收检日期:	Reporting Date:Oct.07,2022 报告日期:
Testing Item: Full test 检验项目: 全检	Specification : Ph. Eur.10.0 检验依据:

Items 检测项目	**Method 方法**	**Acceptance Criteria 标准规定**	**Results 检验结果**
Appearance 性状	Visual 目测	White or almost white powder. 本品为白色或类白色粉末。	White powder 白色粉末
Solubility 溶解度	Visual 目测	Sparingly soluble in water, freely soluble in ethanol(96%),practically insoluble in methylene chloride 本品在水中略溶，在乙醇（96%）中易溶，在二氯甲烷中几乎不溶。	Conforms 符合规定
pH pH 值	EP2.2.3	4.0 to 6.0 应为 4.0~6.0。	5.6
Appearance of solution 溶液的澄清度与颜色	EP2.2.1 EP2.2.2	Clear and not more intensely coloured than reference solution BY5 溶液应澄清无色；如显色，与 BY5 标准比色液比较，不得更深。	Conforms 符合规定
Identification 鉴别 (a)IR 红外 (b)TLC 薄层色谱 (c) Loss on drying 干燥失重	EP2.2.24 EP2.2.27 EP2.2.32	(a)The infrared spectrum of the product should beconsistent with that of the control product anhydrous phloroglucinol CRS. 本品的红外光吸收图谱应与无水间苯三酚对照品的图谱一致。 (b)The principal spot in the chromatogram obtained with the test solution is similar in position and size to the reference solution 供试品溶液所显主斑点的位置和大小应与对照品溶液的主斑点一致 (c) Maximum 1.0per cent 不得过 1.0%	Conforms 符合规定 Conforms 符合规定 0.2%

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Related substances 有关物质	EP2. 2. 29	Impurity A not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 A 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出
		Impurity D not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 D 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出
		Impurity E not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 E 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出
		Impurity K not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 K 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出

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Items 检测项目	**Method 方法**	**Acceptance Criteria 标准规定**	**Results 检验结果**
Related substances 有关物质	EP2.2.29	Impurity L not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 L 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出
		Impurity I not more than 1.5 times the principal peak in the chromatogram obtained with reference solution (0.15 per cent) 杂质 I 不得大于对照溶液色谱图中主峰的峰面积的 1.5 倍（0.15%）	Not detected 未检出
		Unspecified impurities impurity for each impurity not more than the principal peak in the chromatogram obtained with reference solution (0.1 per cent) 对于任一杂质，其峰面积应不得大于对照溶液色谱图中主峰的峰面积（0.10%）	Not detected 未检出
		Total not more than 3 times the principal peak in the chromatogram obtained with reference solution (0.3 per cent) 总杂质不得大于对照溶液色谱图中主峰的峰面积的 3 倍（0.3%）	Not detected 未检出

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Loss on drying 干燥失重	EP2.2.32	Maximum 1.0per cent 不得过 1.0%	0.2%
Chlorides 氯化物	EP2.4.4	Maximum 200ppm 不得过 200ppm	Conforms 符合规定
Sulfates 硫酸盐	EP2.4.13	Maximum 500ppm 不得过 500ppm	Conforms 符合规定
Sulfated ash 硫酸盐灰分	EP2.4.14	Maximum 0.1 per cent 不得过 0.1%	0.05%
Residual solvent 残留溶剂	GC	1,2,4-trimethyl benzene not more than 20ppm 1, 2, 4-三甲苯应不得过 20ppm	Not detected 未检出
Content 含量	EP2.2.20	99.0 per cent to 101.0 per cent（dried substance） 按干燥品计算，含间苯三酚（$C_6H_6O_3$）为 99.0%-101.0%	99.8%
Conclusion: The results conform with Ph. Eur.10.0 结论：本批号产品符合 EP10.0			

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KAIFENG MINGREN PHARMACEUTICAL CO.,LTD

Analyst: HAN JIAYUE Reviewer: ZHU JUNMEI Quality Manager: LIANG JUAN

化验员: 复核人: 质量经理: