

ADMAC LIFESCIENCES LIMITED



Plot No. 107A, 107-B & 108-D EPIP, Phase-I, Jharmajri, Baddi, Distt.-Solan (H.P.)

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

| | | | |
|---------------------------------|--|---------------------------|----------------|
| Name of product(Generic) | LEUCOVORIN CALCIUM INJECTION IP 50mg/5.0ml | | |
| Name of product(Brand) | FOLVORIN 50 | | |
| Product Code | ALI/026A | A .R No. | AL/FG/I/26/028 |
| Mfg. Date | FEB.2026 | Generic Batch No. | LCIB26A05 |
| Exp. Date | JAN.2028 | Generic Batch Size | 20200 vials |
| Specification No. | ALI/SP026A/03 | Brand Batch No. | LCIB26A05-B |
| STP No. | ALI/ST026A/03 | Dispatch Qty. | 5000 vials |
| Date of sampling | 08/02/2026 | Date of Reporting | 12/02/2026 |
| Reference | IP&IHS | Page No. | Page 2 of 2 |

| | | | | |
|------------|--|---|------------------------------------|----|
| 8. | Related substances (By HPLC) i)Formylfolic acid ii)Any individual impurity iii)Total impurities (other than formyl folic acid) Folate impurity A | NMT 1.0% NMT 1.0% NMT 2.5% | Not Detected 0.39% 0.69 % | IP |
| 9. | Assay (By HPLC) Each ml contains Leucovorin Calcium IP Equivalent to Leucovorin 10mg | NLT 9.0 mg/ml (90.0%) to NMT 12.0 mg/ml (120.0%) | 10.47 mg (104.67%) | IP |
| 10. | Sterility (Membrane Filtration) | Must be sterile | Under sterility | IP |
| 11. | Bacterial Endotoxins (Gel clot) | NMT 1.0 EU/mg of Leucovorin Calcium | LT 1.0 EU/mg of Leucovorin Calcium | IP |

Remark:In the opinion of the undersigned the sample Complies/Does not comply with IP/BP/USP/In House specification.

Detail of Examiner(s)/Approver:
Name: Atul Sarswat
Qualification: M. Tech (Biotechnology)
Reg. No./Enrollment No.: A0510709051
University Name: Amity University
Place: Noida (U.P)

| | PREPARED BY | CHECKED BY | APPROVED BY |
|--------------------|--------------------|-------------------|--------------------|
| NAME | Vikas Kumar | Atul Sarswat | Atul Sarswat |
| DESIGNATION | Executive | QC Executive | Head of |
| SIGN | | | |
| DATE | 12/02/2026 | 12/02/2026 | 12/02/2026 |

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| <i>Sr. No.</i> | <i>Test</i> | <i>Specification</i> | <i>Results</i> | <i>Ref.</i> |
|----------------|-------------------------------|---|--|-------------|
| 1. | Description | Clear yellowish solution filled in 5ml amber coloured moulded glass vial USP Type I. | Clear yellowish solution filled in 5ml amber coloured moulded glass vial USP Type I. | IHS |
| 2. | Identification (By IR) | Compare the spectrum with that obtained with calcium folinate RS or with the reference spectrum of calcium folinate. | Compare the spectrum with that obtained with calcium folinate RS or with the reference spectrum of calcium folinate. | IP |
| 3. | Clarity of solution | The solution should be transparent in comparison with the standard. | The solution is transparent in comparison with the standard. | IHS |
| 4. | Colour of solution | The solution should bear comparison with standard | The solution bears comparison with standard | IHS |
| 5. | Average fill volume | NLT 5 ml | 5.0ml | IHS |
| 6. | pH (at 25±2°C) | 6.5 to 8.5 | 7.00 | IP |
| 7. | Particulate matter | Particles equal to or greater than 10 microns LT 6000/vial Particles equal to or greater than 25 microns LT 600/vial | 124 16 | IP |

| | PREPARED BY | CHECKED BY | APPROVED BY |
|--------------------|--------------------|-------------------|--------------------|
| NAME | Vikas Kung | [Signature] | Atul Sandhu |
| DESIGNATION | Executive | [Signature] | Head QC |
| SIGN | [Signature] | [Signature] | [Signature] |
| DATE | 12/02/2026 | 12/02/2026 | 12/02/2026 |

ADMAC LIFESCIENCES LIMITED

Corporate office: Admac House, SCO-84, Sec-5, Panchkula-134112 (India).

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