

Certificate of analysis

Manufacturing site

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Issued QP

09.12.2024

Code

500832

Ref. DDT.

80016974

Ref. Order

PO07864

Batch Nr.

2314486

Mfg. date

16.11.2023

Retest date

15.11.2028

Analysis nr.

80000021163

Buyer

20425

MAGIS-PHARMA NV

Neerlandweg 24

2610 WILRIJK

Belgium

End User

20425

MAGIS-PHARMA NV

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	0,2
Sulphated ash	%	max 0,1	EP/USP	0,00
Optical rotation	deg	11,0 - 13,0	EP	12,7
Assay (potentiometric)	%	99,0 - 101,0	EP/Company	99,6
Cholic acid (HPLC-1)	%	max 0,1	Company	0,13
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	0,13
Lithocholic acid (HPLC-2)	%	max 0,10	Company	< 0,03
EP impurity I (HPLC)	%	max 0,5	EP	0,25
Acetonitrile (HS-GC)	ppm	max 410	Company	< 25
Bulk density	g/ml	min 0,20	EP	0,33
Particle size (Jet sieve) > 150 micron	%	max 10	Company	7
Particle size (Jet sieve) > 75 micron	%	max 20	Company	10
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: 01.03.2024 14:13:25

Name and Surname: GIULIA GIAIMI

Title: Quality Assurance

Approved

Date: 12.02.2024 18:13:56