



Spett.le

METAPHARMACEUTICAL IND S.L.
D.ssa Miriam Miguel Sala
C/Josep Pla, n° 163, 2° 5ª
08020 Barcelona

Fiorenzuola, 27 mar. 14

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta confermiamo la corrispondenza dei seguenti lotti:

003341 ACIDO URSODEOSSICOLICO EP
Lotto 13109001

cod. 003341
Lotto fornitore UDCA1112230

002484 PANCREATINA 8 NF
Lotto 13326001

cod. 002484
Lotto fornitore 177/13

002484 PANCREATINA 8 NF
Lotto 13246002

cod. 002484
Lotto fornitore 106/13

Restando a disposizione per eventuali chiarimenti porgiamo distinti saluti.

A.C.E.F. S.p.A.

C.Q.

CERTIFICATE OF ANALYSIS N° 4/634

PRODUCT : Ursodeoxycholic Acid EP 7.0

BATCH : UDCA 1112230

Manufacturing date : 10/12

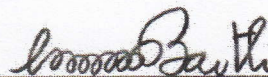
Reptest date : 09/17

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 %	0,1 %
Heavy Metals	≤ 20 ppm	< 20 ppm
Specific Optical Rotation [α] _{20°D}	(+58,0 - +62,0) °	+ 60,6 °
Sulphated ash	≤ 0.1 %	0,0 %
Assay (potentiometric)	(99,0 - 101,0) %	99,9 %
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: 05/12/12

Signed



Dr. Enzo Bartoli

(Qualified Person)

