



CERTIFICATE OF ANALYSIS No. 4/348

PRODUCT: **URSODEOXYCHOLIC ACID Ph. Eur. 6.0** Manufacturing Date: 05/2010

BATCH: **UDCA 0610078**

Retest Date: 04/2015

<u>TEST</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Description:	White or almost white powder.	Complies
Identification:	IR T.L.C.	Positive Positive
Solubility:	Very slightly soluble in water, freely soluble in alcohol. Slightly soluble in acetone and in methylene chloride.	Complies
Melting point:	(200 - 204)°C (Ph. Eur. 6.0 spec.: about 202°C)	203 °C
Loss on drying: (105°C)	Not more than 0.5 % (Ph. Eur. 6.0 spec.: n.m.t. 1.0%)	0.1 %
Heavy Metals:	Not more than 20 ppm	Less than 20 ppm
Specific optical rotation:	+58.0° - +62.0°	+60.1 °
Sulphated ash:	Not more than 0.1%	0.0 %
Assay:	99.0 - 101.0%	100.2 %
IMPURITIES (T.L.C.)		
Lithocholic acid	Not more than 0.1%	Less than 0.1%
Cholic Acid	Not more than 0.5%	Less than 0.5%
Chenodeoxycholic Acid	Not more than 1.0%	Less than 1.0%
Other Impurities	Not more than 0.1% (Ph. Eur. 6.0 spec.: n.m.t. 0.25%)	Less than 0.1%

APPROVED

DATE: 18/06/2010

SIGNED: _____

Dr. Enzo Bartoli
(Qualified Person)

