

黄冈赛康药业有限公司

HUANGGANG SAIKANG PHARMACEUTICAL CO., LTD

Add: YuHu village ZhongYi Town MaCheng city HuBei Province Tel:86-713-8667500

分析单

CERTIFICATE OF ANALYSIS

品名: 牛磺熊去氧胆酸

批重量: 350 千克

Name of product: Tauroursodeoxycholic acid

Batch Weight: 350kg

批号: 20240501

包装: 25kg/桶

Batch No: 20240501

Packing in: 25kg/drum

生产日期: 2024.05.21

保质日期: 2026.05.20

Manufacturing Date: May.21,2024

Expiry Date: May.20,2026

性状: 白色结晶粉末。溶于甲醇、乙醇, 略溶于水, 不溶于丙酮。

Characteristics: A white crystals. Dissolve in methanol, in ethanol, sparingly soluble in water, do not dissolve in acetone.

储藏条件: 遮光, 密闭保存。

Storage: Store in a well-closed container, protected from light.

化验结果

RESULT OF ANALYSIS

项目 (ITEMS)	标准 (STANDARDS)	实测结果 (RESULT)
外观 Appearance	白色结晶粉末 white crystals	白色结晶粉末 white crystals
鉴别 Identification		
A、Infrared Identification test	POSITIVE	POSITIVE
B、TLC Identification test	POSITIVE	POSITIVE
C、HPLC Identification test	POSITIVE	POSITIVE
比旋度 Specifies rotation	+41° ~ +47°	+46.0°
酸度(pH) Acidity	1.3~2.3	1.9
水分 Moisture	6.5%~7.5%	6.71%
炽灼残渣 Sulphated ash	0.1% MAX	0.05%
重金属 Heavy metal	20ppm MAX	<20ppm
氯化物 Chloride	0.02% MAX	PASS
硫酸盐 Sulphate	0.05% MAX	PASS
砷盐 AS	0.0002% MAX	PASS
有关物质 Related compounds	牛磺酸 Taurine	0.15% MAX PASS
	熊去氧胆酸 Ursodeoxycholic acid	0.4% MAX PASS
	牛磺鹅去氧胆酸 Taurochenodeoxycholic acid	0.8% MAX PASS
	其它杂质 Other Impurity	0.4% MAX PASS
残留溶剂 Residual Solvent	Acetone \leq 0.5% Ethyl acetate \leq 0.5%	PASS
含量 Assay	\geq 98%	99.7%

结论: 符合企业标准。

Conclusion: CONFORM TO THE REQUIREMENT OF CORPORATION STANDARD.

主管(DIRECTOR)

化验(INSPECTOR)