

SINOWAY INDUSTRIAL CO.,LTD.

16/F., HUICHENG COMM.COMPLEX, 839 XIAHE RD., XIAMEN, CHINA

TEL: 0086-592-5881075

POSTCODE: 361004

FAX: 0086-592-5854960

E-MAIL: lv@china-sinoway.com

检验报告书 CERTIFICATE OF ANALYSIS

产品名称: 阿仑膦酸钠 批号: HD-2211004-301 数量: 93.18kg
Product Name: Sodium Alendronate Trihydrate Batch No: Quantity
生产日期: 2022.07.09 复检日期: 2026.07.08 检验日期: 2022.11.27
MFG.Date: RetestDate: Test Date
分析依据: 日本药典 储存条件: 密闭保存
Analysis Reference: JP Storage condition: Kept in a tightly closed container

检验项目 Items	标准 Specification	结果 Results
01 外观 Appearance	白色结晶性粉末 White crystalline powder	白色结晶性粉末 white crystalline powder
02 鉴别 Identification	化学鉴别 Chemical	符合规定 Complies
	红外鉴别 IR	与标准图谱一致 Complies with the standard spectrum
	磷酸盐鉴别 Phosphate	符合规定 Complies
	钠盐鉴别 Sodium salt	符合规定 Complies
03 熔点 Melting poin	大约252℃ (熔融同时分解) About 252℃ (With decomposition, after drying)	253℃~255℃
04 pH值	4.0~5.0	4.4
05 重金属 Heavy metal	≤10ppm	<10ppm
06 有关物质 (HPLC) Related substance	单个杂质 Individual impurities: ≤0.10%	<0.05%
07 干燥失重 Loss on drying	16.1%~17.1%	16.1%
08 含量 Assay (HPLC)	99.0%~101.0% (以干品计 based on dry basis)	100.1%

内控标准 In-house specification:

01 颗粒度 Particle size	D90: <20 μm	<15 μm
结论 Conclusion	产品符合日本药典 The product meets the specification of JP	

SINOWAY INDUSTRIAL CO.,LTD.