

CERTIFICATE OF ANALYSIS

Product Name	L-5-Methyltetrahydrofolate Calcium		
CAS NO.	151533-22-1		
Batch No.	JK0012-01-2403M03	Batch Quantity	27.8kg
Manufacture Date	13, Mar., 2024	Retest Date	12, Mar., 2026
Analysis Date	22, Mar., 2024	Standard	USP-NF 2023

ITEMS	SPECIFICATION	RESULT
Appearance	White to light yellow crystalline powder	Conforms
Identification	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	Conforms
	IR	Conforms
	Calcium (5g/ml)	Conforms

◆ Assay (on dry basis)

L-5-Methyltetrahydrofolate Calcium (HPLC)	95.0%~102.0%	99.7%
L-5-Methyltetrahydrofolate	≥75.0%	92.0%

◆ Impurity

Chloride	≤0.5%	0.005%
D-5-Methylfolate	≤1.0%	0.2%
Elemental Impurities***		
B	≤50µg/g	Conforms

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Pt	≤10μg/g	Conforms
As	≤1.5μg/g	Conforms
Cd	≤0.5μg/g	Conforms
Pb	≤1.0μg/g	Conforms
Hg	≤1.5μg/g	Conforms

Related Compounds

4-aminobenzoyl-glutamic acid	≤0.5%	Not Detected
4a-Hydroxy-5-methyltetrahydrofolic acid	≤1.0%	0.2%
(6R)-Mefox	≤1.0%(6R+6S)	0.1%
(6S)-Mefox		
Tetrahydrofolic acid	≤0.5%	Not Detected
7,8-dihydrofolic acid	≤0.5%	Not Detected
Folic Acid	≤0.5%	Not Detected
5,10-methyltetrahydrofolic acid	≤0.5%	Not Detected
5-methyltetrahydropteroic acid	≤0.5%	Not Detected
Dimethyltetrahydrofolic acid	≤0.15%	Not Detected
Individual unknown impurity	≤0.10%	0.05%
Total impurity	≤2.5%	0.3%

Residual solvents

Ethanol	≤5000ppm	3399ppm
Acetone	≤5000ppm	Not Detected
Isopropyl alcohol	≤5000ppm	Not Detected

◆ Specific Tests

Water Content (Karl-Fischer)	6.0%~17.0%	14.1%
Calcium (on dry basis)	7.0%~8.5%	8.2%

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◆ **Microbial Limit**

Aerobic bacteria total count	<1000cfu/g	<10cfu/g
Mold and yeast count	<100cfu/g	<10cfu/g
Bile resistance of gram-negative bacteria	<100cfu/g	Not Detected
E.coli	Not Detected/g	Not Detected/g
Staphylococcus aureus	Not Detected/g	Not Detected/g
Salmonella	Not Detected/10g	Not Detected/10g

Note: The items with ***, means we test them every 5 batches.

◆ **Conclusion:**

Conforms to USP-NF 2023 Standard

Analyst	QC Supervisor	QA Director
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