HETERO LABS LIMITED (UNIT-IX)
Plot No.2,Hetero Infrastructure SEZ Ltd.,N.Narasapuram (Village.), Nakkapalli (Mandal),Visakhapatnam (Dist.)-531081, A.P., India.Tel : +91891-2877770, Fax : +91891-2877755.

CERTIFICATE OF ANALYSIS
(Working Standard)

Product/ Material: ZIDOVUDINE

A.R. No.	HL09WS22000024	**STP No.**	ZD-001-07
W.S. Lot No.	HLLIX/ZDWS/22/1	**Source Batch No.**	ZD22020002
Pharmacopeia Lot No.	R052L0	**W.S. Lot Valid Upto**	29-12-2024
Reference	USP	**W.S. Validated on**	30-12-2022 15:46
Traceable Lot No.	R052L0	**Status**	Initial-Certification

S. No.	TEST	RESULT	SPECIFICATION
1	**Description (Ref:Visual Inspection)**	An Off white powder	White to Yellowish powder
2	**Solubility (Ref:Visual Inspection)**	Complies	Sparingly soluble in water. Soluble in alcohol
3	**Melting Point (Ref:USP<741>)**	123.3 °C	Melts between 120.0°C and 127.0°C
4	**Identification by**		
4.1	**Infrared absorption (Ref:USP<197K>)**	Matches with Reference standard	The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Zidovudine Reference Standard.
4.2	**HPLC (Ref:USP<621>)**	Matches with Reference Standard	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC test.
5	**Specific rotation on anhydrous basis[a] $_{D}^{25}$ (c=1%w/v in alcohol) (Ref:USP<781S>)**	61.2 °	Between + 60.5° and + 63.0°
6	**Water by KF (Ref:USP<921>)**	0.08 % w/w	Not more than 0.50%w/w
7	**Residue on ignition (Ref:USP<281>)**	0.03 %w/w	Not more than 0.25%w/w
8	**Chromatographic Purity**		

Remarks: APPROVED (Sample Conforms to above Specification)

Out Sourced Test(s): Solubility (Ref:Visual Inspection)
Melting Point (Ref:USP<741>)
Specific rotation on anhydrous basis[a] $_{D}^{25}$ (c=1%w/v in alcohol) (Ref:USP<781S>)
Residue on ignition (Ref:USP<281>)
Test A – by TLC (Ref:USP< 201>)
Test B – by HPLC (Ref:USP <621>In- House)
Residual Solvents by GC (Ref:USP <467>In-House)
N-Nitrosoamine content by GC-MS/MS(Ref : In-House)

Analyzed By	Korra.Lovaraju	Checked By	Lamba.Venkata Ramana	Approved By	Mule.Rajasekhar Reddy
Analyzed On	29-12-2022 17:57	Checked On	29-12-2022 18:09	Approved On	30-12-2022 15:46

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8.1	**Test A – by TLC (Ref:USP< 201>)**		
8.1.1	**Max. Single Unknown Impurity**	Below LOD (LOD=0.3%)	Not more than 0.5%
8.1.2	**Triphenyl methanol**	Below LOD (LOD=0.3%)	Not more than 0.5%
8.1.3	**Total Impurities (From Test A)**	0.6 %	Not more than 3.0%
8.2	**Test B – by HPLC (Ref:USP <621>In- House)**		
8.2.1	***Related compound-A**	0.03 %	Not more than 0.10%
8.2.2	**Related compound-B**	0.02 %	Not more than 0.15%
8.2.3	**Related compound-C**	Not Detected	Not more than 0.15%
8.2.4	**Any unspecifiedImpurity**	0.05 %	Not more than 0.10%
8.2.5	**Total Impurites (from Test-A and Test -B)**	0.8 %	Not more than 3.0 %
9	**Assay by HPLC on anhydrous basis (Ref:USP <621>In-House)**	99.5 % w/w	Not less than 98.0% and Not more than 102.0%w/w
10	**Residual Solvents by GC (Ref:USP <467>In-House)**		
10.1	**Methanol**	Below LOQ(LOQ=73 ppm)	Not more than 600 ppm
10.2	**Ethyl Acetate**	257 ppm	Not more than 1000 ppm
10.3	**Toluene**	Not Detected	Not more than 60 ppm
10.4	**Dimethyl Sulphoxide**	Not Detected	Not more than 500 ppm
11	**N-Nitrosoamine content by GC-MS/MS(Ref : In-House)**		
11.1	**N-Nitrosodiethylamine(NDEA) content**	Not Detected	Not more than 0.03 ppm.
11.2	**N-Nitrosodibutylamine(NDBA**	Not Detected	Not more than 0.03 ppm.

Remarks: APPROVED (Sample Conforms to above Specification)

Out Sourced Test(s): Solubility (Ref:Visual Inspection)
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	) content		
11.3	**Total content of Nitrosoamine impurities**	Not Detected	Not more than 0.03 ppm.

Test Plan Remarks: * In-house impurity.$ Reduced testing: Multiple of every 30th batch shall be tested

Remarks: APPROVED (Sample Conforms to above Specification)

Out Sourced Test(s): Solubility (Ref:Visual Inspection)
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