

Batch Release Certificate

Product: Ursodeoxycholic Acid Ph. Eur. 11.1

Batch: UDCA 0323121 ✓

Analysis n° : 231375

RCS nr. : 290/23

Manufacturing date: 03/2023

Retest Date: 02/2028 ✓

Manufacturing site: Reggio Emilia

Certificate of Analysis

Characters: Practically insoluble in water, freely soluble in ethanol (96%), slightly soluble in acetone, practically insoluble in methylene chloride.
Melting point: about 202 °C

TESTS	SPECIFICATIONS	U.M.	RESULTS
Description	White or almost white powder		Complies
Identification (TLC)	Positive (RF comparison against UDCA WS)		Positive
Identification (IR)	Positive (comparison against UDCA WS IR spectra)		Positive
Specific Optical Rotation	$\geq +58,0 \quad \leq +62,0$	°	+61,4
Impurity C (Lithocholic Acid, TLC)	$\leq 0,1$	%	< 0,1
Related Substances (HPLC)			
Chenodeoxycholic Acid (impurity A)	$\leq 1,0$	%	< 1,0
Other impurities (each)	$\leq 0,10$	%	< 0,10
Total	$\leq 1,5$	%	< 1,5
Loss on drying	$\leq 0,5$	%	0,1
Sulphated Ash	$\leq 0,1$	%	0,0
Assay (potentiometric)	$\geq 99,0 \quad \leq 101,0$	%	99,4

APPROVED

Date 11/04/2023

Quality Control Manager

I hereby confirm that the API has been manufactured and packaged in compliance with c-GMP, product registrations and applicable laws.

Signed

Francesca Ruggera
Qualified Person

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Capitale Sociale € 120.000.00 i.v.

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