WRS L3.

CORPORATION LIMITED

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CERTIFICATE OF ANALYSIS

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Woulding stondard	T			Shangai Desano Chemical
Working standard name	Lamivudine	Raw material source		Pharmaceutical Co. Ltd
Working standard number	TV		-	
	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		Reference standard		
batch number	105232	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	C. The Infrared absorption spectrum of the sample is concordant with the spectrum obtained with reference spectrum of Lamivudine		C. The Infrared absorption spectrum of the sample is concordant with the spectrum obtained with reference spectrum of Lamivudine.	
D. Optical rotation	D135° to -144°		D139.83°	
Heavy Metals	NMT 20PPM		<20PPM	
Loss on drying	NMT 5.0 mg/g.		0.3 mg/g.	
Sulphated ash	NMT 2.0 mg/g.		1.4 mg/g.	
Assay				0
(% 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			
he above referred material complies/ does not comply with the PH INT specifications				

ernal **complies**/ does not comply with the PH.INT.specifications

Vaine: SIMON

NALYST

Signature: 20/03/6

QUALITY CONTROL MANAGER

HEAD QUALITY ASSURANCE

CORPORA 2 D MAR 2015 CONTROL D



DIRECTORS: P.R Dhanani (British), R.R. Dhanani (Kenyan), P. Keskitalo (Finnish) S. Mwaura (Kenyan), R.M. Haria (Kenyan), Pekka Kaivola (Finnish), L.Kranck (Finnish), C.Otolo (Kenyan)