



LIVZON SYNTPHARM CO. LTD ( ZHUHAI FTZ )

CERTIFICATE OF ANALYSIS

Product Name	CEFEPIME HCL (Buffered with Arginine)		
Batch NO.	70605001	Quantity	30g
Mfg. Date	May. 15, 2006	Expiry Date	Nov. 14, 2007
Based on	IH Standards	Date of Report	May. 30, 2006
TEST ITEMS	SPECIFICATIONS		RESULT
Description	White to pale yellow crystalline powder		Pale yellow crystalline powder
Identification	Should meet the requirements		Complies
Water	Not more than 4.0%		3.5%
pH	4.0~6.0		4.6
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 solution Y <sub>9</sub>		Not more intensely colored than solution Y <sub>3</sub>
Bacterial endotoxins	Less than 0.06Eu/mg		Complies
Visible foreign matter	Should meet the requirements		Complies
Particulate mater	Particles ≥ 25μm: Not more than 600 part/g		4
	Particles ≥ 10μm: Not more than 6000 part/g		133
Limit of N-methyl Pyrrolidine	Not more than 0.5%		0.1%
L-Arginine	33% ~ 38%		34%
Assay (on the anhydrous basis and L-Arginine free)	78.1% ~ 91.1%		85.1%
Storage Condition	Be kept in an airtight container, sealed and protected from light. Stored at a temperature between 2°C ~ 10°C		

RESULT: The above product complies as per the above specification

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