安徽科宝生物工程有限公司
Anhui Chembright Bioengineering Co.,Ltd
检 验 报 告 书
Certificate of Analysis

编 号：REC-ZL-01-050

Product name	Ursodeoxycholic acid	Specification	/
Batch No	210301	Quantity	/
Offer Dapartment	Department 1	Sampling Quantity	100g
Testing number	/	Testing date	2021/03/25
Testing purposes	Sample testing	Report date	2021/03/27
Testing standard	EP 7.0		

Testing items	Standards	Testing results	Results
Appearance	White or near white powder	white powder	Pass
Melting Point	about 202℃	202℃	Pass
Specific optlcal rotation	+58.0° ~+62.0°	+61.1°	Pass
Identification			
(1)	The infrared absorption spectrum of this product should be consistent with that of the control group	The infrared absorption spectrum of this product is consistent with that of the control group	Pass
(2)	Chromatogram of impurity C obtained during testing: Whether the main spots on the chromatogram obtained with test solution (b) are similar in position, color and size to those obtained with reference solution (a)	The main spots on the chromatogram obtained with the test solution (b) are similar in position, color and size to those obtained with the reference solution (a)	Pass
(3)	The suspension should be blue-green	The suspension is blue-green	Pass
Inspection			

impurity	-Applicability of the system: reference solution (c) - chromatogram shows 2 prominent major spots; -Detection limit: detection solution (a) - impurity c: the intensity of any spots caused by impurity c does not exceed the main spot (0.1%) on the chromatographic chart of reference solution (b).	-Applicability of the system: reference solution (c) - chromatogram shows 2 prominent major spots; -Detection limit: detection solution (a) - impurity c: the intensity of any spots caused by impurity c does not exceed the main spot (0.1%) in the chromatographic diagram of reference solution (b).	Pass
Detection limit of related substances	-Impurity A: not more than 10 times (1.0%) of the main peak area of chromatogram obtained with reference Solution (b); -Unspecified impurities: for each impurity, do not exceed the area of the main peak in the chromatogram obtained with reference solution (b) (0.10%); -Total amount: no more than 15 times (1.5%) of the main peak area in the chromatographic diagram of reference solution (b); -Disregard limit:0.5 times (0.05%) of the main peak area in the chromatogram obtained by reference solution (b)	-Impurity A: not more than 10 times (1.0%) of the main peak area of the chromatogram obtained with reference solution (b); -Unspecified impurities: for each impurity, the area (0.10%) of the main peak of a chromatographic diagram not exceeding that obtained with reference solution (b); -Total amount: no more than 15 times (1.5%) of the main peak area in the chromatographic diagram of reference solution (b); -Disregard limit:0.5 times (0.05%) of the main peak area in the chromatogram obtained by reference solution (b)	Pass
Loss on drying	≤1.0%	0.4%	Pass
Heavy metal	≤20ppm	<20ppm	Pass
Sulfated ash	≤0.1%	0.04%	Pass
Content	Considered as dry product, the content if $C_{24}H_{40}O_4$ in This product should be 99.0%~101.0% (dry product)。	99.8%	Pass
Conclusion	This product meets the EP 7.0 standard		
Inspector	Re-inspector	Person in Charge	