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分析证明书

CERTIFICATE OF ANALYSIS

Product name 品名: Mupirocin 莫匹罗星 USP42	
Batch no. 批号: 20221216	Quantity 数量: 30kgs
Manuf. date 生产日期: 2022/12/23	Expiry date 有效期: 2024/12/23

项目 Item	标准 Specifications	结果 Results	
Appearance	White or off-white solid	Conforms	
Solubility	Slightly soluble in water, freely soluble in acetone, in anhydrous ethanol and in methylene chloride	Conforms	
Identification	IP spectrum of the test specimen should be consistent with the IP spectrum of reference standard	Conforms	
Identification	The particles show birefringence(interference colors)and extinction positions when the microscope stage is revolved	Conforms	
Ph	3.5 ~4.5	3.85	
Water	≤1.0%	0.18%	
Residual solvents	Ethyl acetate	≤5000 ppm	2106ppm
	Isopropyl acetate	≤5000ppm	N.D.
	Acetone	≤5000ppm	N.D.
	n-Heptane	≤5000ppm	N.D.
Related substance	Impurity C	≤4.0%	2.5%
	Any other impurity	≤1.0%	0.8%
	Total impurity	≤6.0%	4.5%
Assay (Anhydrous)	920µg/mg~1020µg/mg	941 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:

