

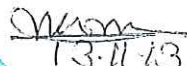
POPULAR PHARMACEUTICALS LTD
QUALITY CONTROL DEPARTMENT
INDUSTRIAL OPERATIONS
TONGI

Certificate of Analysis for Working Standard

Material Name	Ceftriaxone Sodium (Sterile)
Material Code No	PPRA0068
Batch No. (In House)	WS/13(2)/048

Raw material details		Reference Standard details	
Manufacturer	Harbin Pharmaceutical Group Co.China	Name of the RS	Ceftriaxone Sodium
Manufacturer's Batch No.	A201308014	Batch No (in-house)	WS/13/048
GRN No.	PR-1013-087	Potency	850.50 µg/mg
Manufacturing date	18.07.2013	Valid upto	10.06.2014
Expiry date	30.06.2018	Testing instruction	USP+ In house
Analysis date	23.10.2013	Analyst's log book reference	LB/SAH/CEP/02 (Page# 187-189)
Valid Upto	13.11.2014		

Tests	Specifications	Results
Appearance	White to yellowish-orange crystalline powder.	Off-white crystalline powder.
Solubility	Freely soluble in water, sparingly soluble in methanol, very slightly soluble in alcohol.	Complies
Identification - IR Spectra	Must comply with the IR spectrum of Ceftriaxone Sodium CRS	Complies
Retention time (HPLC)	For the analysis of assay, retention time of principal peak for sample & standard must correspond.	Complies
Reaction of Sodium	It gives the reaction of sodium.	Complies
pH	Between 6.0 and 8.0 in a solution (1 in 10)	6.5
Water	Between 8.0% to 11.0%	9.38%
Particulate Matter	Meets the requirement for small volume of injection.	Complies
Assay	Not less than 795 µg of Ceftriaxone per mg on anhydrous basis.	944.35 µg/mg
Assay (As such)	N/A	855.77 µg/mg
Bacterial Endotoxins	Not more than 0.20 USP Endotoxin Unit per mg of Ceftriaxone.	<0.1 EU/mg
Sterility	Must be sterile	Sterile
Absorbance of 10% w/v solution in WFI	Not more than 0.100 Absorbance Unit at 430 nm	0.097
Reconstituted Time	Not more than 2 minutes	LT 2 Min

Conclusion :	Released to use as working standard. Valid up to three months from the date of opening.
Authorized person :	Md. Feroz Alam; Quality Control Manager
Signature :	

Certificate issued on 13/11/2013 by
Popular Pharmaceuticals Limited

End of report

