QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

Product:	Ceftriaxone Sodium USP (Sterile)	**Page No.:**	1 of 1
Batch Size:	170.00 kg	**Mfg. Date:**	05/2024
AR No.:	RAL/FP/24/0206	**Exp. Date:**	04/2027
Lic. No.:	Raj.2104	**Batch No.:**	UICFTR240191

S.No.	Test	Result	Specification
1.	Description	A white crystalline powder.	A white to yellowish orange crystalline powder.
2.	Solubility	Freely soluble in water, sparingly soluble in methanol and very slightly soluble in alcohol.	Freely soluble in water, sparingly soluble in methanol and very slightly soluble in alcohol.
3.	Identification: A. (By IR)	The Infra-red spectrum of sample is concordant with the spectrum of the working standard of Ceftriaxone Sodium.	The Infra-red spectrum of sample should concordant with the spectrum of the working standard of Ceftriaxone Sodium.
	B. (By HPLC)	The retention time of major peak in the sample solution is corresponds to that standard solution, as obtained in the assay.	The retention time of major peak in the sample solution should correspond to that standard solution, as obtained in the assay.
	C. (Test for Sodium)	Positive for Sodium	Should be positive for Sodium
4.	Crystallinity	Complies	Meets the requirements.
5.	Appearance of solution	0.079AU	Should be not more than 0.12AU
6.	pH	7.08	Between 6.0 to 8.0
7.	Water	9.42%	Between 8.0% to 11.0%
8.	Organics Impurities: a) Deacetylcefotaxime Lactone [a]	ND	NMT 0.5%
	b) 7-Aminocephalosporanic acid [b,c](If present)	ND	NMT 0.5%
	c) Ceftriaxone triazine analog [d]	ND	NMT 1.0%
	d) Ceftriaxone benzothiazolyloxime[e]	ND	NMT 0.2%
	e) Deacyl ceftriaxone [f]	BDL	NMT 0.5%
	f) Ceftriaxone-3-ene isomer [g]	ND	NMT 0.3%
	g) Ceftriaxone E-isomer[h]	ND	NMT 0.5%
	h) Any individual unspecified impurity	BDL	NMT 0.2%
	i) Total Impurities	BDL	NMT 2.5%
9.	Assay (By HPLC):	924.29µg/mg	Ceftriaxone Sodium contains the equivalent of NLT 795µg/mg of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$), calculate on the anhydrous basis.
10.	BacterialEndotoxins	Lessthan 0.20EU/mg	NMT 0.20EU/mg of ceftriaxone.
11.	Sterility	Sterile	Should be sterile
12.	Particulate matter: (a) Visible Particulate matter (b) Sub Visible Particulate matter ≥ 10µm ≥ 25µm	Free from Visible Particles 520 20	Free from Visible Particles NMT 6000 Particles/gm NMT 600 Particles/gm
13.	ResidualSolvents (By GC-HS): Acetone	25ppm	NMT 5000 ppm
14.	Tapped density	0.53g/ml	For Information only
Storage: - Protect from light, moisture and heat during storage and product handling.			
Remarks:-The product complies as per USP &In-house with respect to above test.			

Analyst by (QC) Date: 29/05/2024

Checked by (QC) Date: 29/05/2024

Approved by (QA) Date: 29/05/2024

RAJASTHAN ANTIBIOTICS LIMITED

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QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

Product:	Ceftriaxone Sodium USP (Sterile)	**Page No.:**	1 of 1
Batch Size:	170.00 kg	**Mfg. Date:**	05/2024
AR No.:	RAL/FP/24/0207	**Exp. Date:**	04/2027
Lic. No.:	Raj.2104	**Batch No.:**	UICFTR240192

S.No.	Test	Result	Specification
1.	Description	A white crystalline powder.	A white to yellowish orange crystalline powder.
2.	Solubility	Freely soluble in water, sparingly soluble in methanol and very slightly soluble in alcohol.	Freely soluble in water, sparingly soluble in methanol and very slightly soluble in alcohol.
3.	Identification: A. (By IR)	The Infra-red spectrum of sample is concordant with the spectrum of the working standard of Ceftriaxone Sodium.	The Infra-red spectrum of sample should concordant with the spectrum of the working standard of Ceftriaxone Sodium.
	B. (By HPLC)	The retention time of major peak in the sample solution is corresponds to that standard solution, as obtained in the assay.	The retention time of major peak in the sample solution should correspond to that standard solution, as obtained in the assay.
	C. (Test for Sodium)	Positive for Sodium	Should be positive for Sodium
4.	Crystallinity	Complies	Meets the requirements.
5.	Appearance of solution	0.065AU	Should be not more than 0.12AU
6.	pH	7.12	Between 6.0 to 8.0
7.	Water	9.26%	Between 8.0% to 11.0%
8.	Organics Impurities: a) Deacetylcefotaxime Lactone [a]	ND	NMT 0.5%
	b) 7-Aminocephalosporanic acid [b,c](If present)	ND	NMT 0.5%
	c) Ceftriaxone triazine analog [d]	ND	NMT 1.0%
	d) Ceftriaxone benzothiazolyloxime[e]	ND	NMT 0.2%
	e) Deacyl ceftriaxone [f]	BDL	NMT 0.5%
	f) Ceftriaxone-3-ene isomer [g]	ND	NMT 0.3%
	g) Ceftriaxone E-isomer[h]	ND	NMT 0.5%
	h) Any individual unspecified impurity	BDL	NMT 0.2%
	i) Total Impurities	BDL	NMT 2.5%
9.	Assay (By HPLC):	924.22µg/mg	Ceftriaxone Sodium contains the equivalent of NLT 795µg/mg of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$), calculate on the anhydrous basis.
10.	BacterialEndotoxins	Lessthan 0.20EU/mg	NMT 0.20EU/mg of ceftriaxone.
11.	Sterility	Sterile	Should be sterile
12.	Particulate matter: (a) Visible Particulate matter (b) Sub Visible Particulate matter ≥ 10µm ≥ 25µm	Free from Visible Particles 447 0	Free from Visible Particles NMT 6000 Particles/gm NMT 600 Particles/gm
13.	ResidualSolvents (By GC-HS): Acetone	55ppm	NMT 5000 ppm
14.	Tapped density	0.53g/ml	For Information only
Storage: - Protect from light, moisture and heat during storage and product handling.			
Remarks:-The product complies as per USP &In-house with respect to above test.			

Analyst by (QC) Date: 29/05/2024

Checked by (QC) Date: 29/05/2024

Approved by (QA) Date: 29/05/2024

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