Lot - 0110619

江西天新药业股份有限公司
JIANGXI TIANXIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product name: **Folic Acid** **Batch No.:** **FA19032003**

Manufacturing date: Mar 1, 2019
Retest date: Feb 28, 2021
Package: 20 kg per drum
Article No.: 09130

Reporting date: Mar 5, 2019
Quantity: 500 kg
Package size: Φ410 × 600 (mm)
Irradiation / ETO treatment: No

Test Item	Specification	Method	Result
Appearance	Yellow, yellow-brownish, or yellowish-orange, odorless, crystalline powder.	USP41	Yellow, yellow-brownish, or yellowish-orange, odorless, crystalline powder
Identification	Ratio: A256/A365: 2.80-3.00	USP41	Comply
Water	NMT 8.5%	USP41	7.9%
Residue on ignition	NMT 0.3%	USP41	0.19%
Residual solvent	No solvent is used or produced in the manufacture of the product.		
Related Compounds	NMT 2.0%	USP41	Comply
Assay (on anhydrous basis)	97.0% ~ 102.0%	USP41	98.4%
Heavy metals			
Lead	≤0.5 mg/kg	AAS, in-house	<0.5 mg/kg
Cadmium	≤0.5 mg/kg	AAS, in-house	<0.5 mg/kg
Arsenic	≤0.5 mg/kg	AAS, in-house	<0.5 mg/kg
Mercury	≤0.1 mg/kg	AAS, in-house	<0.1 mg/kg
Microbials			
Total Aerobic Microbial Count	NMT 100 cfu/g	ChP	<100 cfu/g
Total Yeasts and Moulds Count	NMT 10 cfu/g	ChP	<10 cfu/g
E. Coli	Negative	ChP	Negative
Salmonella	Negative	ChP	Negative
S. Aureus	Negative	ChP	Negative

Conclusion: ***This batch complies with the specification of USP41 and additional requirements for heavy metals and microbials.***

Remark: Preserve in well-closed, light-resistant containers.

Reported by: 邓勤芹 **Approved by:**

END OF CERTIFICATE

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