

<b>Product Name: Ceftaburg (Ceftriaxone Injection IP 1.0 gm)</b>			
Batch No.	: B087023C	A. R. No.	: FP/17/728
Mfg. date	: 05/2017	Sampling date	: 22/05/2017
Exp. date	: 04/2019	Analysis date	: 22/05/2017
Sampled qty	: 40 vials	Release date	: 05/06/2017
Batch size	: 25100 vials	Sampled by	: IPQA
S.No.	Test	Specification	Observation
1.	Description	A white or almost white powder, filled in 10 ml clear colorless glass vials, plugged with grey butyl rubber plugs & sealed with F/O aluminum seal.	White powder filled in 10 ml clear colorless glass vials, plugged with grey butyl rubber plugs & sealed with F/O aluminum seal.
2.	Identification A. By IR  B. By HPLC  C. Test of Sodium Salt	A. Compare the spectrum with that obtained with Ceftriaxone sodium RS or with the reference spectrum of Ceftriaxone sodium.  B. In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.  C. It responds to the test for sodium.	A. The spectrum corresponds with the spectrum that obtained with Ceftriaxone sodium RS or with the reference spectrum of Ceftriaxone sodium.  B. The principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.  C. Responds to the test for sodium.
3.	Average filled weight	1191.99 mg $\pm$ 5 %	1182.68 mg
4.	Appearance of solution	The solution is clear and not more intensely colored than reference solution BY55 or Y55	The solution is clear than reference solution BY55 or Y55
5.	Uniformity of weight	$\pm$ 8 % of Average fill weight	Min.-1145.60mg Max.-1228.90mg
6.	pH (10% w/v solution)	6.0 to 8.0	7.10
7.	Water Content (by KF)	NMT 11.0 %w/w	6.38 %w/w
8.	Particulate Matter	Particle size $\geq$ 10 $\mu$ m/container- NMT 6000 Particle size $\geq$ 25 $\mu$ m/container- NMT 600	673 07
9.	Constituted Solution A. Completeness of solution  B. Clarity of solution	The solid dissolves completely, leaving no visible residue as undissolved matter.  The constituted injection is not significantly less clear than an equal volume of diluents or water for injections contained in a similar container and examined in the same manner.	The solid dissolves completely, leaving no visible residue as undissolved matter.  The constituted injection is clear when compared with equal volume of diluents or water for injections contained in a similar container and examined in the same manner.
10.	Related Substances (Individual Impurity) (Total Impurity)	NMT-1.0% NMT-5.0%	0.064% 0.100%
11.	Bacterial Endotoxins	Not more than 0.20 EU/mg	Less than 0.20EU/mg
12.	Sterility	Must be sterile	Sterile
13.	Assay Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1000 mg	Limit 900.0 mg to 1150.0 mg <b>(90.0% to 115.0% of label claim)</b>	1007.63 mg <b>(100.76%)</b>

**Conclusion:** - The above Batch Complies/Does not complies as per IP and In House specifications.

<b>Analyzed By:</b> Date: 05/06/17	<b>Checked By:</b> Date: 05/06/17	<b>Approved By:</b> Date: 05/06/17
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