

检验报告书  
CERTIFICATE OF ANALYSIS

品名 Name of Product	洛索洛芬钠水合物 Loxoprofen Sodium Hydrate	包装规格 Packaging Specification	25kg/drum×20+ 2.6kg/drum×1
批号 Lot No.	LSH-2303001	批量 Batch Weight	502.6kg
检验单号 COA No.	LSH-23032401	报告日期 Report Date	2023.03.31
生产日期 MFG. Date	2023.03.11	复检期 Retest Date	2026.03.10

分析项目 Analytical Contents	标准 Standards	分析结果 Analytical Results
性状 Characters	A. 白色或略带黄色的结晶或结晶性粉末。 It occurs as white to yellowish white crystals or crystalline powder.	White crystalline
A. 外观 Appearance		
B. 溶解性 Solubility	B. 易溶于水和甲醇，溶于95%的酒精，几乎不溶于乙醚。 It is very soluble in water and in methanol, freely soluble in ethanol (95), and practically insoluble in diethyl ether.	Meets
C. 旋光性 Optical Rotation	C. 无旋光性 Not show optical rotation	Meets
鉴别 Identification	A. 本品溶液的紫外图谱与标准图谱比较：两个图谱在相同波长处的吸收强度相似。 Compare the spectrums between the solution of Loxoprofen Sodium and CRS, both spectra exhibit similar intensities of absorption at the same wavelengths.	Meets
A. 紫外吸收 UV Absorption		
B. 红外吸收 IR Absorption	B. 本品的红外图谱与标准图谱比较：两个图谱在相同波数处的吸收强度相似。 Compare the infrared absorption spectrum of Loxoprofen Sodium with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.	Meets
C. 钠盐 Sodium Salt	C. 本品的水溶液(1→10)显钠盐的鉴别反应。 A solution of Loxoprofen Sodium (1→10) responds to the Qualitative Tests for sodium salt.	Meets
pH值	6.5~8.5	7.5
溶液的澄清度和颜色 Clarity&Color of Solution	溶液澄清无色或呈浅黄色。且颜色不深于稀溶液颜色A(1→2)。 The solution is clear and colorless or pale yellow. The color is not darker than that of diluted Matching Fluid for Color A (1 in 2).	Clear and colorless
纯度 Purity	≤10ppm	<10ppm
重金属 Heavy Metals		
有关物质 Related Substances	样品溶液中除主斑点外的其它斑点不得深于标准溶液。 The spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.	Meets
水份 Water	11.0~13.0%	11.9%
含量(以干品计) Assay(calculated on dried substance)	≥98.5%	99.6%

结论：符合《日局方》18版  
Conclusion: Complies with JP18

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Reviewer: 2023.03.31

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Reporte: 2023.3.31