

Specification

L-5-Methyltetrahydrofolate Calcium

USP43 standard

CAS. 151533-22-1

Items	Specification
Appearance	White to light yellow crystalline powder
Solubility	Sparingly soluble in water and very slightly soluble or insoluble in most organic solvents; soluble in alkaline solutions
Identification	
IR	In accordance with standard atlas
Calcium(5mg/ml)	Conformance to Requirements
HPLC	The retention time of the major peak in the chromatogram of the sample solution corresponds to that of the reference standard in the assay test .
Crystal type	I Crystal
Assay(on dry basis)	
L-5- Methyltetrahydrofolate Calcium (HPLC)	95.0%~102.0%
Impurity	
Chloride	NMT 0.5%
Calcium D-5-Methyltetrahydrofolate	NMT 1.0 %
Elemental Impurities	
Total Heavy metal	NMT 20ug/g
Boron	NMT 50ug/g
Platinum	NMT 10ug/g
Arsenic	NMT 1.5ug/g
Cadmium	NMT 0.5ug/g
Lead	NMT 1.0ug/g
Mercury	NMT 1.5ug/g
Related compounds	
4-aminobenzoyl-glutamic acid	NMT 0.5%
4a-Hydroxy-5-methyltetrahydrofolic acid	NMT 1.0%
(6R)-Mefox	NMT 1.0% (6R+6S)
(6S)-Mefox	
Tetrahydrofolic acid	NMT 0.5%
7,8 -Dihydrofolic acid	NMT 0.5%
Folic acid	NMT 0.5%
5,10-Methylenetetrahydrofolic acid	NMT 0.5%
5-Methyltetrahydroptericoic acid	NMT 0.5%
Dimethyltetrahydrofolic acid	NMT 0.15%
Total impurity	NMT 2.5 %

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Residual solvents

Ethanol NMT 5000ppm

2-propanol NMT 5000ppm

Specific Tests

Water content(Karl-Fischer) 6.0%~17.0%

Calcium (on anhydrous and solvent-free basis) 7.0%~8.5%

Microbial Limit

Total Plate count NMT 1000cfu/g

Mold and yeast count NMT 100cfu/g

Salmonella Not Detected

E.coli Not Detected

Staphylococcus aureus Not Detected

Pseudomonas aeruginosa Not Detected

Candisa albicans Not Detected

Clostridia Not Detected