

## L-5-Methyltetrahydrofolate USP Calcium Powder

### Product Characteristics

Common name	L5 Methylfolate Ca USP Powder
Appearance	Light yellow to white powder
Country of origin	China
Manufacturer	Shanghai Jinli Pharmaceutical Co, Ltd

Profile	Method	Specification
Identification		
A. Infrared absorption	USP	Meets USP
B. Calcium	USP	Meets USP
C. HPLC	USP	Meets USP
Water	USP	6.0 – 17.0%
Calcium	USP	7.0 – 8.5%
Chloride	USP	≤ 0.5%
Elemental impurities		
Boron	USP	< 50 ppm
Platinum	USP	< 10 ppm
Arsenic	USP	< 1.5 ppm
Cadmium	USP	< 0.5 ppm
Lead	USP	< 1.0 ppm
Mercury	USP	< 1.5 ppm
Residual solvents	USP	Meets USP <467>
Enantiomeric purity		
D-5-methyltetrahydrofolate	USP	< 1.0%
Assay (anhydrous)	USP	95.0 – 102.0%
Related compounds		
4-Aminobenzoylglutamic acid	USP	≤ 0.5%
4a-Hydroxy-5-methyltetrahydrofolic acid	USP	≤ 1.0%
6R-Mefox	USP	-
6S-Mefox (6R+6S)	USP	≤ 1.0%
Tetrahydrofolic acid	USP	≤ 0.5%
7,8-Dihydrofolic acid	USP	≤ 0.5%
Folic acid	USP	≤ 0.5%
5,10-Methylenetetrahydrofolic acid	USP	≤ 0.5%
5-Methyltetrahydropteroic acid	USP	≤ 0.5%
Dimethyltetrahydrofolic acid	USP	≤ 0.15%
Total impurities	USP	≤ 2.5%

Total aerobic plate count	USP	$\leq 1000$ CFU/g
Yeast and mold	USP	$\leq 100$ CFU/g
Salmonella	USP	Negative/10g
E. coli	USP	Negative/10g

**Storage**

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Long term: Store at 2-8° C in tight containers, protected from light and moisture. Short term (30 days maximum): Store below 25° C in tight containers, protected from light and moisture.

Revision: 11/9/23