APEX HEALTHCARE LIMITED

METAPHARMACEUTICAL

N DE LOTE: 0191225

18/12/2025

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	ACYCLOVIR	**Page No.**	01 of 01
Standard for Release	EP (NON DMF GRADE)	**Drug Lic. No.**	G/25/1642

Batch No.:	AVAH0030525	**Batch Quantity**	139.600 Kg
Mfg. Date:	MAY-2025	**Date of Sampling**	30/05/25
Exp. Date:	APR-2030	**Date of Approval**	03/06/25
A.R.NO.	FP/AV/009/25	**Dispatched Qty.**	15.000 Kg
C.A.S. No.	59277-89-3		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	**Appearance**	white or almost white, crystalline powder.	Complies
2.	**Solubility**	Slightly soluble in water, very slightly soluble in ethanol (96 %), practically insoluble in heptane. It dissolves in dilute solutions of mineral acids and alkali hydroxides.	Complies
3.	**Identification (by IR)**	The Infrared spectrum of test sample should be concordant with the standard spectrum of Acyclovir.	Complies
4.	**Appearance of solution**	The solution is clear and not more intensely coloured than reference solution Y_7.	Complies
5.	**Related Substance**	Impurity B: NMT 0.7 % Impurity J: NMT 0.2 % Sum of impurities K and R: NMT 0.15 % Sum of impurities O and Q: NMT 0.15 % Impurity C: NMT 0.15 % Impurity N: NMT 0.15 % Impurity P: NMT 0.15 % Unspecified impurities: NMT 0.05 % Total: NMT 1.0 %	0.291 % 0.040 % 0.053 % 0.100 % ND BDL BDL BDL 0.484 %
6.	**Water**	Maximum 6.0 %	5.52 %
7.	**Sulfated Ash**	Maximum 0.1%	0.03 %
8.	**Assay (By Potentiometrically)**	98.5 % to 101.0 % (anhydrous substance)	100.54 %

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP'11.6.

Name	Mr. Pankaj Pateliya	Mr. Manoj Salunke	Mr. Samir Mehta
Designation-Dept.	Executive - QC	Executive - QC	Manager - QC
Sign. /Date	20/11/25	20/11/25	20/11/25
	Prepared by	**Reviewed by**	**Approved by**

Mfg. Site Address: Plot no.- 4710, 4711, 4707-A/8, 4707-A/9, GIDC Industrial Estate, Ankleshwar, Dist.-Bharuch– 393002 Gujarat, India. Phone no.: +91 2646 222525/223525/227289.