



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

2004

8641

ACIDO TAUROURSODESOSSICOLICO

2013100323

kg

25

October 2013

October 2018

Via Novi 78, I-15060 Basaluzzo (AL), Italy

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

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	+37.1
Water content (by K.F.)	6.0 - 8.0	6.9
pH	1.0 - 2.0	1.3
Sulphated ash	<=0.2	0.06
Heavy metals	<=20	<=20
Chloride	<=500	<=500
Assay	98.0 - 101.0	99.3
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	<=0.5
Residual solvents: Acetone	<=500	180

18/03/2014

G.Soldani

Complies to Specifications

M. Coiro D. Scainelli

Specifications

Ed.1 issued on 15/04/2011

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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29017 FIORENUOLA D'ARDA (PC)
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TEL 0523.241911
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E-MAIL acef@acef.it



C.FISC. E PARTITA IVA 00098610330
CAP.SOC. EU RO 2.000.000 I.V.
R.I. PC 032-1483
R.D. PC 44507
MECC.EXPORT PC002237

Spett.le

METAPHARMACEUTICAL IND S.L.
D.ssa Miriam Miguel Sala
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

Fiorenzuola, 30 marzo '15

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta confermiamo la corrispondenza dei seguenti lotti:

ACIDO SALICILICO POLV. EP 99,5%
Lotto M0010701

cod. 000107
Lotto produttore RAS1407600

ACIDO TAUROURSODESSOSSICOLICO
Lotto 15048001

cod. 009176
Lotto produttore 2013100323

Restando a disposizione per eventuali chiarimenti porgiamo distinti saluti.

A.C.E.F. S.p.A.

C.Q.