



LIVZON SYNTPHARM CO. LTD (ZHUHAI FTZ)

CERTIFICATE OF ANALYSIS

Product Name	CEFPIROME SULPHATE (Buffered with Sodium Carbonate)		
Batch NO.	70603003	Batch Size	12.43kg
Mfg. Date	March 10, 2006	Expiry Date	March 09, 2008
Based on	In-House Standards	Date of Report	March 28, 2006
TEST ITEMS	SPECIFICATIONS		RESULT
Description	Off-White to pale yellow powder		Off-White powder
Identification	Should meet the requirements		Complies
Loss on drying	Not more than 2.5%		1.7%
pH	5.5 ~ 7.5		6.2
Clarity of Solution	Not more opalescent than reference suspension I		Not more opalescent than reference suspension 0.5
Color of Solution	Not more intensely colored than reference solution Y6		Equal to reference solution Y6
Bacterial endotoxins	Less than 0.06Eu/mg		Complies
Visible foreign matter	Should meet the requirements		Complies
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		249
Total Impurity	Not more than 1.5%		0.5%
Single Impurity	Not more than 0.5%		0.1%
Content of Cefpirome (on anhydrous basis)	67.5% ~ 75.0%		70.3%
Assay (on anhydrous basis)	Not less than 82.3%		83.6%
Storage Condition	Be kept in an airtight container, sealed and protected from light. Stored at a temperature not exceed 20°C		

RESULT: The above product complies as per the above specification

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