

**HETERO LABS LIMITED**  
Unit-III, # 22-110,IDA,  
Jeedimetla,  
Hyderabad – 500 055, T.S., INDIA.



**CERTIFICATE OF ANALYSIS**  
**(Finished product)**

Product Name: Zidovudina 50mg/5mL solution oral (Zidovudine Oral Solution USP 50mg/5mL)

Product Code	4025881	A.R. No.	03FP24000114
Batch No.	E240010	Batch Size	4167 No's
Mfg. Date	01/2024	Pack size/Type	240 ML HDPE(WITH FSE WAD)
Exp. Date	12/2025	Specification No.	FPS/4025881-1-01
Re-test Date	--	Date of Release	19-01-2024 19:03

S. No.	TEST	RESULT	SPECIFICATION
1	<b>Description (Visual inspection)</b>	Colorless strawberry flavored liquid, filled in 250cc HDPE opaque bottles and child resistant cap with induction sealing wads (FSE).	Colorless to pale yellow, strawberry flavored liquid, filled in 250cc HDPE opaque bottles and child resistant cap with induction sealing wads (FSE).
2	<b>Identification</b>		
2.1	<b>By TLC</b>	The Rf value of the principal spot obtained from the sample solution corresponds to that of the principal spot obtained from the standard solution.	The Rf value of the principal spot obtained from the sample solution should correspond to that of the principal spot obtained from the standard solution.
2.2	<b>By HPLC</b>	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3	<b>Microbiological examination</b>		
3.1	<b>Microbial enumeration tests</b>		
3.1.1	<b>Total aerobic microbial count</b>	Less than 10 cfu per mL	Not more than 100cfu per mL
3.1.2	<b>Total combined yeast and molds count</b>	Less than 10 cfu per mL	Not more than 10cfu per mL
3.2	<b>Test for specified Microorganisms</b>		
3.2.1	<b>Staphylococcus aureus</b>	Absent per mL	Should be absent per mL
3.2.2	<b>Pseudomonas aeruginosa</b>	Absent per mL	Should be absent per mL
3.2.3	<b>Salmonella species</b>	Absent per 10mL	Should be absent per 10mL
3.2.4	<b>Escherichia coli</b>	Absent per mL	Should be absent per mL
4	<b>Deliverable volume</b>		

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Nookala.Lakshmi Sravani	Approved By	Venkata Rama Prasad.Dangeti
Checked On	19-01-2024 17:48	Approved On	19-01-2024 19:03
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4.1	<b>Average fill volume</b>	248 mL	Not less than 240mL
4.2	<b>Fill volume variation</b>	Meets the requirements	Should meet the requirements
5	<b>pH</b>	3.92	Between 3.0 and 4.0
6	<b>Related compounds (By HPLC)</b>		
6.1	<b>Zidovudine related compound C (Thymine)</b>	Not Detected	Not more than 3.0%w/w
6.2	<b>Impurity at RRT 0.17</b>	0.05 %w/w	Not more than 0.20%w/w
6.3	<b>Maximum single unknown impurity</b>	Not Detected	Not more than 0.20%w/w
6.4	<b>Total impurities</b>	0.05 %w/w	Not more than 4.0%w/w
7	<b>Assay (By HPLC)</b>		
7.1	<b>Zidovudine (C<sub>10</sub>H<sub>13</sub>N<sub>5</sub>O<sub>4</sub>), in mg</b>	49.39	Not less than 45.00 and Not more than 55.00
7.2	<b>(%) Labeled amount</b>	98.8	Not less than 90.0 and Not more than 110.0
8	<b>Content of preservative (By HPLC)</b>		
8.1	<b>Sodium benzoate, in mg</b>	9.94	Not less than 9.00 and Not more than 11.00
8.2	<b>(%) Labeled amount</b>	99.4	Not less than 90.0 and Not more than 110.0



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