BUREAU VERITAS Certification

NLS E29-1

CORPORATION LIMITED

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CERTIFICATE OF ANALYSIS

Working standard name	Efythromycin Ethyl Succinate	Raw material source		Anuh Pharma Ltd
Working standard number				
Tr.CC.	WRS EE15-137	Raw material B/No		EES103C14
Effective date	02/2015	Raw material Mfg date		03/2014
Valid up to	02/2016	Raw material Exp date		02/2017
Reference standard batch				
number	2.0	Reference standard source		EDQM
Test(s) qualified for	Assay	Certificate No:		WRS-282
Test protocol	BP2013.		·	
ITEMS	SPECIFICATION	TONS RES		ΓS
Description	White or almost white crystalline powder		White crystalline powder	
Identification:			 	
A. IR Spectrophotometry	A. The IR absorption spectrum of the substance is concordant with the spectrum of Erythromycin Ethyl succinate CRS		A. The IR absorption spectrum of the substance is concordant with the spectrum of Erythromycin Ethyl succinate CRS	
Water	NMT 3.0%		1.37%	
Sulphated Ash	NMT 0.3%		0.07%	
Free erythromycin	NMT 6.0%		2.33%	
Assay % w/w on anhydrous basis) Erythromycin (A+B+C) Erythromycin B Erythromycin C	Min 78.0% Max 5.0% Max 5.0%		81.27% 0.53% 2.02%	
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 BP2013 specifications				
	Name: DR . RADIYAH . J		Name	Complete 11112
ignature:	Signature:		Signature:	
Date: 12/03/15	Date: 13 03 15	TO SECURE OF THE SECOND	Date:	3/13/15
NALYST QUALITY CONTROL MANAGER ORPORATION ASSURANCE				
13 MAR 2015 SEP 2015 DIRECTORS: P.R Dhanani (Britishi), R.R. Dhanani (Kenyan), P. Keskitalo (Finnish)				
S. Mwaura (Kenyan), R.M. Haria (Kenyan), Pekka Kaivola (Finnish), Wangk (Finnish), C. Otolo (Kenyan)				