

HANGZHOU DINGYAN CHEM CO.,LTD

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## CERTIFICATE OF ANALYSIS

NO: DYC091507241

Product name	Lincomycin Hydrochloride
CAS Number	859-18-7
Molecule Structure	H <sub>3</sub> C S
Molecule Formula	C <sub>18</sub> H <sub>35</sub> CIN <sub>2</sub> O <sub>6</sub> S
Batch number	20150422
Manuf&Exp. Date	2015-04-22,2018-04-21
Testing date	2015-04-28

Items	Standard	Result
Characters	A white or almost white, crystalliine powder Dissolves in water and methanol, slightly Soluble in ethanol	A white crystalliine powder
Identification	Soluble in ethanol	
A. Infrared Absorption	Infrared Absorbtion spectrum accord with the spectrum of Lincomycin Hydrochlorid CRS	Meets the requirements
D. Reactions of chlorides	The solution gives the reactions of chlorides	Meets the requirements
Appearance of solution	The solution is clear, and not more intensely coloured than reference solution Y6	The solution is clear, and not more intensely coloured than reference solution Y6
PH	3.5-5.5	4.9
Specific optical rotation	+135°-+150°	+141°
Related substances	Impurity A ≤0.5%	0.2%
	Impurity B ≤0.5%	0.2%
	Impurity C ≤0.2%	0.03%
	Any unspecified impurity ≤0.1%	0.04%
	Total impurities ≤2.0%	0.5%
Heavy metals	≤5ppm	<5ppm
Sulphated ash	≤0.5%	<0.1%

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Water	3.1%-4.6%	3.6%
<b>Bacterial endotoxins</b>	<0.50 IU/mg	<0.50 IU/mg
n-butanol	≤0.5%	Not detected
Acetone	≤0.5%	0.07%
Crystallinity	Meets the requirements	Confirm
Assay	Lincomycin B ≤5%	3.1%
	Sum of the contents of Lincomycin	98.4%
	Hydrochloride and Lincomycin B	
	Hydrochloride: 96.0%-102.0%	
Conclusion:	The above product conforms to EP7	



CHECK:姚仙娟

INSPECTOR: 刘清风

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