SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	ZIDOVUDINE IP	**CAS No:**	30516-87-1
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	A white or almost white powder.	White powder.
2	Solubility	Soluble in ethanol (95%), Methanol and sparingly soluble in water.	Complies
3	Identification – By IR	The absorption maxima in the spectrum obtained with the sample should correspond to the spectrum obtained with the Zidovudine RS/working standard or reference spectrum of Zidovudine.	Complies
4	Identification – By HPLC	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the Reference solution (a), as obtained in the test for Assay by HPLC.	Complies
5	Melting Range	Between 122°C to 125°C	124.2°C to 124.8°C
6	Specific optical rotation	Between +60.5° to +63.0°	+62.0°
7	Water content by KF	Not more than 1.0% w/w	0.13% w/w
8	Sulphated ash	Not more than 0.25% w/w	0.06% w/w
9	Related substances - Test A by TLC Before spray	Compare the intensities of any secondary spots observed in the chromatogram obtained with the test solution corresponding to those of the principal spot in the chromatogram obtained with the reference solution. No other secondary spot in the chromatogram obtained with the test solution is more intense than the principle spot in the chromatogram obtained with the reference solution (0.5%).	Not detected
10	Related substances - Test A by TLC (Cont.) After spray	No spot corresponding to Triphenyl methanol is more intense than the corresponding spot obtained with the reference solution (0.5%). No secondary spot in the chromatogram obtained with the test solution is more intense than the principle spot in the chromatogram obtained with the reference solution	Not detected
11	Test B by HPLC Zidovudine impurity-B	Not more than 1.0% w/w	0.05%
12	Test B by HPLC Zidovudine impurity-C	Not more than 2.0% w/w	Not detected
13	Test B by HPLC β-Thymidine	Not more than 0.15% w/w	0.01%
14	Test B by HPLC Stavudine	Not more than 0.15% w/w	0.002%

Sr No	Test	Acceptance Criteria	Results
15	Test B by HPLC Total impurities (Test A & Test B)	Not more than 3.0% w/w	0.1%
16	Assay by HPLC (On anhydrous basis)	Not less than 97.0% and not more than 102.0% of C10H13N5O4.	100.0% w/w
17	Heavy metals	Not more than 20 ppm	Less than 20 ppm
18	Residual solvents by GC Method-1 Ethyl acetate	Not more than 3000 ppm	188 ppm
19	Residual solvents by GC Methanol	Not more than 500 ppm	5 ppm
20	Residual solvents by GC Toluene	Not more than 500 ppm	6 ppm
21	Residual solvents by GC 1,4-Dioxane	Not more than 380 ppm	Not detected
22	Residual solvents by GC DMSO	Not more than 500 ppm	Not detected
23	Residual solvents by GC Method-2 Triethylamine	Not more than 100 ppm	Not detected
24	Bulk density	Not less than 0.5 g/ml	0.64 g/ml
25	Tapped density	Not less than 0.7 g/ml	0.98 g/ml
26	Particle size (By sieve analysis) Passed through ASTM sieve No.25	Not less than 95% w/w	99.8% w/w
27	Particle size (By sieve analysis) Retained on ASTM sieve No.100	Not less than 50% w/w	59.2% w/w

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

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

Swanroop Drugs And Pharmaceuticals Quality Assurance Aurangabad