



博爱新开源制药有限公司  
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### 检验报告/Certificate of Analysis

检验报告单号 Report No: RPG05S01008-2511013860

Page 2 of 2

商品名称/Trade Name	KoVidone®K30		
产品名称/Product Name	聚维酮K30/Povidone K30		
产品编号/Product Code	G05S01008	产品等级/Product Grade	USP26级/USP26 Grade
批号/Batch Number	2511013860	生产日期/Mfg. Date	2025. 11. 01
批量/Batch Size	7,300.00 KG	复验日期/Retest Date	2028. 10. 31
依据/According to	企业内控标准/Enterprise internal control standards/ (Spe-G05S01)		

检验项目 Item	质量标准 Tolerance	检验结果 Test Result
过氧化物 (以H <sub>2</sub> O <sub>2</sub> 计) Peroxides (as H <sub>2</sub> O <sub>2</sub> )	≤ 400ppm <= 400ppm	89ppm
K值 K-value	27.0 ~ 32.4	30.1
氮含量 Assay (Nitrogen)	11.5% ~ 12.8%	12.1%
需氧菌总数 TAMC	≤ 10 <sup>3</sup> cfu/g <= 10 <sup>3</sup> cfu/g	20cfu/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 in 1g	未检出/Negative
*本项测试仪通过随机样品确认 * This test is verified on random samples only.		
检验结论: 本批产品符合USP 26标准。 Conclusion: The product complies with the USP 26 Monograph.		

报告人Report/日期Date: 侯利平/Liping Hou/2025. 11. 13/11:18:31  
批准人Approve/日期Date: 高山/Shan Gao/2025. 11. 13/14:03:09  
打印人Print/日期Date: 侯利平/Liping Hou/2025. 11. 13/14:44:40



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SOP-QC-GEN-014-14



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### 检验报告/Certificate of Analysis

检验报告单号 Report No: RPG05S01008-2511023861

Page 1 of 2

商品名称/Trade Name	KoVidone®K30		
产品名称/Product Name	聚维酮K30/Povidone K30		
产品编号/Product Code	G05S01008	产品等级/Product Grade	USP26级/USP26 Grade
批号/Batch Number	2511023861	生产日期/Mfg. Date	2025. 11. 02
批量/Batch Size	7,300.00 KG	复验日期/Retest Date	2028. 11. 01
依据/According to	企业内控标准/Enterprise internal control standards/(Spe-G05S01)		

检验项目 Item	质量标准 Tolerance	检验结果 Test Result
外观 Appearance	白色或乳白色吸湿性粉末或片状颗粒 White or slightly creamy white, hygroscopic powder or flakes.	符合要求/Complies
鉴别A Identification A	生成橙黄色沉淀 An orange-yellow precipitate is formed.	符合要求/Complies
鉴别B Identification B	生成浅蓝色沉淀 A pale blue precipitate is formed.	符合要求/Complies
鉴别C Identification C	显深红色 A deep red color is produced.	符合要求/Complies
pH (1→20) pH (1 in 20)	3.0 ~ 7.0	3.5
水分 Water	≤ 5.0% <= 5.0%	3.6%
炽灼残渣* Residue on Ignition*	≤ 0.1% <= 0.1%	符合要求/Complies
铅* Lead*	≤ 10ppm <= 10ppm	符合要求/Complies
醛 Aldehydes	≤ 0.05% <= 0.05%	0.03%
肼 Hydrazine	≤ 1ppm <= 1ppm	< 1ppm
N-乙烯基吡咯烷酮 Vinylpyrrolidinone	≤ 0.2% <= 0.2%	<0.2%
2-吡咯烷酮 2-Pyrrolidone	≤ 3.0% <= 3.0%	1.3%



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