



博爱新开源制药有限公司
Boai NKY Pharmaceuticals Ltd.

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检验报告/Certificate of Analysis

检验报告单号 Report No: RPG05S01008-2606196433

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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	2606196433	生产日期/Mfg. Date	2026.06.19
批 量/Batch Size	7,300.00 KG	复验日期/Retest Date	2029.06.18
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%	3.9%
炽灼残渣* Residue on Ignition*	≤ 0.1% ≤ 0.1%	< 0.1%
铅* Lead*	≤ 10ppm ≤ 10ppm	< 10ppm
醛 Aldehydes	≤ 0.05% ≤ 0.05%	0.02%
胍 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%

地址: 河南省焦作市博爱县文化路(东段)1888号 邮编: 454450

Address: No.1888 East Wenhua Road, Boai County, Jiaozuo City, Henan Province, China 454450

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SOP-QC-GEN-014-14



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过氧化物 (以H ₂ O ₂ 计) Peroxides (as H ₂ O ₂)	≤ 400ppm ≤ 400ppm	89ppm
K值 K-value	27.0 ~ 32.4	30.2
氮含量 Assay (Nitrogen)	11.5% ~ 12.8%	12.1%
需氧菌总数 TAMC	≤ 10 ³ cfu/g ≤ 10 ³ cfu/g	<10cfu/g
霉菌和酵母菌 TYMC	≤ 10 ² cfu/g ≤ 10 ² cfu/g	<10cfu/g
大肠埃希菌 E. Coli	不得检出 (1g) Negative in 1g	未检出/Negative

*本项测试仅通过随机样品确认

* 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/2026.06.29/14:59:20

批准人 Approve/日期 Date: 高山/Shan Gao/2026.06.29/17:57:25

打印人 Print/日期 Date: 侯利平/Liping Hou/2026.06.30/08:33:21



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