

**AKUMS DRUGS & PHARMACEUTICALS LTD.**22, Sector-6A, I.I.E., SIDCUL Ranipur
Haridwar-249403, Uttarakhand, INDIA**QUALITY CONTROL****CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name :	URSODEC SUSPENSION		
Generic Name :	Ursodeoxycholic Acid Oral Suspension BP		
Mfg. Lic. No. :	123/UA/2007	Market:	DOMESTIC
Batch No. :	XSAA01	A. R. No.:	F20240803004
Mfg. Date :	Aug. 2024	Pack Size:	100 ml
Expiry date:	Jul. 2026	Pack Type:	PET Bottle
Batch Size :	5000 Bottle	Sampled On:	03/08/24
Product Code :	40069297	Sample Quantity:	12 Bottle
Specification No, Ver No.:	STS/FP/40069297-00	Sampled By:	Sunil Rana
Ref. STP No. , Ver No.:	STP/FP/40069297-00	Analyzed By:	HITESH CHAUHAN
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	05/08/24
Manufactured By :	Akums Drugs (Plant-2)	Analysis Completion Date:	12/08/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Orange colour homogeneous viscous suspension, 100 ml filled in amber coloured PET bottle.	Orange colour homogeneous viscous suspension, 100 ml filled in amber coloured PET bottle.
2	Odour	Having pleasant odour.	Having pleasant odour.
3	Identification	As below	As below
a.	By Chemical Test	The suspension obtained is greyish-blue.	The suspension obtained is greyish-blue.
b.	By Liquid chromatography	In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).	In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

	Prepared By	Reviewed By	Approved By QC
Date	13/08/24	13/08/24	13/08/24
Name	HITESH CHAUHAN	RAVI KANT AGNIHOTRI	DHIRAJ KANDWAL
Designation	SR. EXECUTIVE	EXECUTIVE	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Suman ; Date : 13/08/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
4	pH	3.8 to 5.2	4.64
5	Weight/ml	1.00 to 1.20 gm/ml	1.05 gm/ml
6	Uniformity of volume	Any Single bottle: Not less than 95.0 ml (Not less than 95.0% of the labelled amount)	100.49 ml to 101.06 ml 100.49% to 101.06%
7	Average Net Volume	Not less than 100.0 ml	100.74 ml
8	Related Substances (By Liquid Chromatography)	As below	As below
a.	Chenodeoxycholic acid	Not more than 1.0%	Not detected
b.	Any other impurities	Not more than 0.2%	Not detected

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
c.	Total impurities (excluding Chenodeoxycholic acid)	Not more than 1.0%		Not detected
9	Assay - Each 5 ml Contains:	Shelf Life Limit	Release Limit	
a.	Ursodeoxycholic Acid IP - 125 mg	NLT 118.750mg to NMT 131.250mg (NLT 95.0% to NMT 105.0% of label claimed)	NLT 121.875mg to NMT 128.125mg (NLT 97.5% to NMT 102.5% of label claimed)	125.560mg 100.4%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
10	Microbial contamination	As below	As below
a.	Total Viable Count	As below	As below
a.1	Total aerobic microbial count	Not more than 100 cfu/ml	Less than 10 cfu/ml
a.2	Total Combined Yeasts/ Moulds Count	Not more than 10 cfu/ml	Less than 10 cfu/ml
b.	Tests for specified microorganisms	As below	As below
b.2	Escherichia coli	Should be absent /ml	Absent /ml

CONCLUSION : The Finished Product complies as per BP & IH Specifications.

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