

**CERTIFICATE OF ANALYSIS
CEFTRIAZONE SODIUM STERILE**

TEST ITEMS	SPECIFICATIONS	RESULT
Description	Almost white or yellowish, crystalline powder	Almost white crystalline powder
Identity	By IR	Positive
	By HPLC	Positive
	It responds to the tests for Sodium	Positive
Crystallinity	Crystalline	Complies
pH	6.0~8.0	6.4
Particulate mater	Particles $\geq 25\mu\text{m}$: Not more than 600 part/g	3
	Particles $\geq 10\mu\text{m}$: Not more than 6000 part/g	39
Water	8.0% ~ 11.0%	9.4%
Bacterial endotoxine	Less than 0.20 EU/mg	Complies
Sterility	It complies with the test for sterility	Complies
Bulk Density	Not less than 0.40	0.47
Tapped Density	Not less than 0.60	0.70
Residual Solvents	N,N-Dimethylaniline Not more than 20ppm	Complies
	2-Ethylhexanoic acid Not more than 0.8% (m/m)	Complies
Assay	Not less than 795 $\mu\text{g}/\text{mg}$ (on the anhydrous basis)	933 $\mu\text{g}/\text{mg}$
Storage Condition	Be kept in an airtight container, sealed and protected from light. Stored at a temperature not exceed 20°C	