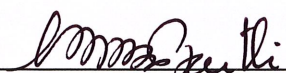


CERTIFICATE OF ANALYSIS No. 4/284 Rev - 01

PRODUCT: URSODEOXYCHOLIC ACID EP 7.0 BATCH: UDCA 0511103 Manufacturing Date: 03/2011 Retest Date: 02/2016		
<u>TEST</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Description:	White or almost white powder	Complies
Identification:	IR T.L.C.	Positive 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 (Ph. Eur. spec.: about 202°C)	202 °C
Loss on drying (t=105°C):	Not more than 0.5 % (Ph. Eur. spec: n.m.t. 1.0%)	0.1 %
Heavy Metals:	Not more than 20 ppm	< 20 ppm
Specific optical rotation:	+58.0° - +62.0°	+59.4°
Sulphated ash:	Not more than 0.1 %	0.0 %
Assay:	99.0 - 101.0 %	100.5%
Impurity C (TLC) Lithocholic acid	Not more than 0.1 %	< 0.1 %
Related substances (HPLC) Chenodeoxycholic acid (Impurity A) Unspecified Impurities Total	Not more than 1.0 % Not more than 0.10 % Not more than 1.5 %	< 1.0 % < 0.10 % < 1.5 %

APPROVED

DATE: 26/05/2011

SIGNED: 
 Dr. Enzo Bartoli
 (Qualified Person)

