



VITALIFE LABORATORIES

(A Division of Arch Pharmalabs Limited)

Factory: Village Pathreri, Bilaspur-Tauru Road, Dist. Gurugram, Haryana -122 413. India.

Tel. : +91-124-3581421/422/423 (7082414465) Website : www.archpharmalabs.com

CERTIFICATE OF ANALYSIS

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| | | | |
|-------------------------------------|------------|---------------------------|--------------|
| Product Name: Ursodiol (USP) | | | |
| Product Code | 18000100 | Inspection Lot No. | 040000234571 |
| Batch No. | 3142600013 | Batch Size | 25.40 KG |
| Manufacturing Date | Mar, 2026 | Expiry Date | Feb, 2031 |
| Dispatch Quantity | 25.00 KG | | |

| S. No. | Tests | Results | Specification |
|--------|--|---|---|
| 1. | Description | White crystalline powder | White or almost white crystalline powder |
| 2. | Solubility | Freely soluble in alcohol and in glacial acetic acid. Sparingly soluble in chloroform, slightly soluble in ether, practically insoluble in water. | Freely soluble in alcohol and in glacial acetic acid. Sparingly soluble in chloroform, slightly soluble in ether, practically insoluble in water. |
| 3. | Identification by IR | Complies | The infrared absorption spectrum is concordant with spectrum obtained from reference/ working standard. |
| 4. | Melting Point (°C) | 202.0°C | 200.0°C to 205.0 |
| 5. | Specific optical rotation (°) | +60.3° | +57° to +62° |
| 6. | Loss on drying (105 °C for 3 hours) (%w/w) | 0.28% w/w | Not more than 0.5 %w/w |
| 7. | Residue on ignition(%w/w) | 0.03% w/w | Not more than 0.1 %w/w |
| 8. | Related Compounds by TLC (%) | | |
| | Lithocholic acid | Less than 0.05% | Not more than 0.05 % |
| 9. | Related Substances by HPLC (%w/w) | | |
| | Impurity A | 0.06%w/w | Not more than 1.0 % |
| | Unspecified impurities | 0.04%w/w (Below disregard limit) | Each not more than 0.10% |
| | Total impurities | 0.06 w/w | Not more than 1.5 % |

VERIFIED BY

06-04-2026

(HOD-QC/DESIGNEE)

Issue Date: 06.04.2026

Format No.:CQA045/F02-03

APPROVED BY

06-04-2026

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| S. No. | Tests | Results | Specification |
|--------|--|--------------|--------------------------|
| 10. | Assay (%w/w, By HPLC) (on dried basis) | 99.3% w/w | NLT 98.5 % & NMT 101.5 % |
| 11. | Residual Solvents by GC-HS (ppm) Method-I | | |
| | Methanol | Not Detected | Not more than 500 ppm |
| | Acetone | 7 ppm | Not more than 300 ppm |
| | Isopropyl Alcohol | Not Detected | Not more than 1000 ppm |
| | Methyl Isobutyl Ketone | 610 ppm | Not more than 3000 ppm |
| | Residual solvents by GC-Autosampler(ppm) Method-II | | |
| | Triethyl amine | Not Detected | Not more than 500 ppm |
| | Triethylene Glycol | Not Detected | Not more than 75 ppm |

Remarks: Material Complies as per above specification FP/SPS/128-17

VERIFIED BY

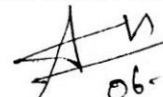

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