

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)

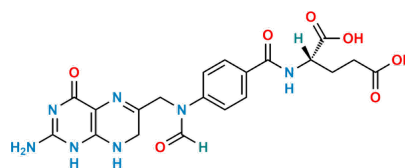
Alt. Name : 10-formyldihydrofolic acid

CAT No. : KML068008

CAS No. : 28459-40-7

Molecular Formula : C₂₀H₂₁N₇O₇

Molecular Weight : 471.4



Analytical Information

Batch No. : L068008-091-304

Description : Light Yellow Solid

HPLC Purity : 96.50 %

Weight Loss By TGA : 4.59 %

% Potency : 92.07 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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