

CERTIFICATE OF ANALYSIS N° 4/119

PRODUCT : Ursodeoxycholic Acid EP 7.0 BATCH : UDCA 0212045 Manufacturing date : 12/11 Restest date : 11/16		
TEST	SPECIFICATIONS	RESULTS
Description	White or almost white powder	Complies
Identification	IR	Positive
	TLC	Positive
Solubility	Practically insoluble in water, freely soluble in ethanol (96 %). Slightly soluble in acetone, practically insoluble in methylene chloride	Complies
Melting point	(200 – 204) °C	202 °C
Loss on drying	≤ 0.5 %	0,0 %
Heavy Metals	≤ 20 ppm	< 20 ppm
Specific Optical Rotation $[\alpha]_{20}^D$	(+58,0 - +62,0) °	+ 58,3 °
Sulphated ash	≤ 0.1 %	0,0 %
Assay (potentiometric)	(99,0 - 101,0) %	99,5 %
Impurity C (TLC)	Lithocolic Acid ≤ 0,1 %	< 0,1 %
Related Substances (HPLC)	Chenodeoxycholic Acid ≤ 1,0 %	< 1,0 %
	Other impurities ≤ 0,10 % (each)	< 0,10 %
	Total ≤ 1,5 %	< 1,5 %

Approved

Date: 22/03/12

Signed



Dr. Enzo Bartoli
(Qualified Person)

