北京沃凯生物科技有限公司
全国免费电话:400-819-385
www.bjoka-vip.com
Tel:010-62971590. Fax:62340519
M-ail:postmaster@oka-vip.com

Certificate of analysis

品名	熊去氧胆酸 Ursodeoxycholic acid	CAS	128-13-2
货号	A57328	批次	OK20250317F
生产日期	2025-03-17	复测日期	2027-03-16

执行标准:企业标准

分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS
性状 Character	本品为白色或类白色粉末。 White or almost white powder.	本品为白色或类白色粉末。 White or almost white powder.
鉴别 Identification	悬浮液是蓝绿色的。 The suspension obtained is greenish-blue	悬浮液是蓝绿色的。 The suspension obtained is greenish-blue
红外鉴别 infrared identification	本品红外图谱应与熊去氧胆酸对照品红外图谱一致。 The infrared spectrum of this product should be consistent with that of the reference product of ursodeoxycholic acid.	本品红外图谱应与熊去氧胆酸对照品红外图谱一致。 The infrared spectrum of this product should be consistent with that of the reference product of ursodeoxycholic acid.
薄层鉴别 Thin-layer identification	供试品色谱图中主斑点的位置、颜色和大小应与对照品溶液色谱图中的主斑点一致。 The position, color, and size of themain spot in the chromatogram ofthe test sample should be consistentwith those of the main spot in thechromatogram of the reference solution.	供试品色谱图中主斑点的位置、颜色和大小应与对照品溶液色谱图中的主斑点一致。 The position, color, and size of themain spot in the chromatogram ofthe test sample should be consistentwith those of the main spot in thechromatogram of the reference solution.
比旋度 Specific optical rotation	+58.0° ～+62.0°	+60.4°

熔点 Melting point	≈202℃	201.5~202.5° C
有关物质 1 Related substances 1	杂质 C Impurity C≤0.10%	0.04%
	杂质 J Impurity J≤0.15%	未检出
有关物质 2 Related substances 2	22-ENE-UDCA≤0.7%	0.3%
有关物质 3 Related substances 3	鹅去氧胆酸 Chenodeoxycholic acid ≤1.0%	0.03%
	最大未知单杂 Maximum unknown single hybrid≤0.1%	0.05%
	总杂 Total of impurities≤1.5%	0.2%
干燥失重 Loss on drying	≤1.0%	0.05%
硫酸盐灰分 Sulfated ash	≤0.1%	0.04%
含量 Assay	99.0%-101.0%	99.6%
重金属 Heavy metals	<10PPM	<10PPM
透光率 Transmittance	≥90.0%	96.8%
粒径 Particle size	D90: 100um-120um	103um
残留溶剂 Residual solvent	丙酮 Acetone≤5000ppm	122ppm
	正戊醇 N-amyl alcohol≤5000ppm	未检出 Not detected
	三乙胺 Triethylamine≤5000ppm	未检出 Not detected

注：此产品仅限用于科研，禁止直接用于临床，如有失误，后果自负。

QA：杜冰冰　　QC：谢辉

北京沃凯生物科技有限公司 质检专用章

地址：　北京市海淀区丰慧中路 7 号新材料创业大厦 B 座 327 室.　邮编:100080