



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

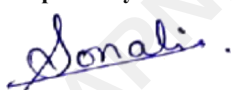
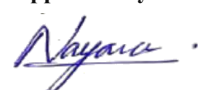
Product Name	Valganciclovir Hydrochloride	CAS No:	175865-59-5
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to off-white powder.	White powder
2	Solubility	Very slightly soluble in alcohol; practically insoluble in 2-propanol, in hexane, in acetone and in ethyl acetate.	Complies
3	Identification by - IR	IR spectrum of test substance should be concordant with that of the working standard spectrum.	Complies
4	Identification by - UV	UV spectrum of the test substance is concordant to that of the working standard spectrum.	Complies
5	Identification by - chloride	A solution meets the requirements of the tests for chloride.	Complies
6	Water content (by KF)	NMT 8.0%	5.8%
7	Residue on ignition	NMT 0.10%	0.05%
8	Limit of Isopropyl alcohol (By GC)	NMT 1.0%	0.001%
9	Related substances (by HPLC) (Test 1) i) Ganciclovir	NMT 1.5%	0.87%
10	ii) Guanine	NMT 0.25%	0.02%
11	iii) Methoxymethylguanine	NMT 0.30%	0.06%
12	iv) Isovalganciclovir	NMT 0.50%	0.01%
13	v) Monoacetoxycyclovir	NMT 0.15%	0.005%
14	vi) Homologue of valganciclovir	NMT 0.25%	0.01%
15	vii) Impurity H	NMT 0.10%	0.004%
16	viii) Impurity I	NMT 0.10%	0.002%
17	ix) Valganciclovir dimer (Stereoisomer A)	NMT 0.10%	Not detected
18	x) Valganciclovir dimer (Stereoisomer B)	NMT 0.10%	Not detected
19	xi) Valganciclovir dimer (Stereoisomer C)	NMT 0.10%	Not detected

Sr No	Test	Acceptance Criteria	Results
20	xii) Other identified impurities a. Bis-valine ester of ganciclovir	NMT 0.10%	0.02%
21	xii) Other identified impurities b. Ganciclovir monopropionate	NMT 0.15%	0.004%
22	xiii) Total other identified impurities	NMT 0.25%	0.02%
23	xiv) Individual unidentified impurity	NMT 0.10%	0.01%
24	xv) Total unidentified impurities	NMT 0.25%	0.05%
25	xvi) Total of all impurities	NMT 3.0%	1.07%
26	xvii) Diastereomer ratio (Test 1)	45:55 to 55:45	53.66% : 46.34%
27	(Test 2) xviii) Ganciclovir mono N-methyl valinate	NMT 0.30%	0.02%
28	Enantiomeric purity of valganciclovir	NLT 97.0%	99.7%
29	Assay by HPLC (On anhydrous and solvent free basis)	NLT 97.0% and NMT 102.0%	99.7%
30	Residual solvents by GC i) Methanol	NMT 3000 ppm	Not detected
31	Residual solvents by GC ii) Dichloromethane	NMT 600 ppm	Not detected
32	Residual solvents by GC iii) N, N-dimethylformamide	NMT 880 ppm	Not detected
33	Bulk density	For information.	0.36 g/mL
34	Tapped density	For information.	0.65 g/mL
35	Sieve retention on 500 micron	For information.	100% passing through 500µm

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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