

CERTIFICATE OF ANALYSIS N° 4/411
PRODUCT : Ursodeoxycholic Acid EP 7.0
BATCH : UDCA 0913204
Manufacturing date : 08/13
Retest date : 07/18

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 [α]_{20°D}	(+58,0 - +62,0) °	+ 61,0 °
Sulphated ash	≤ 0.1 %	0,0 %
Assay (potentiometric)	(99,0 - 101,0) %	100,1 %
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: 16/09/13

Signed



Dr. Enzo Bartoli

(Qualified Person)

