

Certificate of analysis

Manufacturing site
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Issued QP
25.10.2023

Code
500832

Ref. DDT.
80015392

Ref. Order
PO06194

Batch Nr. 2311232
Mfg. date 28.09.2023
Retest date 27.09.2026
Analysis nr. 80000020671

Buyer 20275

FSA CHEMICALS - MAGIS
Oostmalsebaan 1c - Unit 5
2960 SINT-LENAARTS
Belgium

End User 20275

FSA CHEMICALS - MAGIS

Product

Chenodeoxycholic Acid Micronized

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	white to off white powder	EP	Conform to description
Solubility (general character)	-	Conform	EP	Conform
Identification: IR spectrum	-	Conform	EP/USP	Conform
Identification: rt in HPLC	-	Positive	Company	Positive
Melting point	°C	165 - 167	EP	166
Loss on drying	%	max 0,5	EP/USP	0,1
Sulphated ash	%	max 0,1	EP/USP	0,04
Optical rotation	deg	11,0 - 13,0	EP	12,9
Assay (potentiometric)	%	99,0 - 101,0	EP/Company	100,5
Cholic acid (HPLC-1)	%	max 0,1	Company	0,03
EP Impurity H (HPLC-1)	%	max 0,1	Company	< 0,03
each other unspecified impurity (HPLC)	%	max 0,10	Company	< 0,03
Total impurities (HPLC)	%	max 0,5	Company	0,03
Lithocholic acid (HPLC-2)	%	max 0,10	Company	< 0,03
EP impurity I (HPLC)	%	max 0,5	EP	0,21
Acetonitrile (HS-GC)	ppm	max 410	Company	85
Bulk density	g/ml	min 0,20	EP	0,25
Particle size (Jet sieve) > 150 micron	%	max 10	Company	3
Particle size (Jet sieve) > 75 micron	%	max 20	Company	9
Elemental Impurities: none of the elemental impurity reported in ICHQ3D is likely to be present				

Name and Surname: Paola Strola
Title: Quality Control
Approved
Date: 04.10.2023 17:29:20

Name and Surname: GIULIA GIAIMI
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Approved
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