

Certificate of analysis

Manufacturing site

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Issued QP

08.07.2022

Code

500832

Ref. DDT.

80013480

Ref. Order

PO04537

Batch Nr.

2103471

Mfg. date

01.03.2021

Retest date

01.03.2024

Analysis nr.

890000008319

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	-	Conform	EP	Conform
Identification: IR spectrum	-	Conform	EP/USP	Conform
Identification: rt in HPLC	-	Positive	Company	Positive
Identification: color test	-	Positive	EP	Positive
Melting point	°C	165 - 167	EP	167
Loss on drying	%	max 0,5	EP/USP	0,2
Sulphated ash	%	max 0,1	EP/USP	0,0
Optical rotation	deg	11,0 - 13,0	EP	12,5
Assay (potentiometric)	%	99,0 - 101,0	EP/Company	99,4
Impurity H (HPLC-1)	%	max 0,2	EP	< 0,05
Cholic acid (HPLC-1)	%	max 0,1	EP	0,07
UDCA (HPLC-1)	%	max 0,1	EP	< 0,05
Each other impurity (HPLC-1)	%	max 0,10	EP	< 0,05
Total impurities (HPLC-1)	%	max 0,5	EP	0,1
Lithocholic acid (HPLC-2)	%	max 0,1	Company	0,00
Impurity I (HPLC-3)	%	max 0,5	EP	0,48
Acetonitrile (HS-GC)	ppm	max 410	Company	87
Bulk density	g/ml	min 0,20	EP	0,32
Particle size (Jet sieve) > 150 micron	%	max 10	Company	4
Particle size (Jet sieve) > 75 micron	%	max 20	Company	11
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: 07.04.2022 12:47:47

Name and Surname: GIULIA GIAIMI

Title: Quality Assurance

Approved

Date: 18.02.2022 15:04:18