



瀚江化工  
Hanjiang Chemical

山东瀚江化工有限公司

Shandong Hanjiang Chemical Co., Ltd.

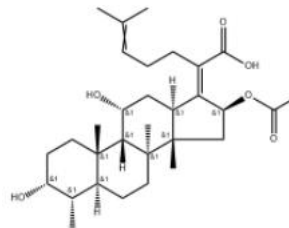
检验报告单

CERTIFICATE OF ANALYSIS

Product: Fusidic Acid

品名: 夫西地酸

CAS: 6990-06-3



Molecular Structure:

Batch No.批号	22060601	Mfg. Date 生产日期	2022-06-06
Ret. Date 复检日期	2024-06-05	Rpt. Date 报告日期	2022-06-13
Source 来源	Workshop 车间		
QCS 检验标准	EPI0.4 欧洲药典 10.4		
<b>TESTS 检验</b>	<b>STANDARD 标准</b>	<b>RESULTS 结果</b>	
Appearance 外观	White or almost white crystalline powder	white crystalline powder	
Solubility 溶解度	Practically insoluble in water, freely Soluble in ethanol(96 percent)	Complies	
Identification 鉴别	The infrared spectrum should be conformed with the fusidic acid CRS	Complies	
	The residue dose not give reaction of sodium	Complies	
Water 水分	1.4%~2.0%	1.71%	
Content(anhydrous substance) 含量(无水物质)	97.5%~101.0%	99.3%	
Sulfated ash 硫酸灰分	≤0.2%	0.14%	
Related Impurity by HPLC 相关杂质	Impurity M≤1.0%	0.28%	
	Impurity G≤0.7%	0.07%	
	Impurity L≤0.5%	ND	
	Impurity B≤0.4%	0.02%	
	Impurity A≤0.3%	0.01%	
	Impurity H≤0.1 %	0.01%	
	Impurity C≤0.2%	0.03%	
Impurity D≤0.2%	0.01%		

	Impurity F $\leq$ 0.2%	0.01%
	Impurity I $\leq$ 0.2%	0.01%
	Impurity K $\leq$ 0.2%	0.02%
	Impurity N $\leq$ 0.2%	0.05%
	Main unspecified impurities $\leq$ 0.1%	0.02%
	Total impurities $\leq$ 2.0%	0.60%
Residual solvents 溶剂残留	Ethanol $\leq$ 5000ppm	Complies
	Methanol $\leq$ 3000ppm	Complies
	Ethyl acetate $\leq$ 5000ppm	Complies
	N-Hexane $\leq$ 290ppm	Complies
Conclusion: Complies With EP 10.4 符合欧洲药典 10.4		

