ESKAYEF PHARMACEUTICALS LIMITED

400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh.

C2-11

SK+F

QUALITY ASSURANCE

CERTIFICATE OF ANALYSIS
WORKING STANDARD

Name of the Material: **Ceftriaxone Sodium Sterile**

Working Std. No.: **WS-MU09-130**

Working standard to be prepared

Manufacturer	: **Sinopharm Weiqida Pharmaceutical Co. Ltd., China**
RR No.	: **RM-U09-17-0056**
Batch No.	: **Q011701011**
Mfg. Date	: **01 / 17**
Exp. Date	: **12 / 19**
Number of Vials Prepared	: **100**
Date of Standardization	: **17.08.17**
Next Standardization Date	: **16.08.18**

Reference standard used

Standard Type	: **Ceftriaxone Sodium USP RS**
Lot / Batch No.	: **HOJ296**
Reference Standard No.	: **RS-MU09-157**
Water Content	: **10.04 % (KF)**
Potency	: **92.40 % as Ceftriaxone on AB** : **83.12 % as Ceftriaxone**

Long Term Storage Condition : **Store in Refrigerator**

Shipping Condition : **Ambient Temperature**

Sl. No.	Tests	USP Specifications	SK+F Specifications	Results
1	Description	White to yellowish orange crystalline powder	Same	Off-white crystalline powder.
2	Identification	Must meet IR, HPLC, Test for Sodium	Must meet IR / HPLC, Test for Sodium	* Positive by HPLC & Soidum Test
3	Water	8.0 – 11.0 % (KF)	Same	9.10 %
4	Assay	NLT 79.5% as Ceftriaxone on AB	Same	84.17 % as Ceftriaxone 92.60 % as Ceftriaxone on AB
5	Impurity	a) Impurity at RRT 0.20: NMT 0.5 % b) Impurity at RRT 0.34: NMT 0.5 % c) Impurity at RRT 0.62: NMT 1.0 % d) Impurity at RRT 0.72: NMT 0.2 % e) Impurity at RRT 0.78: NMT 0.5 % f) Impurity at RRT 1.30: NMT 0.3 % g) Impurity at RRT 1.40: NMT 0.5 % h) Any Ind. Un-specified Impurity: NMT 0.2 % i) Total Impurities: NMT 2.5 %	Same	a) Impurity at RRT 0.20: 0.0 % b) Impurity at RRT 0.34: 0.0 % c) Impurity at RRT 0.62: 0.1 % d) Impurity at RRT 0.72: 0.0 % e) Impurity at RRT 0.78: 0.0 % f) Impurity at RRT 1.30: 0.0 % g) Impurity at RRT 1.40: 0.0 % h) Any Ind. Un-specified Impurity: 0.0 % i) Total Impurities: 0.1 %

Remarks: * Result has been taken from the Raw Material Certificate.
Certified to use this working standard having **potency 84.17 % as Ceftriaxone.**

Reference: Attached Sheets

C2-11

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
04 JAN 2018
TEL: 2726963 / 3544525/30
FAX: 2710073
P.O. BOX 29726 – 00202, NAIROBI

Asif 19.08.17
Prepared by
Asst. QC Manager

19.08.17
Checked by
Sr. Deputy QC Manager

19.08.17
Approved by
Sr. QA Manager

C2-11

SINOPHARM WEIQIDA
PHARMACEUTICAL CO., LTD
Address: Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China
Tel: +86-0352-7698000
Fax: +86-0352-7698001
Web Site: www.weiqida.com
Postal Code: 037300

CERTIFICATE OF ANALYSIS

No. 3-17-05-B-1-060 DATE: May.25,2017

PRODUCT	CEFTRIAXONE SODIUM (STERILE)		
Batch No	Q011701011	Manufacturing date	Jan.10,2017
Quantity	220.00kg	Expiry date	Dec.2019

ANALYSIS		SPECIFICATIONS	RESULTS
Appearance		White to yellowish-orange crystalline powder	Complies
Identification		A: IR	Complies
		B:(HPLC)same retention time with the standard	
		C:It responds to the tests for Sodium	
Solubility		Freely soluble in water,sparingly soluble in methanol,very slightly soluble in alcohol	Complies
Crystallinity		Particles show birefringence and exhibit extinction positions	Complies
pH		6.0~8.0	6.8
Water		8.0%~11.0%	8.5%
Assay(on the anhydrous basis)		≥79.5%	92.4%
Related substances	Deacetylcefotaxime lactone	≤0.5%	Undetectable
	7-Aminocephalosporanic acid	≤0.5%	Undetectable
	Ceftriaxone triazine analog	≤1.0%	0.077%
	Ceftriaxone benzothiazolyloxime	≤0.2%	Undetectable
	Deacyl ceftriaxone	≤0.5%	0.06%
	Ceftriaxone 3-one isomer	≤0.3%	Undetectable
	Ceftriaxone E-Isomer	≤0.5%	Undetectable
	Any individual unspecified impurity	≤0.2%	Undetectable
	Total impurities	≤2.5%	0.34%
Sterility		Sterility	Complies
Bacterial Endotoxins		≤0.2EU/mg	Complies
Particulate Matter		≥10μm ≤3000	149
		≥25μm ≤300	19
Specific optical rotation		-155°~-170°	-164°
Bulk density	Untapped	0.40~0.65g/ml	0.49g/ml
	Tapped	0.50~0.75g/ml	0.56g/ml
Particle size		D(90):100nm~350nm	141.6nm

Conclusion:Conform to USP38 and Internal Standards.

