

杭州凌禾医药科技有限公司

Hangzhou Linghe Medical Technology Co.,Ltd.

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Certificate of Analysis

产品名称 Product Name	Bromfenac Sodium INN	数量 Quantity	10kg
批号 Batch Number	21050010108102501	有效期至 Expiry Date	May 06, 2023
生产日期 Manufacturing Date	May 07, 2021	报告日期 Report Date	June 17, 2021
检验标准 Quality Standard	企业标准 Company Standard		
检验项目 ANALYTICAL ITEMS	标准规定 SPECIFICATION	检验结果 RESULTS	
性状 Description	应为本品为黄色或橙黄色结晶性粉末 Yellow or orange -yellow crystalline powder or granules.	符合规定 Conforms	
鉴别 Identification	1.在 268nm 和 379nm 的波长处有最大吸收 Max. Absorption occurs at the wavelengths of 268nm and 379nm 2.红外光吸收图谱应与对照品图谱一致 IR-spectrum of the substance should fully coincide with the location of the reference 3.炽灼后显钠盐的鉴别反应 Identification of sodium salt after incandescence	符合规定 Conforms	
有关物质 Related Substances	最大单个杂质 Max Individual impurity: NMT 0.1%	0.07%	
	总杂质 Total impurity: NMT 0.5%	0.27%	
水分 Water	NMT 1.0%	0.25%	
氯化物 Chlorides	≤0.05%	符合规定 Conforms	
重金属 heavy metals	Not more than 0.002 %	符合规定 Conforms	
含量 Assay (on dried base) C ₁₅ H ₁₁ BrNNaO ₃	98.0%~102.0%	99.7%	
结论: 本品按企业内控标准检验, 结果符合规定。 Conclusion: After inspection, the sample meet company standard.			
Reporter: Caoyi	Checker: Liyong	Reviewer: Caoyi	