

质检报告单——CERTIFICATE OF ANALYSIS

Established in accordance with <Specifications of Fusidic Acid EP> (QA-SMP-J017)

Product Name	Fusidic Acid	Packaging Specification:	15kg/Barrel
CAS Number	6990-06-3	Batch#:	KL20210806147
Man. Date	2021-08-06	Test Date	2021-08-07
Expiry Date	2024-08-05	Report Date	2021-08-07
Item	Specification	Result	
Appearance	White or almost white, crystalline powder	White crystalline powder	
Solubility	Practically insoluble in water, freely soluble in ethanol (96 per cent)	Practically insoluble in water, freely soluble in ethanol (96 per cent)	
Identification A (IR)	(IR) IR absorption spectrum of sample is identical with that of reference substance	IR absorption spectrum of sample is identical with that of reference substance	
Identification B (Reaction of sodium)	The residue does not give reaction (a) of sodium	The residue does not give reaction (a) of sodium	
Impurity M	≤1.0%	0.1%	
Impurity G	≤0.7%	Not Detected	
Impurity L	≤0.5%	Not Detected	
Impurity B	≤0.4%	Not Detected	
Impurity A	≤0.3%	Not Detected	
Impurity H	≤0.10%	Not Detected	
Impurity C	≤0.2%	Not Detected	
Impurity D	≤0.2%	Not Detected	
Impurity F	≤0.2%	Not Detected	
Impurity I	≤0.2%	Not Detected	
Impurity K	≤0.2%	Not Detected	
Impurity N	≤0.2%	Not Detected	
Max un-known Impurity	≤0.1%	Not Detected	
Total impurities	≤0.2%	0.1%	

**Emergency contact number: +86-18040586360****E-mail: chinakanal@163.com Address: Building 1, International Enterprise Center No. 1, Guanggu Avenue, Donghu New Technology Development Zone, Wuhan**

KANAL

武汉可奈尔科技有限公司

Wuhan Kanal Technology Co., Ltd.

Water	1.4%-2.0%	1.8%
Sulfated ash	≤0.2%	0.1%
Assay (on anhydrous basis)	97.5%-101.0%	99.30%
Residual solvents	Ethanol ≤5000ppm	Not Detected
	Methanol ≤3000ppm	Not Detected
	Ethyl acetate ≤5000ppm	Not Detected
	N-hexane ≤290ppm	Not Detected
Particle Size	Particle diameter <20μm >90%	100%
	Particle diameter <30μm 100%	100%
Microbial limit	Bacteria ≤100cfu/g	/
	Total molds and yeasts ≤10 cfu/g	/
	Staphylococcus aureus	None
	Pseudomonas aeruginosa	None
Conclusion	Comply with EP10.0.	

Tester(化验): Liushuangping Re-tester(复核): Liangshang Director(主管): Liuxiao



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