



Lianyungang Jinkang Pharmaceutical Technology Co., Ltd.

The most professional MFG & Supplier for L-Methylfolate

CERTIFICATE OF ANALYSIS

Product Name	L-5-Methyltetrahydrofolate Calcium		
CAS NO.	151533-22-1		
Batch No.	JK0012-01-2403M01	Batch Quantity	28.9kg
Manufacture Date	09, Mar., 2024	Retest Date	08, Mar., 2026
Analysis Date	13, 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%	92.1%

◆ Impurity

Chloride	≤0.5%	0.006%
D-5-Methylfolate	≤1.0%	0.14%

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Elemental Impurities***

B	≤50µg/g	Conforms
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%	0.05%
4a-Hydroxy-5-methyltetrahydro-folic 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%	Not Detected
Total impurity	≤2.5%	0.3%

Residual solvents

Ethanol	≤5000ppm	466ppm
Acetone	≤5000ppm	37ppm
Isopropyl alcohol	≤5000ppm	Not Detected

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◆ **Specific Tests**

Water Content (Karl-Fischer)	6.0%~17.0%	13.0%
Calcium (on dry basis)	7.0%~8.5%	8.2%

◆ **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
陈海/2024.03.19	李松/2024.03.19	吴晓丹/2024.03.19

Cordoba, 16 de Junio de 2026

Se procedió a analizar los parámetros contenidos en la especificación del producto METILFOLATO DE CALCIO, art. nº 1-0077, correspondiente al lote JK0012-01-2403M01, con los siguientes resultados:

Pureza: 99.6%

En virtud de los resultados obtenidos por el elaborador, considerando la calidad del packaging se resuelve extender el vencimiento del producto por 12 meses, siendo su nueva fecha de vencimiento 08/03/2027, para uso industrial exclusivamente.


Atte. Pamela Sagasti

Control de Calidad.