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分析证明书

CERTIFICATE OF ANALYSIS

Product name 品名: Mupirocin Calcium dehydrate 莫匹罗星钙 USP42	
Batch no. 批号: 20230201	Quantity 数量: 30kgs
Manuf. date 生产日期: 2023/02/23	Expiry date 有效期: 2025/02/22

项目 Item	标准 Specifications		结果 Results
Appearance	White or off-white solid		Conforms
Solubility	Very slightly soluble in water, sparingly soluble in anhydrous ethanol and in methylene		Conforms
Identification	IR	IR spectrum of the test specimen should be consistent with the IR	Conforms
	HPLC	The retention time of the major peak of the sample solution corresponds	Conforms
	Calcium	Positive	
Specific optical	-16° ~ -20°		-18°
Water	3.0%~4.5%		2.18%
Chlorides	≤0.5%		Conforms
Microbial Limit	Total Aerobic Microbial Counts	≤1000 cfu/g	Conforms
	Total yeast and Mold Counts	≤100 cfu/g	Conforms
	E Coli	Absent	Conforms
Related substance	Impurity C	≤2.5%	1.5%
	Any other impurity	≤1.0%	0.8%
	Total impurity	≤4.5%	4.2%
Assay (Anhydrous)	920μg/mg~1020μg/mg		932 μg/mg
Storage	Store in an airtight container, protected from light and store at 2-8°C		
Conclusion	The product complies USP42 and In-house Specifications		

复核人 Checker:

化验人 Analyst:

