

BACTO CHEM LABORATORIES

CERTIFICATE OF ANALYSIS

Product	:	Tauroursodeoxycholic Acid			
Batch No.	:	TUDCA003/25	A.R.No	:	BCL/TUDCA/003/ JUNE -2025
Manufacturing Date	:	JUNE 2025	Expiry date	:	MAY 2028
Dispatch Quantity	:	3.0 kg	Analysis completed on	:	16/06/2025

S.No	Test	Specification	Result
01	Description	White or almost white color powder	White color powder
02	Identification by IR	The Infrared spectrum of test sample should be concordant with infrared spectrum of standard.	The IR spectrum of the sample is concordant with the IR spectrum of Tauroursodeoxycholic Acid standard.
	Identification by HPLC	Retention time of the principle peak in the chromatogram obtained with sample solution should match with that of principle peak in chromatogram obtained with standard solution in a test chromatographic purity by HPLC.	Retention time of the principle peak in the chromatogram obtained with sample solution is matches with that of principle peak in chromatogram obtained with standard solution in a test chromatographic purity by HPLC.
03	Loss on drying at 105 ⁰ C for 3 hrs (%w/w)	Not more than 1.0%	0.3%
04	Sulphated ash (% w/w)	Not more than 0.1%	0.06 %
05	Assay by Titrimetry (on dried basis)	Not less than 98.0% and Not more than 102.0%	98.9 %

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
CERTIFICATE OF ANALYSIS


Product	:	Tauroursodeoxycholic Acid		
Batch No.	:	TUDCA003/25	A.R.No	: BCL/TUDCA/003/ JUNE -2025
Manufacturing Date	:	JUNE 2025	Expiry date	: MAY 2028
Dispatch Quantity	:	3.0 kg	Analysis completed on	: 16/06/2025


S.No	Test	Specification	Result
06	Chromatographic purity by HPLC (% area normalization)		
	Purity	Not less than 98.0%	99.11%
	Taurine	Not more than 1.0%	0.003%
	Ursodeoxycholic acid	Not more than 1.0%	0.64%
	Any other Individual impurity	Not more than 1.0%	0.25%
	Total Impurities	Not more than 2.0%	0.89%
07	Residual solvents by GC (PPM) Acetone	Not more than 5000 ppm	Complies

Storage condition: Store in a well closed container at temperature below 30°C

Remarks : The product **complies** with the above specifications.

