

## *Shilpa Medicare Limited*

### **Corporate & Admin Office:**

"Shilpa House", # 12-6-214/A-1, Hyderabad Road,  
Raichur – 584 135, Karnataka, India  
Tel: +91-8532-238704, Fax: +91-8532-238876  
Email: info@vbshilpa.com, Web: www.vbshilpa.com  
CIN: L85110KA1987PLC008739

Date: August 9,2025

To,

Corporate Relationship Department,  
BSE Limited  
Phiroze Jeejeebhoy Towers,  
Dalal Street, Fort,  
**Mumbai-400 001**

National Stock Exchange of India Ltd.  
Exchange Plaza, 5<sup>th</sup> Floor,  
Plot No.C/1, G Block  
Bandra Kurla Complex, Bandra (E)  
**Mumbai-400 051**

Dear Sir/Madam,

Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg. Ref: Stock Code: NSE: SHILPAMED/BSE-530549

***Shilpa Medicare announces the approval of Nor Ursodeoxycholic Acid Tablets 500 mg for the treatment of Non-Alcoholic Fatty Liver Disease in India***

Shilpa Medicare Limited announces the approval of its, Nor Ursodeoxycholic Acid (NorUDCA) Tablets 500 mg, by the Central Drugs Standard Control Organization (CDSCO), marking a major milestone in innovative NAFLD therapy in India. The approval reinforces Shilpa Medicare's commitment to addressing unmet medical needs in hepatology through innovation and evidence-based solutions. This approval will allow Shilpa to become the first company in the World to launch this novel product in any part of the World for NAFLD.

NorUDCA is the first-in-class treatment for Non-alcoholic Fatty Liver Disease (NAFLD) in India, addressing a significant unmet medical need.

NAFLD is currently the most prevalent liver condition globally, affecting about 25% of the world's population (approximately 1.2 billion people) and impacting an estimated 188 million individuals in India alone. If not managed early, NAFLD may progress to non-alcoholic steatohepatitis (NASH) and severe liver complications, underscoring the urgent necessity for effective therapy.

These results collectively demonstrate a significant improvement in both liver structure and function, confirming NorUDCA's superior efficacy compared to placebo in NAFLD.



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Nor UDCA demonstrated superior efficacy over placebo, and no significant safety concerns were identified. NorUDCA is uniquely positioned with its choleric and anti-inflammatory properties, enhancing bile flow, reducing hepatic inflammation, and offering therapeutic potential in halting the progression of NAFLD and associated cholestatic liver disorders.

Commenting on this approval, **Mr. Vishnukant Bhutada, Managing Director, Shilpa Medicare Limited, said:**

*"We are delighted to receive historic approval for NorUDCA, India's first-in-class therapy for NAFLD—making Shilpa the first company globally to obtain approval for NorUDCA in this indication. This milestone is a moment of immense pride for Shilpa and the nation, as we now pioneer the launch of its finished dosage form. This breakthrough exemplifies Shilpa's unwavering dedication to innovation and accessible healthcare to millions battling liver disease in India and beyond. We are excited to introduce NorUDCA tablets in India immediately, while advancing global regulatory efforts to bring this vital therapy to patients internationally."*

About Shilpa Medicare Limited:

Shilpa Medicare Limited is an integrated pharmaceutical group with expertise in niche Oncology & Non-Oncology APIs, Peptides, Polymers and differentiated finished dosage formulations including Orally Dispersible Films, Transdermal Patches. The company also offers end-to-end CDMO services to global pharmaceutical partners, backed by four R&D units and seven manufacturing facilities.

This is for your information and records.

**For SHILPA MEDICARE LIMITED**

**Ritu Tiwary**

**Company Secretary & Compliance Officer**