



ICE

S.p.A.

Batch Release Certificate

Product: Ursodeoxycholic Acid EP ed. 8.0

Analysis n° : 140570

RCS nr. : 890/14

Retest Date: 08/2019

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	203
Specific Optical Rotation	≥ +58,0 ≤ +62,0	°	+59,6
Impurity C (Lithocholic Acid, TLC)	≤ 0,1	%	< 0,1
Related Substances (HPLC)			
Chenodeoxycholic Acid (impurity A)	≤ 1,0	%	< 1,0
Other impurities (each)	≤ 0,10	%	< 0,10
Total	≤ 1,5	%	< 1,5
Heavy Metals	≤ 20	ppm	< 20
Loss on drying	≤ 0,5	%	0,0
Sulphated Ash	≤ 0,1	%	0,0
Assay (potentiometric)	≥ 99,0 ≤ 101,0	%	100,5

APPROVED

Date 27/10/2014

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

Good Barthi

Enzo Bartoli
(Qualified Person)

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42122 REGGIO EMILIA - ITALY - Via Sicilia 8/10
Tel. 0522 55.12.50 - Fax: 0522 55.89.63
www.iceitaly.com
E-mail: info@iceitaly.com



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