


CERTIFICATE OF ANALYSIS

Product name	LincomycinHydrochloride	Batch No.	170304
Manuf. Date	2017-03-23	Expiry Date	2020-03-22
Quantity	400Kgs	Test Standard	EP9

TEST	SPECIFICATIONS	RESULTS
Description	A white or almost white powder	white powder
IDENTIFICATION	A. IR conform to requirement B. Chloride positive	Pass pass
Appearance of solution	Clear and not more intensely Conform than Y6	pass
Specific rotation	+135° ~+150°	+141°
Solubility	Conform to requirements	pass
pH	3.5-5.5	4.3
Water	3.1%- 4.6%	3.7%
Sulfated ash	≤0.5%	0.06%
Heavy metals	≤5ppm	<5ppm
Related substance: Impurity A Sum of peaks due to Impurity B Impurity C Any other Impurity Total Impurities:	≤0.5% ≤0.5% ≤0.2% ≤0.10% <2.0%	0.31% 0.31% none detected none detected 0.61%
Bacterial Endotoxins	<0.5IU/mg	<0.5IU/mg

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Residual Solvents by GC:		
Acetone:	$\leq 500\text{ppm}$	78ppm
Butanol:	$\leq 1000\text{ppm}$	246ppm
2-octanol:	$\leq 500\text{ppm}$	none detected
Assay(anhydrous substance)		
Lincomycin Hydrochloride	96.0%-102.0%	99.1%
+Lincomycin B Hydrochloride		
Lincomycin B Hydrochloride	$\leq 5.0\%$	2.0%

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light

Conclusion: The product complies with the requirements of EP9.0 standard

Quality Manager:



Rechecker:



Analyst:





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