

Ude: 0050413



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: 2004 Analysis No: 8337 Product Description: ACIDO TAUROURSODESOSSICOLICO

Batch: 2013010018 Quantity: kg 50 Manufacturing date: January 2013 Expiry date: December 2017 Manufacturing site: Via Novi 78, I-15060 Basaluzzo (AL), Italy

Customer: A.C.E.F. Fiorenzuola D'Ardia 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	7.3	%
pH	1.0 - 2.0	1.4	
Sulphated ash	≤0.2	0.03	%
Heavy metals	≤20	≤20	ppm
Chloride	≤500	≤500	ppm
Assay	98.0 - 101.0	100.0	% 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	≤0.2	%
Residual solvents: Acetone	≤500	270	ppm

Date of issue
25/01/2013

Chemical Lab.
G.Soldani

Biological Lab.

Opinion

Complies to Specifications

Laboratory Manager

M.Collo

Quality Control Manager

D.Scainelli

Specifications

Ed.1 issued on 15/04/2011

Sede Legale, amministrativa e stabilimento - Via Novi 78, I-15060 Basaluzzo (AL) - Italia - Tel. 0039 0143 489711 - Fax 0039 0143 489716
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