



PRODOTTI CHIMICI E ALIMENTARI S.p.A.

ANALYSIS CERTIFICATE

COMPANY WITH QUALITY MANAGEMENT
SYSTEM CERTIFIED BY DIN
= ISO 9001:2008 =

COMPANY WITH ENVIRONMENTAL
MANAGEMENT SYSTEM CERTIFIED BY DIN
= ISO 14001:2004 =

FDA inspected
manufacturing site

PCA Code	Analysis No.	Product Description		
2004	7994	ACIDO TAUROURSODEOSSICOLICO		
Batch	Quantity	Manufacturing date	Expiry date	Manufacturing site
2012040147	kg 25	April 2012	April 2017	Via Novi 78, I-15060 Basaluzzo (AL), Italy
Customer		Customer Annotations		
A.C.E.F. Fiorenzuola D'Arda				

Test	Requirement	Results	U.M.
Description	White odourless microcrystalline powder	White odourless microcrystalline powder	
Solubility	Very soluble in methanol and ethanol; slightly soluble in water; very slightly soluble in dioxane and ether; practically insoluble in acetone and ethyl acetate	Very soluble in methanol and ethanol; slightly soluble in water; very slightly soluble in dioxane and ether; practically insoluble in acetone and ethyl acetate	
Identification	Positive (IR)	Positive (IR)	
Specific optical rotation	+35.5 - +37.5	+36.2	°
Water content (by K.F.)	6.0 - 8.0	6.7	%
pH	1.0 - 2.0	1.2	
Sulphated ash	≤ 0.2	0.07	%
Heavy metals	≤ 20	≤ 20	ppm
Chloride	≤ 500	≤ 500	ppm
Assay	98.0 - 101.0	99.8	% o.d.b.
Ursodeoxycholic acid (TLC)	≤ 0.5	< 0.4	%
Taurochenodeoxycholic acid (TLC)	≤ 1.0	< 1.0	%
Taurine (TLC)	≤ 0.2	< 0.2	%
Other unid. rel. subs. Tot (TLC)	≤ 0.5	< 0.5	%
Residual solvents: Acetone	≤ 500	180	ppm

Date of issue	Chemical Lab.	Biological Lab.	Opinion
06/06/2012	G. Soldani		Complies to Specifications

Laboratory Manager	Quality Control Manager	Specifications
M. Corno	D. Scainelli	Ed. 1 issued on 15/04/2011

Sede Legale, amministrativa e stabilimento - Via Novi 78, 15060 Basaluzzo (AL) - Italia - Tel. 0339 0143 489671 - Fax 0339 0143 489715
Capitale Sociale: € 120.000.000 i.v. - P.I.C.F. 02339850352 - VAT: IT02339850352 - Reg. Imprese di Alessandria n. 02339850352 - REA: 241372

Page 1 of 1