

CERTIFICATE OF ANALYSIS

(Certificate No. KMV009018-01)

Release Date: 14/03/2025

Re-test Date: 13/03/2028

Valaciclovir EP Impurity H

Identification

Chemical Name :

2-[(2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl L-alaninate Hydrochloride ;

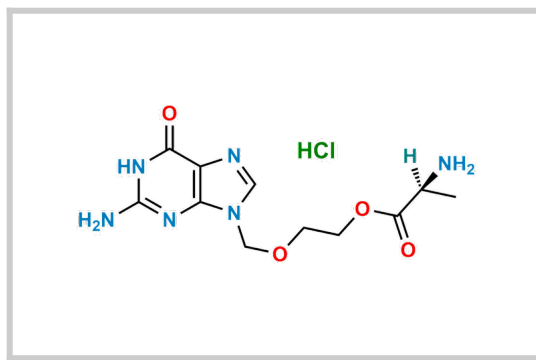
Alt. Name : Valaciclovir USP Related Compound H ; Acyclovir L-Alaninate ; Didesmethyl Valacyclovir ;

CAT No. : KMV009018

CAS No. : 84499-63-8

Molecular Formula : C₁₁H₁₆N₆O₄ : HCl

Molecular Weight : 296.3 : 36.5



Analytical Information

Batch No. : V009018-091

Description : Off white solid

HPLC Purity : NLT 95.1 %

Weight Loss By TGA : NLT 0.1 %

% Potency : 95 %

Solubility : Methanol

Mass : Should be Confirm

IR : Should be Confirm

¹H NMR : Should be 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 - 0.1(Weight Loss By TGA)] x [95.1(HPLC Purity)]/100 = 95 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		14/03/2025

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