

HEBEI JIHENG PHARMACEUTICAL CO., LTD.

河北冀衡药业股份有限公司

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26/08/2024

REC-BG00219-00

CERTIFICATE OF ANALYSIS

Name of Product (品名)	Folic Acid Hydrate (叶酸)		
Lot No. (批号)	COS022407002	Report No. (编号)	0207002(COS)
Quantity (数量)	125Kg	Test Date (检验日期)	2024/07/07
Mfg. date (生产日期)	2024/07/04	Report Date (报告日期)	2024/07/15
Quality Standard (质量标准)	EP11	Re-test date (复验期)	2028/07/03
COS No.	R1-CEP 2005-031-Rev 01		

项目 Tests	标准 Standards	结论 Results
Appearance (外观)	Yellowish or orange, crystalline powder. (黄色或橙黄色结晶性粉末)	Yellowish crystalline powder. (黄色结晶性粉末)
Identification (鉴别)	A: Specific optical rotation (比旋度) +18° to +22°(anhydrous substance 以无水物计)	+20.9°
	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 %)	8.1%
Related substances (相关物质)	Impurity A not more than 0.5% (杂质 A 不大于 0.5%)	0.22%
	Impurity D not more than 0.4% (杂质 D 不大于 0.4%)	0.11%
	Impurity C not more than 0.3% (杂质 C 不大于 0.3%)	0.21%
	Impurity E not more than 0.3% (杂质 E 不大于 0.3%)	0.01%
	Impurity G not more than 0.3% (杂质 G 不大于 0.3%)	0.10%
	Impurity H not more than 0.15%(杂质 H 不大于 0.15%)	0.05%
	Impurity I not more than 0.15% (杂质 I 不大于 0.15%)	ND(<LOD) (未检测到)
	Individual unspecified impurity not more than 0.10% (单个未知杂质不大于 0.10%)	0.06%
	Total impurities not more than 1.2% (所有杂质总和 不大于 1.2%)	0.76%
Sulfated ash (硫酸盐灰分)	Not more than 0.2% (不大于 0.2%)	0.07%
Water (水分)	5.0 %- 8.5 %	8.1%
Assay (含量)	96.0-102.0% (anhydrous basis 以无水物计)	100.1%
Particle size (粒度)	D50	4.348um
	D90	13.068um
Aerobic bacterial (需氧菌总数)	NMT 1000CFU/g (不得过 1000cfu/g)	Less than 20cfu/g
Mold and Yeasts (霉菌及酵母菌总数)	NMT 100CFU/g (不得过 100 cfu/g)	Less than 20cfu/g
Escherichia Coli (大肠埃希菌)	Should be absent per g(每 g 不得检出)	ND (未检出)
Conclusion (结论):	Complies with EP11 (符合 EP11 规定)	
Reported by 报告:	何立强	Reviewed by 审核: 陈付 Approved by 批准: 李伟

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