

CERTIFICATE OF ANALYSIS

(Certificate No. KMV009018-01)

Release Date: 18/04/2025

Re-test Date: 17/04/2028

Valaciclovir EP Impurity H

Identification

Chemical Name :

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

Alt. Name

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

CAT No.

: KMV009018

CAS No.

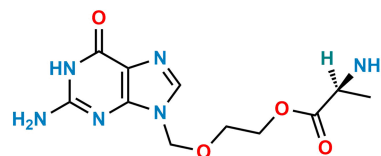
: 84499-64-9 (free base) ; 84499-63-8
(HCl salt)

Molecular Formula

: C₁₁H₁₆N₆O₄

Molecular Weight

: 296.3



Analytical Information

Batch No.

: V009018-091-329

Description

: White Solid

HPLC Purity

: 99.14 %

Weight Loss By TGA

: 3.57 %

% Potency

: 95.6 %

Solubility

: Water

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 - 3.57(Weight Loss By TGA)] x [99.14(HPLC Purity)]/100 = 95.6 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		21/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		21/04/2025

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