CERTIFICATE OF ANALYSIS

(Certificate No. KML068008-01)

Release Date: 01/04/2025 **Re-test Date:** 31/03/2028

Levofolinate EP Impurity F

Identification

Chemical Name :
(2S)-2-[4-[[(2-amino-4-oxo-1,4,7,8-tetrahydropteridin-6-yl)methyl](formyl)amino]benzamido]pentanedioic acid (as per EP)

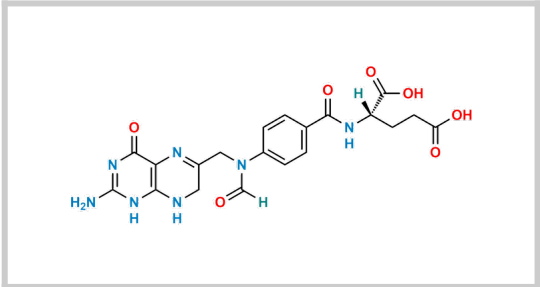
Alt. Name : 10-formyldihydrofolic acid

CAT No. : KML068008

CAS No. : 28459-40-7

Molecular Formula : C20H21N7O7

Molecular Weight : 471.4



Analytical Information

Batch No.	: L068008-091-304	**Solubility**	: ACN : Water (1:1)
Description	: Light Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 96.50 %	**IR**	: Confirm
Weight Loss By TGA	: 4.59 %	**1H NMR**	: Confirm
% Potency	: 92.07 %		

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 4.59(Weight Loss By TGA)] x [96.50(HPLC Purity)]/100 = 92.07 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/04/2025

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA