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Certificate Of Analysis

Product: Cefotaxime Sodium

Batch No: SN202209007

Quantity : 275.00kg

Packing: 5kg/tin; 2tin/carton

Mfg date: 2022-09-20

Expiry date: 2024-08

Test Item	Specification	Results
1. Appearance	White to yellowish , crystals or powder, Odourless or slightly special odorous	Off-white like crystals, odourless
2. Specific optical rotation	+58°~ +64°	+63°
3. Identification	A. Infrared Absorption B. The retention time of the major peak for cefotaxime in the sample solution corresponds to that of the standard solution, as obtained in the assay C. It responds to the tests for sodium	Complies Complies Complies
4. pH	4.5~6.5	5.0
5.Loss on drying	≤3. 0%	1.9%
6. Related compounds	(1)Deacetylcefotaxime[a]≤1.0% (2)Cefetamet[b]≤1.0% (3)Cefotaxime related compound E[c]≤1.0% (4)N-Formyl cefotaxime[d]≤1.0% (5)E-Cefotaxime[e]≤1.0% (6)Cefotaxime dimer[f]≤1.0% (7)Cefotaxime dioxime[g]≤0.2% (8)Any individual unspecified impurity≤0.2% (9)Total impurities≤3.0%	0.3% 0.3% 0.1% N.D 0.1% 0.3% 0.05% 0.1% 2.0%
7. Bacterial endotoxins	<0.025EU/mg	Complies
8. Sterility	Should be sterile	Complies
9. Assay	916~964μg/mg (dry base)	952μg/mg

PACKAGING AND STORAGE:Preserve in tight containers.

Conclusion: the above batch complies referred above USP43 specifications.

Reporter: **Checker:** **QC Manager:** **Date: 2022-11-08**