

QUALITY ASSURANCE

CERTIFICATE OF ANALYSIS WORKING STANDARD				
Name of the Material: Ceftriaxone Sodium Sterile				Working Std. No.: WS-MU09-066
Working standard to be prepared			Reference standard used	
Manufacturer	: Shandong Lukang Pharmaceutical Co. Ltd., China		Standard type	: USP RS
RR No.	: RM-U09-14-0045		Lot / Batch No.	: H02296
Batch No.	: 2081403054		Reference Standard No.	: RS-MU09-051
Mfg. Date	: 03 / 14		Water Content	: 10.18 % (KF)
Exp. Date	: 02 / 17		Potency	: 92.40 % as Ceftriaxone on AB
Number of vial prepared	: 14			: 82.99 % as Ceftriaxone
Date of Standardization	: 13.08.14			
Next Standardization Date : Within One year from Standardization date				
Sl. No.	Tests	USP Specification	SK+F Specification	Result
1	Description	White to yellowish orange crystalline powder	Same	Off-white powder
2	Identification	Must meet A, B, C	Must meet A / B, C	* Positive (B & C)
3	Water	Between 8.0 and 11.0 % KF	Same	9.62 % (KF)
4	Potency	Not less than 79.5% as Ceftriaxone on AB	Same	81.59 % as Ceftriaxone 90.27 % as Ceftriaxone on AB
Remarks : * Results taken from previous CoFA. Certified to use this working standard having potency 81.59 % as Ceftriaxone.				
Reference : Book - 30 ; Page - 247				

14.08.14
Analyzed by
(Sr. QC Executive)

16.08.2014
Checked by
(Sr. Asst. QC Manager)

18.08.14
Approved by
(AGM - QA)