

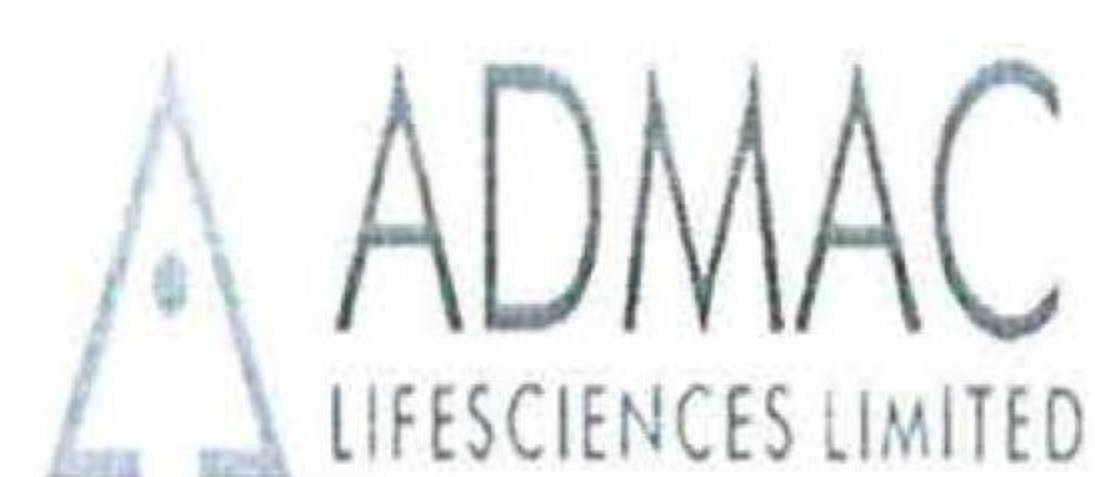


**CERTIFICATE OF ANALYSIS ( FINISHED PRODUCT )**

<b>Name of product(Generic)</b>	LEUCOVORIN CALCIUM INJECTION IP 50mg/5.0ml		
<b>Name of product(Brand)</b>	FOLVORIN 50		
<b>Product Code</b>	ALI/026A	A .R No.	AL/FG/I/25/322
<b>Mfg. Date</b>	DEC.2025	Generic Batch No.	LCIL25A14
<b>Exp.Date</b>	NOV.2027	Generic Batch Size	20200 vials
<b>Specification No.</b>	ALI/SP026A/03	Brand Batch No.	LCIL25A14-E
<b>STP No.</b>	ALI/ST026A/03	Dispatch Qty.	1800 vials
<b>Date of sampling</b>	17/12/2025	Date of Release	01/01/2026
<b>Reference</b>	IP&IHS	Page No.	Page 1 of 3

Sr. No.	Test	Specification	Results	Ref.
1.	<b>Description</b>	Clear yellowish solution filled in 5 ml amber coloured moulded glass vial USP Type I.	Clear yellowish solution filled in 5 ml amber coloured moulded glass vial USP Type I.	IHS
2.	<b>Identification (By IR)</b>	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.	<b>Clarity of solution</b>	The solution should be transparent in comparison with the standard.	The solution is transparent in comparison with the standard.	IHS
4.	<b>Colour of solution</b>	The solution should bear comparison with standard	The solution bears comparison with standard	IHS
5.	<b>Average fill volume</b>	NLT 5 ml	5.0 ml	IHS
6.	<b>pH (at 25±2°C)</b>	6.5 to 8.5	7.05	IP

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Ankit	Chandhar Kumar	Atul Saini
DESIGNATION	offices	Executive	Head of
SIGN			
DATE	13/01/2026	13/01/2026	13/01/2026



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<b>Name of product(Generic)</b>	LEUCOVORIN CALCIUM INJECTION IP 50mg/5.0ml		
<b>Name of product(Brand)</b>	FOLVORIN 50		
<b>Product Code</b>	ALI/026A	<b>A .R No.</b>	AL/FG/I/25/322
<b>Mfg. Date</b>	DEC.2025	<b>Generic Batch No.</b>	LCIL25A14
<b>Exp.Date</b>	NOV.2027	<b>Generic Batch Size</b>	20200 vials
<b>Specification No.</b>	ALI/SP026A/03	<b>Brand Batch No.</b>	LCIL25A14-E
<b>STP No.</b>	ALI/ST026A/03	<b>Dispatch Qty.</b>	1800 vials
<b>Date of sampling</b>	17/12/2025	<b>Date of Release</b>	01/01/2026
<b>Reference</b>	IP&IHS	<b>Page No.</b>	Page 2 of 3

<b>7.</b>	<b>Particulate matter</b>	Particles equal to or greater than 10 microns LT 6000/vial Particles equal to or greater than 25 microns LT 600/vial	157 64	IP
<b>8.</b>	<b>Related substances (By HPLC)</b> 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%	0.14% 0.33 % 0.97 %	IP
<b>9.</b>	<b>Assay (By HPLC)</b> 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%)	10.789 mg (107.89%)	IP
<b>10.</b>	<b>Sterility (Membrane Filtration)</b>	Must be sterile	Sterile	IP

	<b>PREPARED BY</b>	<b>CHECKED BY</b>	<b>APPROVED BY</b>
<b>NAME</b>	Ankit	Chandrayan	Atul Sangwan
<b>DESIGNATION</b>	officer	Executive	Head dc
<b>SIGN</b>			
<b>DATE</b>	13/01/2026	13/01/2026	13/01/2026



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/25/322	
Mfg. Date	DEC.2025	Generic Batch No.	LCIL25A14	
Exp.Date	NOV.2027	Generic Batch Size	20200 vials	
Specification No.	ALI/SP026A/03	Brand Batch No.	LCIL25A14-E	
STP No.	ALI/ST026A/03	Dispatch Qty.	1800 vials	
Date of sampling	17/12/2025	Date of Release	01/01/2026	
Reference	IP&IHS	Page No.	Page 3 of 3	
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	Atul	T. Chakraborty	Atul Sarswat
DESIGNATION	Officer	QC Executive	Head QC
SIGN			
DATE	13/01/2026	13/01/2026	13/01/2026