



LIVZON SYNTPHARM CO., LTD. (ZHUHAI FTZ )

CERTIFICATE OF ANALYSIS

Product	: CEFPIROME SULFATE (Buffered with Sodium Carbonate)	
Batch No.	: 70605101	Mfg Date : May 2006
Quantity	: 10.0 kg	Exp Date : May 2009
Tests	Specification	Results
Description	Off-white to pale yellow powder.	Off-white powder.
Solubility	Freely soluble in water.	Freely soluble in water.
Identification	a) HPLC RT should correspond to that of standard. b) Should give characteristic reaction for sodium.	a) HPLC RT corresponds to that of standard. b) Gives characteristic reaction for sodium.
Loss on drying	Not more than 5.0% w/w	2.2%
pH	Between 5.0 and 8.0	6.1
% Transmittance at 600nm	Not less than 90.0%(10% w/v solution in water)	98.5%
Absorbance at 430nm	Not more than 0.3 A (10% w/v solution in water)	0.135 A
Sulphate Content	Between 11.6 and 14.3 % w/w, on as is basis	13.2%
Heavy metals	Not more than 20 ppm	<20 ppm
Bacterial Endotoxins	Not more than 0.2 EU/mg	<0.010 EU/mg
Pyrogenicity	Should meet the requirements	Complies
Sterility	Should be sterile	Sterile
Constituted solution	Should meet the requirements	Complies
Particulate Matter	Should be essentially free from any type of visual particles.	Free from visual particles.
a) Visual		
b) Particles $\geq 10\mu\text{m}$	Not more than 1000	195
c) Particles $\geq 25\mu\text{m}$	Not more than 100	6
Related substances	Not more than 1.0% w/w, on as is basis by HPLC	0.16%
a) Highest individual		
b) Total	Not more than 3.0% w/w, on as is basis by HPLC	0.17%
Content of 2,3-Cyclopentenopyridine	Not more than 0.5% w/w, on as is basis by HPLC	0.1%
Content of Cefpirome	Between 67.5 and 75.0% w/w as Cefpirome on dried basis by HPLC	71.7%
Assay	etween 80.3 and 89.2% w/w as Cefpirome sulphate on dried basis by HPLC	85.0%

RESULT: CONFORMS TO THE MANUFACTURE' S STANDARD

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