



# 湖北楚维药业有限公司

HUBEI TRUEVITA PHARMACEUTICAL CO.,LTD.

## Certificate of Analysis

Product Name : L-5-methyltetrahydrofolate calcium      Quantity : 10.000Kg  
Standard : In-house Standard      Package : 1kg/bag  
Batch Number : LFC250629031      Production Date : Jun.29,2025  
Date of inspection : Jul.13,2025      Expiry Date : Jun.28,2027

Inspection item	Standard provisions	Method	Result	
1. Appearance	White to light yellow crystalline powder,odorless	Visual	Conforms	
2. Identification	Infrared detection	IR	Conforms	
	Calcium detection	USP43	Conforms	
	The retention time of HPLC main peak was in line with the standard	USP43	Conforms	
3. Content (on dry basis)	95.0%~102.0%	USP43	97.40%	
4. Water	6.0%~17.0%	USP43	12.40%	
5. Calcium (on dry basis)	7.0%~8.5%	USP43	8.34%	
6. Impurities	4-aminobenzoyl-glutamic acid	≤0.5%	USP43	0.05%
	4- $\alpha$ -Hydroxy-5-methyltetrahydrofolic acid	≤1.0%	USP43	0.06%
	(6S,R)-Mefox	≤1.0%	USP43	0.09%
	Tetrahydrofolic acid	≤0.5%	USP43	0.10%
	7,8-Dihydrofolic acid	≤0.5%	USP43	Undetected
	Folic acid	≤0.5%	USP43	Undetected
	5,10-methylenetetrahydrofolic acid	≤0.5%	USP43	Undetected
	5-methyltetrahydro p teroic acid	≤0.5%	USP43	Undetected
	Dimethylterahydrofolic acid	≤0.15%	USP43	Undetected
Total impurities	≤2.5%	USP43	0.68%	
7. Heavy metals	≤20mg/kg	USP43	<20mg/kg	
8. Elemental impurity	Plumbum	≤1.0mg/kg	USP43	<1.0mg/kg
	Arsenic	≤1.5mg/kg	USP43	<1.5mg/kg
	Mercury	≤1.5mg/kg	USP43	<1.5mg/kg
	Cadmium	≤0.5mg/kg	USP43	<0.5mg/kg
	Boron	≤50mg/kg	USP43	<50mg/kg
	Platinum	≤10mg/kg	USP43	<10mg/kg
	Chloride	≤0.5%	USP43	0.05%

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9. Residual solvents (Ethanol)		≤0.5%	USP43	0.01%
10. D-5- methyltetrahydrofolic acid		≤1.0%	USP43	0.16%
11. Microbial Limits	Total aerobic bacteria	≤500CFU/g	USP43	Undetected
	Total number of mold and yeast	≤50CFU/g	USP43	Undetected
	Salmonella	Non-detectable	USP43	Undetected
	Escherichiacoli	Non-detectable	USP43	Undetected
	Staphylococcus aureus	Non-detectable	USP43	Undetected
	Pseudomonas aeruginosa	Non-detectable	USP43	Undetected
	Candida albicans	Non-detectable	USP43	Undetected
	Clostridia	Non-detectable	USP43	Undetected

Determination Comply with In-house Standard

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