NAME OF ISSUING BANK :COMMERCIAL BANK OF CEYLON PLC,BANGLADESH

L/C NUMBER :265517020274 DATE :170522

IRC NO.BA-0168960, LCA NO.80783, TIN:130399322525, VAT/BIN REGISTRATION NO.1805100448 2 AND H.S.CODE NUMBER :2941.90.90

Approved 贺卫伟
Date May. 25. 2017

Head-QC
Date May. 25. 2017

Analyser
Date May. 25. 2017

RECEIVED
04 JAN 2018

CHECKED
By : 13.06.17

17.08.17

C2-11

ESKAYEF PHARMACEUTICALS LIMITED

SK+F Excellence through quality

Cephalosporin Plant (Manufacturing Unit-09)
400, Tongi Industrial Area, Squibb Road, Tongi, Gazipur, Bangladesh

C2-11

QUALITY ASSURANCE

CERTIFICATE OF ANALYSIS
RAW MATERIAL

Materials	: Ceftriaxone Sodium Sterile			**RM Code**	: RM0054
Manufacturer	: Sinopharm Weiqida Pharmaceutical Co. Ltd., China	**Receiving Quantity**	: 22 x 10 Kg = 220 Kg	**Storage**	: COOL
Supplier	: Sinopharm Weiqida Pharmaceutical Co. Ltd., China	**Packing**	: Sealed in aluminium container in sealed master carton.	**Ana. Ref. No.**	: RCT170077
Date Received	: 13.06.17	**Sampling Date**	: 13-06-17 to 13-06-17	**RR No.**	: RM-U09-17-0056
RR Rev. date by QC	: 13.06.17	**Container Sampled**	: 1	**Bx./Lot No.**	: Q011701011
Declared Potency	: 92.4% as Ceftriaxone on AB	**Quantity Sampled**	: 70 g	**Mfg. Date**	: 01/17
Assigned Potency	: 83.9 % as Ceftriaxone	**Analysis Date**	: 14-06-17 to 19-07-17	**Exp. Date**	: 12/19
				Re-evaluation	: 07/18

Sl. No.	TEST	USP SPECIFICATION	SK+F SPECIFICATION	RESULT
01	Description	White to yellowish orange crystalline powder	Same	Off white crystalline powder.
02	Solubility	Freely soluble in water, sparingly soluble in methanol and very slightly soluble in alcohol	Freely soluble in water	1 g soluble in 5 mL water.
03	Identification	Meet IR, HPLC, Test for Sodium	Meet IR / HPLC, Test for Sodium	Positive by HPLC & Na Test
04	Crystallinity	Particles show birefringence and exhibit extinction positions	Same	Particles show birefringence and exhibit extinction positions.
05	pH	6.0 - 8.0	Same	6.6
06	Water	8.0 - 11.0 % (KF)	Same	9.0 %
07	Assay	NLT 79.5 % as Ceftriaxone on AB	Same	83.9 % as Ceftriaxone 92.2 % as Ceftriaxone on AB
08	Impurity	a) Impurity at RRT 0.20 : NMT 0.5 % b) Impurity at RRT 0.34 : NMT 0.5 % c) Impurity at RRT 0.62 : NMT 1.0 % d) Impurity at RRT 0.72 : NMT 0.2 % e) Impurity at RRT 0.78 : NMT 0.5 % f) Impurity at RRT 1.30 : NMT 0.3 % g) Impurity at RRT 1.40 : NMT 0.5 % h) Any Ind. un-specified Impurity : NMT 0.2 % i) Total Impurities : NMT 2.5 %	Same	Impurity at RRT 0.20 : 0.0 % Impurity at RRT 0.34 : 0.0 % Impurity at RRT 0.62 : 0.1 % Impurity at RRT 0.72 : 0.0 % Impurity at RRT 0.78 : 0.1 % Impurity at RRT 1.30 : 0.0 % Impurity at RRT 1.40 : 0.0 % Any Ind. un-specified Impurity : 0.0 % Total Impurities : 0.1 %
09	Sterility Test	Sterile	Same	No microbial growth found
10	Bacterial endotoxins	NMT 0.2 USP EU per mg of Ceftriaxone	Same	Less than 0.2 USP EU/ mg
Additional Tests				
11	Particulate Matter (No. of particle per g)	---	≥ 10 µm particle: NMT 6000 ≥ 25 µm particle: NMT 600	220 2
12	Sp. Optical Rotation	---	- 155.0° to - 170.0° on AB	- 158.0 ° on AB
13	Bulk Density	---	Untapped: 0.40 - 0.65 g / cc Tapped: 0.50 - 0.75 g / cc	0.49 g / cc 0.60 g / cc
14	Particle size (by Malvern MS 3000)	---	Dv 90: 100 µm to 350 µm	150 µm
15	Residual Solvents	---	Must meet USP requirements (USP - 467)	Methanol = 759 ppm, Ethanol = 0 ppm, Acetone = 176 ppm, Acetonitrile = 2 ppm, Dichloromethane = 1 ppm.

Remarks : Ok

Reference : Book - 95 & 97 **Page -** 226, 189 & Attached Sheet

☑ Released for Use : 220 Kg
☐ Rejected

04 JAN 2018

C2-11

Sampled by	Prepared by	Checked by	Approved by
23.07.17	23.07.17	24.07.17	30.12.17
Md. Saiful Islam	Md. Saiful Islam	Qazi Asif Mahmood	Milan Mahboob
Quality Control Executive	Quality Control Executive	Asst. QC Manager	Sr. Quality Assurance Manager

17.08.