



Lianyungang Jinkang Pharmaceutical Technology Co., Ltd.

*The most professional MFG & Supplier for L-Methylfolate*

## CERTIFICATE OF ANALYSIS

|                         |                                    |                       |                |
|-------------------------|------------------------------------|-----------------------|----------------|
| <b>Product Name</b>     | L-5-Methyltetrahydrofolate Calcium |                       |                |
| <b>CAS NO.</b>          | 151533-22-1                        |                       |                |
| <b>Batch No.</b>        | JK0012-01-2403M01                  | <b>Batch Quantity</b> | 28.9kg         |
| <b>Manufacture Date</b> | 09, Mar., 2024                     | <b>Retest Date</b>    | 08, Mar., 2026 |
| <b>Analysis Date</b>    | 13, Mar., 2024                     | <b>Standard</b>       | USP-NF 2023    |

| ITEMS          | SPECIFICATION                                                                                                                                   | RESULT   |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Appearance     | White to light yellow crystalline powder                                                                                                        | Conforms |
|                | 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 |
| Identification | 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**

|                         |       |        |
|-------------------------|-------|--------|
| <b>Chloride</b>         | ≤0.5% | 0.006% |
| <b>D-5-Methylfolate</b> | ≤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-methyltetrahydrofolic acid | ≤1.0%        | 0.2%         |
| (6R)-Mefox                              |              |              |
| (6S)-Mefox                              | ≤1.0%(6R+6S) | 0.1%         |
| 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-methyltetrahydroptericoic 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<br>(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      |
|-----------------|-----------------|------------------|
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