

SHIJIAZHUANG LONZEAL PHARMACEUTICALS CO., LTD.
 NO. 16, WEST RING ROAD, SHENZE, SHIJIAZHUANG,
 HEBEI PROVINCE - 052560, CHINA

CERTIFICATE OF ANALYSIS

COMMERCIAL NAME: LAMIVUDINE USP
 PRODUCT NAME: (2R, CIS)-4-AMINO-1-(2-HYDROXYMETHYL-1, 3-OXATHIOLAN-5-YI)-(1H)-PYRIMIDIN-2-ONE
 CAS No. : 134678-17-4
 CHEMICAL FORMULA: C₈H₁₁N₃O₃S

Batch No.	Date of Manufacture	Date of Retest	Date of Analysis	Package	Quantity
1900536000	Apr-05-2019	Apr-04-2023	Apr-06-2019	6Kg/Drum	6Kg
ASSAY ITEMS	SPECIFICATION			TEST RESULTS	
Description	White to off-white solid			Complies	
Solubility	Soluble in water			Complies	
Melting Point	Melts at about 176°C			Complies	
Identification	A) By IR ---The IR absorption spectrum of sample is concordant with the spectrum obtained from Lamivudine reference standard.			Complies	
	B) By HPLC --- The retention time of the major peak of sample solution corresponds to that of the System Suitability solution, as obtained in the test for Limit of Lamivudine Enantiomer.			Complies	
Light Absorption	Absorptivity not more than 0.0015			0.000090	
Limit of Lamivudine Enantiomer	Not more than 0.3%			Not detected	
Water (% w/w,By KF)	Not more than 2.0%			0.04%	
Related Compounds	Lamivudine carboxylic acid impurity not more than 0.3%			Not detected	
	Lamivudine-trans (Lamivudine diastereomer) impurity not more than 0.2%			0.09%	
	Salicylic acid impurity not more than 0.1%			Not detected	
	Any other individual impurity not more than 0.1%			0.013%	
	Total impurities not more than 0.6%			0.1%	
Assay (HPLC)	98.0%~102.0% (Anhydrous and solvent-free basis)			100.0%	
Residual	Ethanol is not more than 0.2%			1308ppm	



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Solvents	Triethylamine (TEA) is not more than 0.032%	Not detected
	Dichloromethane is not more than 0.06%	Not detected
	Toluene is not more than 0.089%	Not detected
	N,N-Dimethylformamide is not more than 0.088%	Not detected
	n-Hexane is not more than 0.029%	1ppm
	Total residual solvents are not more than 0.3%	1311ppm
<i>Storage: Preserve in well-closed, light-resistant containers. Store at room temperature.</i>		
Conclusion	Batch No. 1900536000 complies with USP41 Specification.	

N/D= NOT DETECTED

REPORT BY: 王雪 2019.11.21

CHECK BY: 李雪 2019.11.21

QA ADMIN: 王雪 2019.11.21

