

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

CERTIFICATE OF ANALYSIS

COMMERCIAL NAME: EMTRICITABINE
 CHEMICAL NAME: (2R, CIS)-4-AMINO-5-FLUORO-1-(2-HYDROXYMETHYL-1,3-OXATHIOLAN-5-YI)-(1H)-PYRIMIDIN-2-ONE
 CAS No. : 143491-57-0
 CHEMICAL FORMULA: C₈H₁₀FN₃O₃S

Batch No.	Date of Manufacture	Date of Retest	Date of Analysis	Package	Batch Size
LZ04104170201	Feb-15-2017	Feb-14-2019	Feb-22-2017	20kg/Drum	165.40kg
ASSAY ITEMS	SPECIFICATION			TEST RESULTS	
Description	White to off-white powder			Off-white powder	
Solubility	Freely soluble in methanol and water, practically insoluble in dichloromethane.			Complies	
Identification	A: By IR 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 Emtricitabine reference standard.			Complies	
	B: By HPLC The retention time of the major peak in the chromatogram of the test solution corresponds to that in chromatogram of the standard solution, as obtained in the test for Assay.			Complies	
Loss on Drying	Not more than 0.5%			0.1%	
Residue on Ignition	Not more than 0.1%			0.04%	
Heavy Metals	Not more than 20ppm			Complies	
Specific Optical Rotation	-105.0° ~ -115.0° (on dried basis)			-110.0°	
Enantiomer and Emtricitabine 5-epimers content by Chiral HPLC	Emtricitabine Enantiomer Not more than 0.3%			0.01%	
	Emtricitabine 5-epimers Not more than 0.2%			0.08%	
Organic Impurities By HPLC	Fluorocytosine not more than 0.1%			Not Detected	
	Emtricitabine acid not more than 0.3%			0.02%	
	Emtricitabine Sulfoxides not more than 0.15%			0.06%	
	Lamivudine not more than 0.15%			0.03%	
	Emtricitabine 5-fluorouracil analog not more than 0.15%			0.02%	



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Organic Impurities By HPLC	Emtricitabine methyl ester not more than 0.1%	0.02%
	Any other Individual Impurity not more than 0.10%	0.06%
	Total Impurity (Including emtricitabine 5-epimers) not more than 0.6%	0.34%
Residual Solvents	Ethanol is not more than 2000ppm	0.029%
	Triethylamine (TEA) is not more than 320ppm	Not detected
	Dichloromethane is not more than 600ppm	Not detected
	Toluene is not more than 890ppm	Not detected
	N,N-Dimethylformamide is not more than 880ppm	Not detected
	Acetonitrile is not more than 410ppm	Not detected
	n-Hexane is not more than 290ppm	Not detected
Assay (on dried basis)	Not less than 98.0% and not more than 102.0%	99.7%
Conclusion	Batch No. <u>LZ04104170201</u> complies with USP specification.	

REPORT BY: [Signature] 2020.02.29 CHECK BY: [Signature] 2020.02.29 QA ADMIN.: [Signature] 2020.02.29

