



PRODOTTI CHIMICI E ALIMENTARI S.p.A.

## ANALYSIS CERTIFICATE

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

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

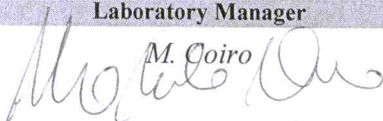
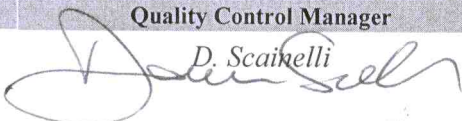
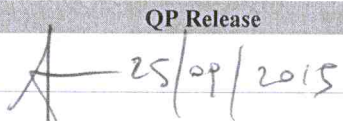
FDA inspected  
manufacturing site

PCA Code	Analysis No.		Product Description		
2004	9497		ACIDO TAUROURSODESSOLICOLICO		
Batch	Quantity	Manufacturing date	Expiry date	Manufacturing site	
2015080318	kg 40	August 2015	July 2020	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	+36.5	°
Water content (by K.F.)	6.0 - 8.0	7.4	%
pH	1.0 - 2.0	1.1	
Sulphated ash	<=0.2	0.01	%
Heavy metals	<=20	<=20	ppm
Chloride	<=500	<=500	ppm
Assay	98.0 - 101.0	101.0	% o.d.b.
Ursodeoxycholic acid (TLC)	<=0.5	<0.5	%
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	370	ppm

Date of issue	Chemical Lab.	Biological Lab.	Opinion
24/09/2015	F.Martano		Complies to Specifications

Ed.1 issued on 15/04/2011

Laboratory Manager	Quality Control Manager	QP Release
 M. Coiro	 D. Scainelli	 25/09/2015

Sede Legale, amministrativa e stabilimento - Via Novi 78, 15060 Basaluzzo (AL) - Italia - Tel. 0039.0143.489671 - Fax. 0039.0143.489719  
Capitale Sociale: € 120.000,00 i.v. - P.I./C.F. 02339850352 - VAT: IT02339850352 - Reg. Imprese di Alessandria n. 02339850352 - REA: 241272

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