



Hebei Huanhao Biotechnology co.,ltd
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质量报告单

CERTIFICATE OF ANALYSIS

产品名称 Product name	盐酸雷尼替丁 Ranitidine HCl		
CAS 号 CAS No.	71130-06-8	包装规格 Outer Packing	25KG 纸板桶 25KG/drum
生产日期 Production date	2018.04.07	有效期 Shelf life	2020.04.06
执行标准 Standard adopted	USP36 USP36		
分析项目 Items of analysis	质量标准 Specification	实测结果 Results	
外观、色泽 Appearance, color	为类白色至淡黄色结晶性粉末；有异臭；味微苦带涩；极易潮解，吸潮后颜色变深 White to light yellow crystalline powder; odor; taste bitter with astringent; easy deliquescence, moisture absorption after dark	符合规定 Conforms	
溶解性 Solubility	在水中易溶，在乙醇中极微溶解，在乙醚中几乎不溶 Soluble in water, very slightly soluble in ethanol, almost insoluble in ether	符合规定 Conforms	
鉴别 Identification	应呈正反应 Whater liquor show chloride	符合规定 Conforms	
澄清度与颜色 Clarity and color	应符合规定 Should Compliance	符合规定 Conforms	
PH PH	4.5-6.0 4.5-6.0	5.4 5.4	
杂质 B impurity B	≤0.3% ≤0.3%	符合规定 Conforms	
单杂 Single impurity	≤0.1% ≤0.1%	符合规定 Conforms	



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总杂 Total impurity	≤0.5% ≤0.5%	符合规定 Conforms
干燥失重 Loss on drying	≤0.75% ≤0.75%	0.25% 0.25%
灼烧残渣 Residue on ignition	≤0.1% ≤0.1%	0.06% 0.06%
重金属 Heavy metal	≤20ppm ≤20ppm	符合规定 Conforms
含量 Assay	97.5-102% 97.5-102%	99.72% 99.72%
结论 Conclusion	合格 Qualified	