



**CERTIFICATE OF ANALYSIS No. 4/164**

PRODUCT: URSODEOXYCHOLIC ACID Ph. Eur. 6.0      Manufacturing Date: 03/2010

BATCH:      UDCA 0410043

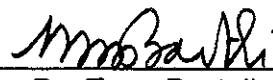
Retest Date: 02/2015

<b><u>TEST</u></b>	<b><u>SPECIFICATIONS</u></b>	<b><u>RESULTS</u></b>
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°	+59.9°
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: 08/04/2010

SIGNED: \_\_\_\_\_

  
Dr. Enzo Bartoli  
(Qualified Person)

