

TECHNICAL DATA SHEET

002898-TDS-ENG-2024

SODIO DESOXICOLATO			
		DESCRIPTION DOE: SODIO DESOXICOLATO	
CAS Nº: 302-95-4	EC Nº: 206-132-7		AEMPS CODE: 719SO
MOL. WEIGHT: 416,58	MOL. FORMULA: C24H41NaO4		ARTICLE CODE: 002898

ATTRIBUTES SHOULD BE

Appearance Powder

Colour White or off white Visible impurities No visible impurities

Odour It has pungent smell, sweet and bitter

Residue on ignition =< 18%Loss on drying =< 5%Sulfated ash =< 0.01%Assay => 90%

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

Sodium Deoxycholate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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