

Mylan Laboratories Limited

Plot No.H-12 & H-13, MIDC Waluj Industrial Area Aurangabad - 431 136, Maharashtra India Tel.:+91-0240-3018888,Fax:+91-0240-3018777

CERTIFICATE OF ANALYSIS WORKING STANDARD

Name

: Lamivudine USP

A.R. No.

MLAWSD15000132

Source Batch No.

22117702

Batch No

50048661

Date of Standardization:

22/11/2015

Retest Date

15/05/2016

Ref.Specification

RMSLMD536-00

Validity

15/11/2016

Storage Condition

Store in well closed, light resistant Standardized against:

Lamiyudine USPRS

containers below 30°C

Lot No.IOM388

S.No.	Test	Specification	Results
1)	Description	White to off-white solid.	Off-white solid.
2)	Identification By Infrared absorption	The infrared absorption spectrum of the finely ground test sample in mineral oil should exhibit maxima only at the same wavelengths as that of a similar preparation of Lamivudine RS/WS.	The infrared absorption spectrum of the finely ground test sample in mineral oil exhibits maxima only at the same wavelengths as that of a similar preparation of Lamivudine USPRS Lot No.I0M388.
3)	Water determination (By Coulometric Titration)	Not more than 0.20% w/w	0.03 % w/w
4)	Assay(By HPLC)	Not less than 98.0% w/w and not more than 102.0% w/w of 'Lamivudine' C ₈ H ₁₁ N ₃ O ₃ S, calculated on the anhydrous and solvent free basis.	100.2% w/w
		Also report on 'as-is'basis.	100.0% w/w

Remarks: This working standard complies/does not comply with above reference specification.

	Prepared By	Checked By
Name	Mohan Mokashi	Jayone REGENKULAKASHOOD
Sign	W.	2 28 JUN 2016 (2016)
Date	23/11/15	28/11/15 TEL: 2720 A31 544525130 008
MLLAGB-SOP-QC-	GEN-0026 A19-02-09-15	O. Box 29726 - 00207 ATORIES LTO

Corporate Office: Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad - 500 034, India. Tel: +91-40-30866666, 23550543, Fax: 30866699