



### 检验报告/Certificate of Analysis

检验报告单号 Report No: RN05S01-202204034A

Page 1 of 2

商品名/Trade Name	KoVidone®K30	产品名称/Product Name	聚维酮K30/Povidone K30
产品编号/Product Code	N05S01	产品等级/Grade	药用级/Pharma grade
批号/Batch Number	NC220401034	生产日期/Mfg. Date	2022.04.01
批量/Batch Size	5075 kg	复验日期/Retest Date	2025.03.31
依据/According to	企业内控标准 Enterprise internal control standards/ (Spe-N05S01)		

检验项目 Item	质量标准 Tolerance	检验结果 Test Result
外观 Appearance	白色至乳白色吸湿性粉末 White to slightly creamy white hygroscopic powder.	符合要求 Complies
溶解度 Solubility	易溶于水、甲醇和乙醇；微溶于丙酮；不溶于乙醚 Freely soluble in water, in methanol, and in alcohol, slightly soluble in acetone, practically soluble in ether	符合要求 Complies
鉴别 Identification	A. 与对照品图谱一致 Consistent with the CRS	符合要求 Complies
	B. 生成橙黄色沉淀 An orange-yellow precipitate is formed.	符合要求 Complies
	C. 生成浅蓝色沉淀 A pale blue precipitate is formed	符合要求 Complies
	D. 显深红色 A deep red colour is produced.	符合要求 Complies
	E. 易溶解 The substance dissolves.	符合要求 Complies
溶液外观 Appearance of Solution	澄清，颜色不深于标准溶液B6, BY6, R6 Solution S is clear and not more intensely coloured than reference solution B6, BY6 or R6	符合要求 Complies
含氮量 Nitrogen	11.5~12.8%	12.0%
炽灼残渣* Residue on ignition	≤0.1% ≤0.1%	符合要求 Complies
铅* Lead*	≤2ppm ≤2ppm	符合要求 Complies
重金属** Heavy Metals**	≤10ppm ≤10ppm	符合要求 Complies
醛 Aldehydes	≤0.05% ≤0.05%	0.009%
肼 Hydrazine	≤1ppm ≤1ppm	<1ppm





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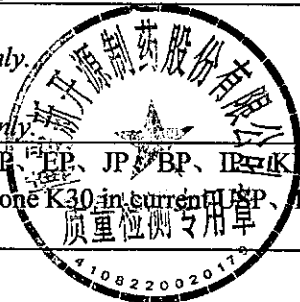
Page 2 of 2

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检验项目 Item	质量标准 Tolerance	检验结果 Test Result
N-乙 烯 基 吡 咯 烷 酮 Vinylpyrrolidinone	≤0.001% ≤=0.001%	0.0002 %
2-吡咯烷酮 2-pyrrolidone	≤3.0% ≤=3.0%	1.5 %
过氧化物 (以H2O2计) Peroxides (as H2O2)	≤400ppm ≤=400ppm	65 ppm
甲酸 Formic Acid	≤0.5% ≤=0.5%	0.3 %
pH pH	3.0 ~ 5.0	3.6
水分(卡尔费休) Water Determination	≤5.0% ≤=5.0%	3.3 %
K值 K-Value	27.0~32.4	30.1
需氧菌总数 TAMC	≤10 <sup>3</sup> cfu/g ≤=10 <sup>3</sup> cfu/g	10 cfu/g
霉菌和酵母菌 TYMC	≤10 <sup>2</sup> cfu/g ≤=10 <sup>2</sup> cfu/g	<10cfu/g
大肠埃希菌 E. Coli	不得检出 (1g) Negative (1g)	未检出 Negative

\*本项测试仅通过随机样品确认。  
\*The test is verified on random samples only.  
\*\*本项测试仅通过定期样品确认。  
\*\*This test is verified on regular sample only.

检验结论: 本批聚维酮K30产品符合USP、EP、JP、BP、IP、KP、FCC、E1201 药典标准  
Conclusion: Meets requirements for Povidone K30 in current USP、EP、JP、BP、IP、KP、FCC、E1201 Pharmacopoeias.



侯利平 2022.04.29  
报告人 Reporter

李艳丽 2022.04.29  
QC经理 QC Manager



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批号/Batch Number	NC220402035	生产日期/Mfg. Date	2022.04.02
批量/Batch Size	5100 kg	复验日期/Retest Date	2025.04.01
依据/According to	企业内控标准 Enterprise internal control standards/ (Spe-N05S01)		

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鉴别 Identification	D. 与对照品图谱一致 Consistent with the CRS	符合要求 Complies
	E. 生成橙黄色沉淀 An orange-yellow precipitate is formed.	符合要求 Complies
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重金属** Heavy Metals**	≤10ppm <=10ppm	符合要求 Complies
醛 Aldehydes	≤0.05% <=0.05%	0.01%
肼 Hydrazine	≤1ppm <=1ppm	<1ppm





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Page 2 of 2

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甲酸 Formic Acid	≤0.5% <=0.5%	0.3%
pH pH	3.0~5.0	3.6
水分(卡尔费休) Water Determination	≤5.0% <=5.0%	3.9%
K值 K-Value	27.0~32.4	30.2
需氧菌总数 TAMC	≤10 <sup>3</sup> cfu/g <=10 <sup>3</sup> cfu/g	<10cfu/g
霉菌和酵母菌 TYMC	≤10 <sup>2</sup> cfu/g <=10 <sup>2</sup> cfu/g	<10cfu/g
大肠埃希菌 E. Coli	不得检出 (1g) Negative (1g)	未检出 Negative

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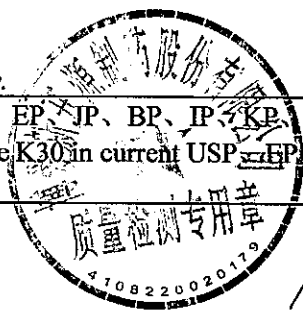
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侯林序 2022.04.29  
报告人Reporter

李艳丽 2022.04.29  
QC经理QC Manager