

WRS
L3-9

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CERTIFICATE OF ANALYSIS

Working standard name	Lamivudine	Raw material source	Shangai Desano Chemical Pharmaceutical Co. Ltd
Working standard number	WRS LE15-105	Raw material B/No	DBH010-4-B15B-120415B
Effective date	03/2015	Raw material Mfg date	04/2012
Valid up to	03/2016	Raw material Exp date	03/2016
Reference standard batch number	105232	Reference standard source	W.H.O
Test(s) qualified for	Assay	Certificate No:	WRS-0293
Test protocol	PH.INT.		
ITEMS	SPECIFICATIONS	RESULTS	
Description	A white or almost white powder	Almost white powder	
Identification: C. Infrared absorption Spectrophotometry D. Optical rotation Heavy Metals Loss on drying Sulphated ash	C. The Infrared absorption spectrum of the sample is concordant with the spectrum obtained with reference spectrum of Lamivudine D. -135° to -144° NMT 20PPM NMT 5.0 mg/g. NMT 2.0 mg/g.	C. The Infrared absorption spectrum of the sample is concordant with the spectrum obtained with reference spectrum of Lamivudine. D. -139.83° ≤ 20PPM 0.3 mg/g. 1.4 mg/g.	
Assay (% w/w on as is basis)	97.0% -103.0%	101.74 %	
Storage	Kept in tightly closed container, protected from light and stored in a cool dry place		

The above referred material **complies/ does not comply** with the PH.INT.specifications

Name: SIMONE KAPIM

Signature: 

Date: 18/03/15

ANALYST

Name: DR-RADNIAH J

Signature: 

Date: 20/03/15

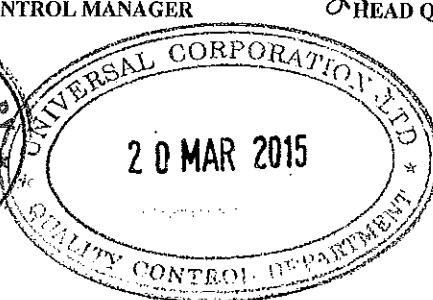
QUALITY CONTROL MANAGER

Name: Dr. Tum, HARA

Signature: 

Date: 20/03/15

HEAD QUALITY ASSURANCE



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