

Lot: 0060913



PRODOTTI CHIMICI E ALIMENTARI S.p.A.

ANALYSIS CERTIFICATE

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

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

FDA inspected
manufacturing site

PCA Code: 2013030086 Analysis No: 8405 Product Description: **ACIDO TAUROURSODESOSSICOLICO**

Batch: 2013030086 Quantity: kg 75 Manufacturing date: March 2013 Expiry date: March 2018 Manufacturing site: Via Novi 78, I-15060 Basaluzzo (AL), Italy

Customer: A.C.E.F. Fiorenzuola D'Arda

Customer Annotations

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	+37.4	°
Water content (by K.F.)	6.0 - 8.0	6.8	%
pH	1.0 - 2.0	1.2	
Sulphated ash	<=0.2	0.04	%
Heavy metals	<=20	<=20	ppm
Chloride	<=500	<=500	ppm
Assay	98.0 - 101.0	99.7	% o.d.b.
Ursodeoxycholic acid (TLC)	<=0.5	<0.4	%
Taurochenodeoxycholic acid (TLC)	<=1.0	<0.5	%
Taurine (TLC)	<=0.2	<0.2	%
Other unid. rel. subs. Tot (TLC)	<=0.5	<0.2	%
Residual solvents: Acetone	<=500	500	ppm

Date of issue
03/07/2013

Chemical Lab.
G. Soldani

Biological Lab.

Opinion

Complies to Specifications

Laboratory Manager

Quality Control Manager

Specifications

Ed. 1 issued on 15/04/2011

Seede Legale: amministrativa e giudiziaria - Via Novi 78, 15060 Basaluzzo (AL) - Italia - Tel. 0039 0143 489671 - Fax 0039 0143 489719

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