



LIVZON SYNTPHARM CO. LTD (ZHUHAI FTZ)

CERTIFICATE OF ANALYSIS

Product Name	<b>CEFTRIAXONE SODIUM STERILE</b>		
Batch NO.	50604006	Batch Size	250kg
Mfg. Date	April 06, 2006	Expiry Date	April 05, 2009
Based on	USP 29	Date of Report	April 14, 2006
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		

RESULT: ALL RESULTS COMPLY TO USP 29

ANALYSIS BY: 黄卫东 APPROVED BY : 霍少芳 Q.C. MANAGER :

ADD: ZHUHAI FREE TRADE ZONE, WANZAI  
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