Analyzed By: 
 Date: 16/06/2025

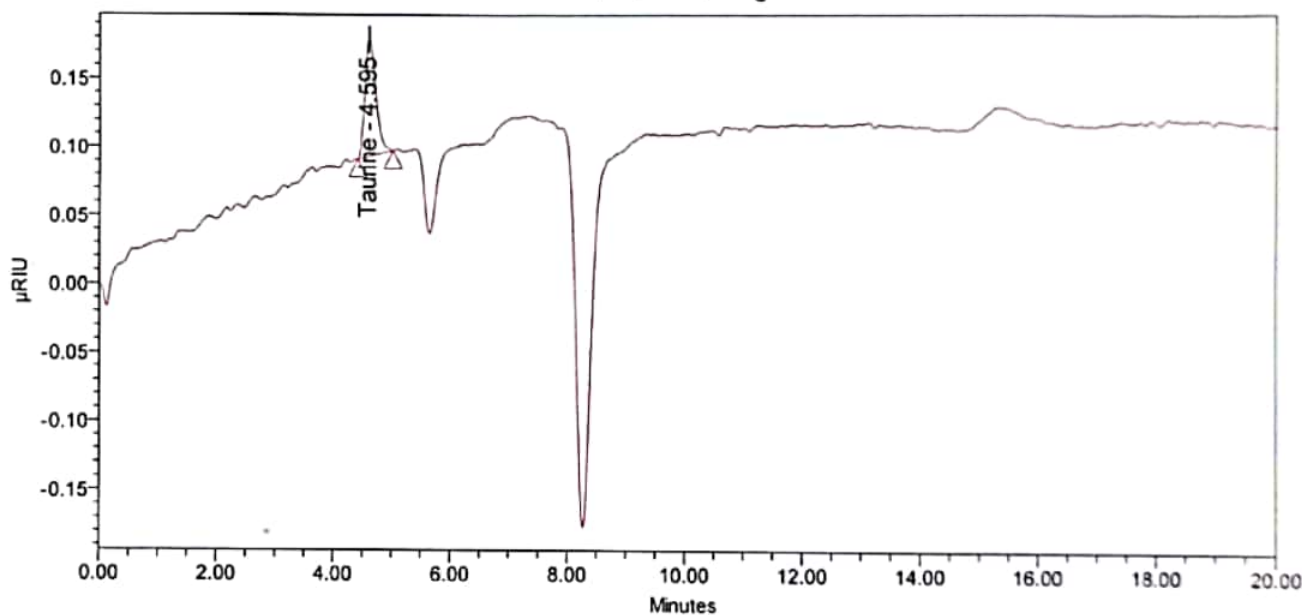
Checked By: 
 Date: 16/06/2025

Approved By: 
 Date: 16/06/2025

SAMPLE INFORMATION

Sample Name:	TUDCA003/25 FP	Acquired By:	Harika
Sample Type:	Unknown	Sample Set Name:	Taurine_13062025
Vial:	3	Acq. Method Set:	Taurine_16032025
Injection #:	1	Processing Method:	Taurine FP sample 13062025
Injection Volume:	50.00 ul	Channel Name:	W2414 RI
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2414 RI
Date Acquired:	6/13/2025 1:44:26 PM IST		
Date Processed:	6/13/2025 2:58:32 PM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area	Height	USP Tailing	USP Plate Count
1	Taurine	4.595	1119	100.00	85	1.273419e+000	2.808857e+003

Reported by User: Harika
Report Method: BCL REPORT 2
Report Method ID: 1109
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Project Name: 2025\TUDCA
Date Printed:
6/16/2025
5:45:28 PM Asia/Kolkata

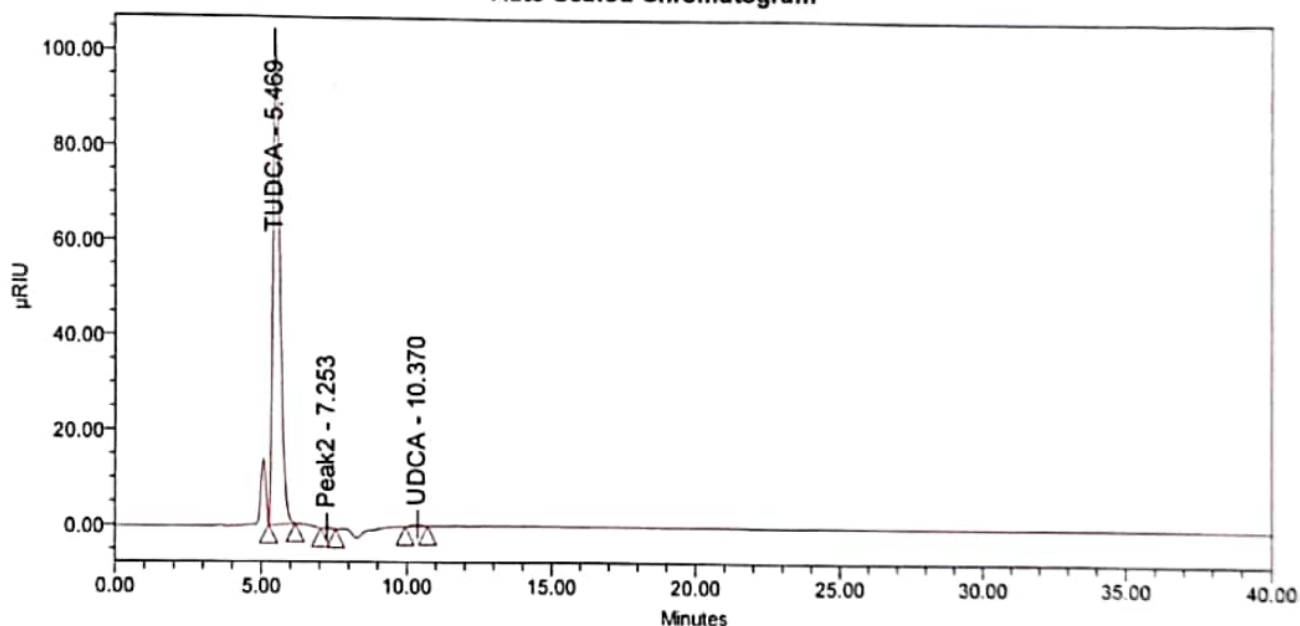
SAMPLE INFORMATION

Sample Name: TUDCA003/25
Sample Type: Unknown
Vial: 4
Injection #: 1
Injection Volume: 50.00 ul
Run Time: 40.0 Minutes

Acquired By: Harika
Sample Set Name: Purity_16062025
Acq. Method Set: Purity_16032025
Processing Method: Purity FP SAMPLE 16062025 4
Channel Name: W2414 RI
Proc. Chnl. Descr.: W2414 RI

Date Acquired: 6/16/2025 4:41:19 PM IST
Date Processed: 6/16/2025 5:26:37 PM IST

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area	Height	USP Tailing	USP Plate Count
1	TUDCA	5.469	1685945	99.11	101710	1.490978e+000	2.505733e+003
2	Peak2	7.253	4280	0.25	285	1.145608e+000	4.924096e+003
3	UDCA	10.370	10899	0.64	447	8.514397e-001	4.104215e+003

Reported by User: Harika
Report Method: BCL REPORT 2
Report Method ID: 1109
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Project Name: 2025\TUDCA
Date Printed: 6/16/2025
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