

Analysis Date: 07-11-2025

Re-test Date: 07-11-2028

METHOTREXATE EP IMPURITY E (HCL SALT)

Identification

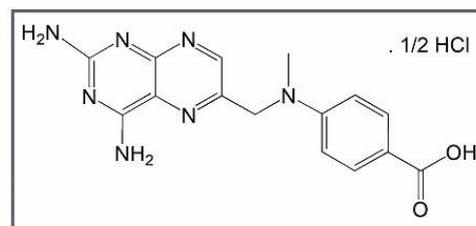
Chemical Name : 4-[[[(2,4-Diaminopteridin-6-yl)methyl]methyl amino]benzoic acid hemihydrochloride salt

CAT No : ALL-MET-483

CAS No : 70844-48-3 (hemihydrochloride salt)

Molecular Formula : C₁₅H₁₅N₇O₂.1/2HCl

Molecular Weight : 343.56



Analytical Information

Batch No	: ALL-MET-483	HPLC Purity	: 96.28 %
Solubility	: MeOH: ACN	Potency	: 95.98 %
Appearance of Product	: Light Brown Solid	Mass	: Confirm
Long Term Storage	: 2-8 0C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.083 %	1HNMR	: Confirm
Residue Of Ignition	: 0.227 %	13C NMR	: Confirm

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 – (0.083+0.227) × 96.28]/100 = 95.98 %

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadse QA Officer	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

Attachment : HPLC, Mass, 1H NMR, IR, TGA, 13C NMR

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office