

HEBEI JIHENG PHARMACEUTICAL CO., LTD.



河北冀衡药业股份有限公司

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06/04/2022

REC-BG00066-02

CERTIFICATE OF ANALYSIS

Name of Product (品名)	Folic Acid Hydrate (叶酸)		
Lot No. (批号)	COS022111019	Report No. (编号)	0211019(COS)
Quantity (数量)	125Kg	Test Date (检验日期)	2021/12/06
Mfg. date (生产日期)	2021/12/01	Report Date (报告日期)	2021/12/09
Quality Standard (质量标准)	EP10	Re-test date (复验期)	2025/11/30
COS No.	R1-CEP 2005-031-Rev 01		

项目 Tests	标准 Standards	结论 Results
Characteristics (外观)	Yellowish to orange, crystalline powder. (黄色至橙黄色结晶性粉末)	Yellowish crystalline powder. (黄色结晶性粉末)
Identification (鉴别)	A: Specific optical rotation (比旋度) $+18^{\circ}$ to $+22^{\circ}$ (anhydrous substance 以无水物计)	$+20.8^{\circ}$
	B: IR absorption (红外吸收) Complies (符合规定)	Complies (符合规定)
	D: Water (水分 5.0 %- 8.5 %)	7.6%
Related substances (相关物质)	Impurity A not more than 0.5% (杂质 A 不大于 0.5%)	0.16%
	Impurity D not more than 0.4% (杂质 D 不大于 0.4%)	0.17%
	Impurity C not more than 0.3% (杂质 C 不大于 0.3%)	0.23%
	Impurity E not more than 0.3% (杂质 E 不大于 0.3%)	Not Detected (未检测到)
	Impurity G not more than 0.3% (杂质 G 不大于 0.3%)	0.11%
	Impurity H not more than 0.15% (杂质 H 不大于 0.15%)	0.04%
	Impurity I not more than 0.15% (杂质 I 不大于 0.15%)	Not Detected (未检测到)
	Individual unspecified impurity not more than 0.10% (其它任何杂质不大于 0.10%)	Not Detected (未检测到)
	Total impurities not more than 1.2% (所有杂质总和不大于 1.2%)	0.71%
Sulfated ash (硫酸盐灰分)	Not more than 0.2% (不大于 0.2%)	0.08%
Water (水分)	5.0 %- 8.5 %	7.6%
Assay (含量)	96.0-102.0% (anhydrous basis 以无水物计)	99.5%
Conclusion (结论):	Complies with EP10 (符合 EP10 规定)	
Reported by 报告: 邢荣荣	Reviewed by 审核: 孙世英	Approved by 批准: 康用

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