



TECHNICAL DATA SHEET

002934-TDS-ENG-2020

ACIDO TAUROURSODESOXICOLICO		
DESCRIPTION DCI: TAUROURSODEOXYCHOLIC ACID		DESCRIPTION DOE: TAUROURSODESOXICOLICO ACIDO
CAS Nº: ---	EC Nº: ---	AEMPS CODE: 8445A
MOL. WEIGHT: 521.69	MOL. FORMULA: C ₂₆ H ₄₅ NO ₆ S.2H ₂ O	ARTICLE CODE: 002934

ATTRIBUTES	SHOULD BE
Appearance	White microcrystalline powder
Identification	Complies
Optical rotation	+35.5 / +37.5
Water	6.0 - 8.0 %
pH	1.0 - 2.0
Sulfated ash	=< 0.2 %
Chlorides	=< 500 ppm
Assay	98.0 - 101.0 %
Related substances	
Ursodeoxycholic acid	=< 0.50 %
Taurochenodeoxycholic acid	=< 0.50 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.5 %
Taurina	=< 0.20 %
Residual solvents	
Acetone	=< 500 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Candida Albicans	Absence/1g
Staphylococcus aureus	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Keep the container tightly closed in a dry and well-ventilated place. Store in a cool place.

REMARKS

Tauroursodeoxycholic acid is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.



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The above information does not exempt from the obligation to identify the product before use.