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Orchid Chemicals & Pharmaceuticals Ltd.

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QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	: *Cefazolin Sodium EP (Sterile)*		
Batch No.	: CZSU120074		
Mfg. Date	: Aug 2012	**Date of Release**	: 29/09/2012
Retest Date	: Jul 2015	**Quantity**	: 200.00 kg

Storage Condition: Store at a temperature not exceeding 25°C, in a sterilized tamper evident aluminum container, protected from light, and closed with sterilized rubber stopper, finally sealed with sterilized aluminum seal.

Tests	Observations	EP Specifications
1. Description	White powder, very hygroscopic	A white or almost white powder, very hygroscopic.
2. Solubility	Freely soluble in water.	Freely soluble in water.
3. Identification	IR spectrum matches with that of standard Gives characteristic reaction for sodium	IR spectrum of test should match with that of standard Should give characteristic reaction for sodium
4. Appearance of solution	Solution S is clear	Solution S should be clear
Absorbance at 430nm	0.015	The absorbance of solution S should be not more than 0.15
5. pH	5.0	Between 4.0 and 6.0 (10.0% w/v aq. solution)
6. Specific optical rotation $[\alpha]_D^{20}$	-18.0 °	Between -15.0° and -24.0°, on anhydrous basis
7. Absorbance	Complies	The solution should show maximum at 272nm
Specific absorbance at 272nm	296	Between 260 and 300, on anhydrous basis
8. Related substances (by HPLC)		
EP Impurity A	Not detected	Not more than 1.0% w/w, on as is basis
EP Impurity B	0.02%	Not more than 1.0% w/w, on as is basis
EP Impurity C	Not detected	Not more than 1.0% w/w, on as is basis
EP Impurity D	Not detected	Not more than 1.0% w/w, on as is basis
EP Impurity E	0.25%	Not more than 1.0% w/w, on as is basis
EP Impurity G	0.06%	Not more than 1.0% w/w, on as is basis
EP Impurity H	Not detected	Not more than 1.0% w/w, on as is basis
EP Impurity I	0.13%	Not more than 1.0% w/w, on as is basis
EP Impurity L	0.01%	Not more than 1.0% w/w, on as is basis
Highest unknown impurity	0.06%	Not more than 0.10% w/w, on as is basis
Total impurities	0.53%	Not more than 3.5% w/w, on as is basis
9. Water	0.9 %	Not more than 6.0% w/w, by KF method
10. Sterility	Sterile	Should be sterile
11. Bacterial endotoxins	< 0.010 EU/mg	Less than 0.15 IU/mg of Cefazolin
12. Particulate matter		
Visual test	Free from visual particles	Should be essentially free from any type of visual particles
(>=10 µm)	53	Not more than 1000/g
(>=25 µm)	16	Not more than 100/g
13. Assay	97.9 %	Between 95.0% and 102.0% w/w, as Cefazolin sodium, on anhydrous basis, by HPLC
Additional tests :		
14. Residual solvents (by GC-HS)		
Acetone	64 ppm	Not more than 5000 ppm
Triethyl amine	221 ppm	Not more than 320 ppm
15. Boron	<1.0 ppm	Not more than 5 ppm
16. Tapped density	0.90 g/cc	As per customer requirments

Remark: The product complies as per above EP specifications.

This material has been manufactured in compliance with EU GMP requirements and Certificate no. R1-CEP 1998-101-Rev 01

29/9/12

Checked by

29.09.12

Approved by

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