

**Anthem Biosciences Limited, Unit-2**
 No. 276-P & 277-P, SY No.20,
 Bannikuppe Road, Harohalli Industrial Area,
 Phase II, Harohalli Taluk Bengaluru South
 District-562112, Karnataka, India
CERTIFICATE OF ANALYSIS

Product Name : Leucovorin Calcium USP
 Material/ Anthem code : 400828
 Batch number : A062540494
 Analytical reference No : AR0625040001205
 Batch Quantity : 51.060 kg
 Manufacturer : Anthem Biosciences Limited., Unit-2
 Plant Code : 1006
 Date of manufacture : 30/11/2025 (dd/mm/yyyy)
 Retest date : 29/11/2029 (dd/mm/yyyy)
 Storage condition : Store between 20°C to 25°C. Preserve in well closed, light and moisture resistant container.

Sl. No.	Tests	Results	Limits
1	Appearance	Yellowish white powder	Yellowish white or yellow powder
2	Identification by IR	Complies	IR Spectrum of sample should be consistent with that of standard
3	Identification test for Calcium	Complies	Solutions of calcium salts should form insoluble oxalates.
4	Identification by HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay
5	Organic impurities (% w/w) by HPLC		
	5-(-Gama-folinoyl) tetrahydrofolate	BDL (DL-0.006%)	Not more than 0.3 %
	5-Formyl-5,6,7,8-tetrahydropteroic Acid ^a	0.03%	Not more than 0.5 %
	4-Aminobenzoylglutamic acid ^b	0.07 %	Not more than 1.5 %
	10-Formyldihydrofolic acid ^c	0.17 %	Not more than 1.0 %
	5,10-Diformyltetrahydrofolic acid ^d	0.04 %	Not more than 1.5 %
	7,8-Dihydrofolic acid ^e	0.04%	Not more than 0.5 %
	10-Formylfolic acid ^f	BQL (QL-0.03%)	Not more than 0.5 %
	Folic acid	0.06%	Not more than 1.5 %
	Individual unspecified impurity	0.07% at RRT 0.404	Not more than 0.3 %
	Total impurities	0.57 %	Not more than 2.5 %
6	Assay on anhydrous basis(% w/w) by HPLC	99.3 %	Between 95.0% - 105.0%

Page 1 of 3

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Sl. No.	Tests	Results	Limits
7	Water content (% w/w) by KF	6.9 %	Not more than 17.0 %
8	Elemental impurities content by ICP-MS		
	Cobalt (Co)	BDL(DL- 0.076 µg/g)	Not more than 5 ppm
	Nickel (Ni)	BDL(DL - 0.30 µg/g)	Not more than 20 ppm
	Vanadium (V)	BDL (DL- 0.15 µg/g)	Not more than 10 ppm
	Cadmium (Cd)	BDL (DL - 0.03 µg/g)	Not more than 0.5 ppm
	Lead (Pb)	BDL (DL - 0.076 µg/g)	Not more than 2.0 ppm
	Arsenic (As)	BDL (DL - 0.23 µg/g)	Not more than 1.5 ppm
	Mercury (Hg)	BDL (DL - 0.045 µg/g)	Not more than 0.5 ppm
9	Residual solvents by GC-HS		
	Methanol	1166 ppm	Not more than 3000 ppm
	Methyl tert-butyl ether (MTBE)	BDL (DL-300 ppm)	Not more than 5000 ppm
10	Microbial analysis		
	TAMC	70 CFU/g	Not more than 1000 CFU/g
	TYMC	< 10 CFU/g	Not more than 100 CFU/g
	<i>E. Coli</i>	Absent for 1 g	Should be absent for 1 g
	<i>Salmonella spp.</i>	Absent for 10 g	Should be absent for 10 g
	<i>Pseudomonas aeruginosa</i>	Absent for 1 g	Should be absent for 1 g
	<i>Staphylococcus aureus</i>	Absent for 1 g	Should be absent for 1 g
11	Bacterial endotoxin test	< 0.25 EU/mg	Not more than 1.95 EU/mg
12	PXRD	Amorphous	Should be Amorphous

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CERTIFICATE OF ANALYSIS

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Additional test parameters

Sl. No.	Tests	Results	Limits
1	Calcium content	7.2 %	Report result
2	Solubility test	Complies	Slightly soluble to freely soluble in water, practically insoluble in alcohol
3	Clarity test	Complies	Should be free from foreign particles
4	Bulk density	0.23 g/cm ³	0.15 to 0.35 g/cm ³
5	Tapped density	0.28 g/cm ³	0.25 to 0.45 g/cm ³

Remarks: The material **complies** with the specification as per SPEC-0507, V-1.0

Revision history

Version	Summary of changes
1.0	Batch release certificate of analysis

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