



ANALYSIS CERTIFICATE

Lot: 0350920

Site Code	Analysis No.	Product Description			
2004	12016	ACIDO TAUOURSODESOSSICOLICO			
Batch	Quantity	Manufacturing date	Expiry date	Manufacturing site	
2020060287	kg 50	June 2020	June 2025	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 microcrystalline powder	White microcrystalline powder	
Identification	Positive (IR)	Positive (IR)	
Specific optical rotation	+35.5 - +37.5	+37.5	*
Water content (by K.F.)	6.0 - 8.0	6.7	%
pH	1.0 - 2.0	1.0	
Sulphated ash	<=0.2	0.04	%
Chloride	<=500	<=500	ppm
Assay (by HPLC)	98.0 - 101.0	99.6	%
Ursodeoxycholic acid (HPLC)	<=0.50	0.35	%
Taurochenodeoxycholic acid (HPLC)	<=0.50	0.09	%
Other unspecified impurities each (HPLC)	<=0.10	<LOQ	%
Other unspecified impurities total (HPLC)	<=0.50	<LOQ	%
Total sum of all impurities (HPLC)	<=1.50	0.44	%
Taurine (TLC)	<=0.2	not traceable	%
Total sum of related impurities	<=1.70	0.44	%
Residual solvents: Acetone	<=500	290	ppm

Date of Issue	Chemical Lab.	Biological Lab.	Opinion
08/07/2020	D'Angio Felice		Complies to Specifications Ed.3 issued on 03/04/2020

Laboratory Manager	Quality Control Manager	On Release

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