



分析证明书

CERTIFICATE OF ANALYSIS

Product name: Calcipotriol monohydrate 钙泊三醇一水合物 (EP8.0 标准)	
Batch no. 批号: 20230101	Quantity 数量: 30G
Manuf. date 生产日期: 2023/01/15	Expiry date 有效期: 2025/01/15

ANALYSIS TEST 检验项目		SPECIFICATIONS 规格	RESULTS 结果	
Appearance 性状		White or almost White, crystalline powder. 白色或类白色结晶性粉末	Conforms 符合规定	
Solubility 溶解性		Practically insoluble in water, freely soluble in ethanol(96%), slightly soluble in methylene chloride 几乎不溶于水, 易溶于乙醇(96%), 微溶于二氯甲烷	Conforms 符合规定	
Identification 鉴别		Identification A IR 红外	Corresponds to the reference spectrum 供试品红外光谱与对照品一致	Conforms 符合规定
		Identification B HPLC 液相色谱	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution 供试品主峰保留时间与对照品一致	Conforms 符合规定
Related compounds 有关物质	A: 薄层色谱 TLC	Impurity A 杂质 A $\leq 0.25\%$	ND	
		$R_f=0.4$ (Impurity G or impurity H and the sum) $R_f=0.4$ (杂质 G 或杂质 H 和它们之和) $\leq 0.25\%$	ND	
		Any other individual impurity $\leq 0.1\%$	ND	
	B: 液相色谱 HPLC	Impurity B 杂质 B $\leq 0.5\%$	0.0%	
		Impurity C 杂质 C $\leq 1.0\%$	0.1%	
		Impurity D 杂质 D $\leq 1.0\%$	0.1%	
		Any other individual impurity 其它单个杂质 NMT0.1%	0.0%	
		Total impurities 总杂质 $\leq 2.5\%$	0.2%	
Residual solvents 残留溶媒	Tetrahydrofuran 四氢呋喃 $\leq 720\text{ppm}$	237ppm		
	Ethyl acetate 乙酸乙酯 $\leq 5000\text{ppm}$	2893ppm		
	Petroleum ether 石油醚 $\leq 1000\text{ppm}$	ND		
	Methanol 甲醇 $\leq 3000\text{ppm}$	ND		
	Toluene 甲苯 $\leq 890\text{ppm}$	ND		
	Methyl formate 甲酸甲酯 $\leq 5000\text{ppm}$	ND		
	Ethanol 乙醇 $\leq 5000\text{ppm}$	ND		
	Acetone 丙酮 $\leq 500\text{ppm}$	ND		
Water 水份	3.3%—5.0%	3.4%		
Assay 含量	97.0%~102.0%	100.08%		
Storage Conditions	In a air tight container,best protected from light at -20°C or below			
Conclusion 结论:	CONCLUSION: THE PRODUCT CONFORMS TO EP8.0 本品符合 EP8.0 标准规定			

复核人 Checker:

化验人 Analyst:

