



## TECHNICAL DATA SHEET

46433081-TDS-ENG-2024

SODIO DESOXICOLATO (PHARMA GRADE)		
		DESCRIPTION DOE: SODIO DESOXICOLATO
CAS Nº: 302-95-4	EC Nº: 206-132-7	AEMPS CODE: 719SO
MOL. WEIGHT: 416,58	MOL. FORMULA: C <sub>24</sub> H <sub>41</sub> NaO <sub>4</sub>	ARTICLE CODE: 46433081

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's 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.