

Shilpa Pharma Lifesciences Limited




Unit-2: Plot No: 33, 33A & 40-47, Raichur Industrial Growth
Center, Chicksugur-584 134, Raichur District,
Karnataka State, India.

CIN No. U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: URSODEOXYCHOLIC ACID	Drug license No.	: KTK/25/564/2009
Batch No.	: UDA2210004	Batch Quantity	: 235.900 Kg
Mfg. Date	: NOV-2021	A.R.No.	: 40000062017
Retest Date	: OCT-2022		

S.No.	Tests	Results	Specifications
1.	Appearance <In-House>	White powder	A White or almost white powder.
2.	Solubility <In-House>	Complies	Practically insoluble in water, Freely soluble in ethanol (96%), Slightly soluble in acetone, Practically insoluble in methylene chloride.
3.	Identification		
	a) By FT-IR <Ph.Eur>	Complies	The infrared absorption spectrum of sample should exhibit maxima only at the same wavelengths as that similar preparation of standard.
	b) By Thin layer chromatography <Ph.Eur>	Complies	Examine the chromatogram obtained in the test solution for Impurity-C.
	c) By Chemical test <Ph.Eur>	Complies	The suspension obtained is greenish blue.
4.	Loss on drying at 105±2°C for 2 hours <Ph.Eur 2.2.32>	0.29%	Not more than 1.0% w/w
5.	Melting point <Ph.Eur>	200.8 to 202.3°C	About 202°C
6.	Sulphated ash <Ph.Eur>	0.04%	Not more than 0.1%
7.	Specific optical rotation (2% in anhydrous ethanol at 20°C on dried basis) <Ph.Eur 2.2.7>	+59.2°	Between +58.0° to +62.0°
8.	Related substances (By HPLC) <Ph.Eur 2.2.29>		
	▪ Impurity-A	0.65%	Not more than 1.0% w/w
	▪ Any unspecified impurity	0.05%	Not more than 0.10% w/w
	▪ Total impurities	0.70%	Not more than 1.5% w/w
9.	Impurity-C content (By TLC) <Ph.Eur 2.2.27>	Less than 0.1%	Not more than 0.1% w/w
10.	Assay by Titrimetry (On dried basis) <Ph.Eur 2.2.20>	100.1%	Between 99.0% to 101.0%
11.	Residual solvents by GC-HS <In-House>		
	▪ Methanol	Below LOQ	Not more than 3000 ppm (LOQ: 90.720 ppm)
	▪ Acetone	Not Detected	Not more than 5000 ppm
	▪ Methylene dichloride	Not Detected	Not more than 600 ppm

	Prepared by	Checked by	Approved by
Name	B.Arvind	B.S.Petarge	K.Rajababu
Designation	Sr.Executive-QC	Sr.Manager-QC	Manager-QA
Sign & Date	 23/07/22	 23/07/22	 23/07/22

Page 1 of 2

Corporate & Admin Office: "Shilpa House", #12-6-214/A1, Hyderabad Road, Raichur – 584 135, Karnataka, India

Tel: +91-8532-238704, Fax: +91-8532-238876, Email: info@vbshilpa.com,

Shilpa Pharma Lifesciences Limited

Unit-2: Plot No: 33, 33A & 40-47, Raichur Industrial Growth
Center, Chicksugur-584 134, Raichur District,
Karnataka State, India.

CIN No. U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: URSODEOXYCHOLIC ACID	Drug license No.	: KTK/25/564/2009
Batch No.	: UDA2210004	Batch Quantity	: 235.900 Kg
Mfg. Date	: NOV-2021	A.R.No.	: 40000062017
Retest Date	: OCT-2022		




S.No.	Tests	Results	Specifications
12.	<ul style="list-style-type: none">2-ButanolEthyl acetateMIBKTriethylamine Microbial limit tests <Ph.Eur> I) Microbial enumeration tests a) Total Aerobic Microbial Count b) Total combined Yeast and Mould Counts II) Test for specified microorganisms a) <i>Escherichia coli</i>	<p>Not Detected</p> <p>600 ppm</p> <p>Not Detected</p> <p>263 ppm</p> <p>Less than 10 cfu/g</p> <p>Less than 10 cfu/g</p> <p>Absent</p>	<p>Not more than 5000 ppm</p> <p>Not more than 5000 ppm</p> <p>Not more than 4500 ppm</p> <p>Not more than 1000 ppm</p> <p>Not more than 1000 cfu/g</p> <p>Not more than 100 cfu/g</p> <p>Should be absent</p>

Storage condition: Preserve in tight closed container, and store at controlled room temperature (20°C to 25°C).

Remarks: The material complies with the above respective specifications.

Chemical name of impurities:

Impurity-A	: 3 α , 7 α -dihydroxy-5 β -Cholan-24-oic acid (Chenodeoxycholic acid) or (4R)-4-((3R,5S,7R,10S,13R,17R)-3,7-dihydroxy-10,13-dimethylhexadecahydro-1H-cyclopenta [a]phenanthren-17-yl) pentanoic acid
Impurity-C	: 3 α , hydroxyl-5 β -Cholan-24-oic acid (Lithocholic acid)

Name	Prepared by B.Arind	Checked by B.S.Petarge	Approved by K.Rajababu
Designation	Sr.Executive-QC	Sr.Manager-QC	Manager-QA
Sign & Date	 23/07/22	 23/07/22	 23/07/22