



PRODOTTI CHIMICI E ALIMENTARI S.p.A.

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

ANALYSIS CERTIFICATE

PCA Code	Analysis No.	Product Description			
2004	9205	ACIDO TAUROURSODESOSSICOLICO			
Batch	Quantity	Manufacturing date	Expiry date	Manufacturing site	
2015010026	kg 50	January 2015	January 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	+36.9	°
Water content (by K.F.)	6.0 - 8.0	6.7	%
pH	1.0 - 2.0	1.1	
Sulphated ash	<=0.2	0.06	%
Heavy metals	<=20	<=20	ppm
Chloride	<=500	<=500	ppm
Assay	98.0 - 101.0	100.2	% o.d.b.
Ursodeoxycholic acid (TLC)	<=0.5	<0.5	%
Taurochenodeoxycholic acid (TLC)	<=1.0	<0.5	%
Taurine (TLC)	<=0.2	<0.2	%
Other unid.rel.subs.Tot (TLC)	<=0.5	<0.1	%
Residual solvents: Acetone	<=500	290	ppm

Date of issue	Chemical Lab.	Biological Lab.	Opinion
25/02/2015	G.Soldani		Complies to Specifications

Ed.1 issued on 15/04/2011

Laboratory Manager	Quality Control Manager	QP Release
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M. Coiro

D. Scainelli

26/12/2015

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