山东久隆信和药业有限公司

SHANDONG JIULONG SINHERO PHARMACEUTICAL CO.,LTD

分析报告单
Certificate of Analysis

品　名 Product Name	盐酸头孢噻呋 Ceftiofur Hydrochloride	检验日期 Analysis Date	FEB.03, 2023
数 量 Batch Quantity	300KG	生产日期 MFG. Date	JAN.30, 2023
批 号 Batch No.	01423013009	有效期 EXP. Date	JAN.29, 2025

分析项目 Analysis Item	标　准 Standard	分析结果 Test results	项目结论 Items Conclusion
外　观 Appearance	白色或类白色结晶性粉末 White or off-white crystalline powder	类白色结晶性粉末 Off-white crystalline powder	符合规定 Conforms
鉴　别 Identification	供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time for the major peak of sample should correspond to that of reference standard	符合规定 Conforms	符合规定 Conforms
	本品的红外光吸收图谱应与对照品的红外图谱一致 The infrared absorption spectrum of sample corresponds to that of reference standard	符合规定 Conforms	符合规定 Conforms
	甲醇溶液应显氯化物的鉴别反应 Methanol solution should show positive reaction of chloride	符合规定 Conforms	符合规定 Conforms
比旋度 Specific Optical Rotation	-115°～-127°	-119°	符合规定 Conforms
PH	2.0-4.0	2.7	符合规定 Conforms
水 分 Water	≤5.0%	3.4%	符合规定 Conforms
炽灼残渣 Residue on Ignition	≤0.5%	0.09%	符合规定 Conforms
重金属 Heavy Metals	≤20ppm	<20ppm	符合规定 Conforms
粒度分布 Particle Size	D90≤10μm	符合规定 Conforms	符合规定 Conforms
细菌内毒素 Bacterial Endotoxins	≤1.0EU/mg	<1.0EU/mg	符合规定 Conforms
无 菌 Sterility	符合规定 Conforms	符合规定 Conforms	符合规定 Conforms
有关物质（HPLC） Related Substances	头孢噻呋肟乙酯应不得过 0.5% Ceftiofur oxime ethyl ester should not more than 0.5%	ND	符合规定 Conforms

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有关物质（HPLC） Related substances	7-氨基头孢烷酸应不得过 0.5% 7-Aminocephalosporanic acid should not more than 0.5%	ND	符合规定 Conforms
	2-呋喃甲酸应不得过 0.5% 2-Furoic acid should not more than 0.5%	ND	符合规定 Conforms
	N-去乙酰头孢噻呋应不得过 0.5% N-Deacyl ceftiofur should not mnore than 0.5%	0.02%	符合规定 Conforms
	头孢噻肟应不得过 0.5% Cefotaxime should not more than 0.5%	0.02%	符合规定 Conforms
	头孢噻呋 δ-3 异构体应不得过 0.5% Ceftiofur delta-3 isomer should not more than 0.5%	0.01%	符合规定 Conforms
	头孢噻呋 E-异构体应不得过 3.6% Ceftiofur E-isomer should not more than 3.6%	0.01%	符合规定 Conforms
	双氢噻吩硫酯应不得过 0.5% Dihydrothiophenyl thioester should not more than 0.5%	ND	符合规定 Conforms
	头孢噻呋氨基二聚物应不得过 0.8% Ceftiofur amide dimer should not more than 0.8%	ND	符合规定 Conforms
	N-三苯甲基头孢噻呋肟应不得过 0.5% N-Trityl ceftiofur oxime should not more than 0.5%	ND	符合规定 Conforms
	其他单一杂质应不得过 0.5% Other single impurities should not more than 0.5%	符合规定 Conforms	符合规定 Conforms
	杂质总和应不得过 6.0% Total of the impurities should not more than 6.0%	1.85%	符合规定 Conforms
含　量 Assay（HPLC） （以无水物计 calculated on the anhydrous basis）	含头孢噻呋不得少于 85.0% Contain Ceftiofur should not less than 85.0%	92.2%	符合规定 Conforms
	含盐酸头孢噻呋不得少于 91.0%。 Contain Ceftiofur HCl should not less than 91.0%	98.7%	符合规定 Conforms
结论 Conclusion	本品符合 CVP2020。 Conclusion: Complies with the requirements of CVP2020		

受控

化验员：
Analyst:

复核人：付英娣
Reviewed:

质保部批准：
Approved by QA:

山东久隆信和药业有限公司 质检专用章

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