

Lot: 0010821

HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD.



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REC-BG00066-00

CERTIFICATE OF ANALYSIS

Name of Product (品名)	Folic Acid Hydrate (叶酸)		
Lot No. (批号)	022005015	Report No. (编号)	0205015(E)
Quantity (数量)	125 Kg	Test Date (检验日期)	2020/05/21
Mfg. date (生产日期)	2020/05/16	Report Date (报告日期)	2020/05/22
Quality Standard (质量标准)	EP10	Re-test.date (复验期)	2024/05/15

项目 Tests	标准 Standards	结论 Results
Characteristics (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 干品计)	+19.8°
	B:HPLC chromatograms (液相色谱鉴别) Complies (符合规定)	Complies (符合规定)
Related substances (相关物质)	Impurity A not more than 0.5% (杂质 A 不大于 0.5%)	0.28%
	Impurity D not more than 0.4% (杂质 D 不大于 0.4%)	0.31%
	Impurity C not more than 0.3% (杂质 C 不大于 0.3%)	0.17%
	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%)	0.03%
	Impurity H not more than 0.15% (杂质 H 不大于 0.15%)	0.07%
	Impurity I not more than 0.15% (杂质 I 不大于 0.15%)	Not Detected(未检测到)
	any other impurity not more than 0.1% (其它任何杂质不大于 0.1%)	Not Detected(未检测到)
	Total impurities not more than 1.2% (所有杂质总和不大于 1.2%)	0.86%
Sulfated ash (硫酸盐灰分)	Not more than 0.2% (不大于 0.2%)	0.09%
Water (水分)	5.0 %- 8.5 %	8.0%
Assay (含量)	96.0-102.0% (anhydrous basis 干品计)	98.5%
Conclusion (结论):	Complies with EP10 (符合 EP10 规定)	
Reported by 报告: 李存宏 王康文 Reviewed by 审核: 刘永强 Approved by 批准: 焦银霞		

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