

Batch Release Certificate

Product: Ursodeoxycholic Acid EP ed. 8.0

Batch: UDCA 0715236

Analysis n° : 152824

RCS nr. : 815/15

Manufacturing date: 06/2015

Retest Date: 05/2020

Certificate of Analysis

TESTS	SPECIFICATIONS	U.M.	RESULTS
Description	White or almost white powder		Complies
Solubility	Practically insoluble in water, freely soluble in ethanol (96 %). Slightly soluble in acetone, practically insoluble in methylene chloride		Complies
Identification (TLC)	Positive (RF comparison against UDCA WS)		Positive
Identification (IR)	Positive (comparison against UDCA WS IR spectra)		Positive
Melting Point	≥ 200 ≤ 204	°C	202
Specific Optical Rotation	$\geq +58,0$ $\leq +62,0$	°	+60,8
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
Heavy Metals	≤ 20	ppm	< 20
Loss on drying		%	0,0
Sulphated Ash		%	0,0
Assay (potentiometric)	$\geq 99,0$ $\leq 101,0$	%	99,4

APPROVED

Date 08/09/2015

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



Enzo Bartoli
(Qualified Person)

