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Shilpa Medicare secures regulatory Nod for nor-ursodeoxycholic acid tablets, targets market launch for NASH treatment

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Nor UDCA to emerge as a breakthrough therapy for NAFLD



Raichur-based Shilpa Medicare Limited, a leading API and formulation manufacturer, has announced that the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) has approved its Investigational New Drug (IND) – Nor Ursodeoxycholic Acid (Nor UDCA) Tablets 500 mg – and recommended marketing authorisation for treating non-alcoholic fatty liver disease (NAFLD).

NAFLD, the most prevalent liver disease, affects approximately 25% of the global population (1.2 billion people), including 188 million in India. Left untreated, NAFLD can progress to non-alcoholic steatohepatitis (NASH), a severe and potentially fatal condition.

Shilpa Medicare had earlier completed phase-3 clinical studies of this novel product SMLNUD07 – Nor Ursodeoxycholic Acid (Nor UDCA) tablets - and presented the results of the trial titled, "A phase - III, Randomised, Double- Blind, placebo controlled, multicenter, Parallel group study", to evaluate the safety and efficacy of Nor-Ursodeoxycholic Acid 500 mg in patients suffering from Non-alcoholic Fatty Liver Disease to the SEC.

The trial met all primary efficacy endpoints, demonstrating a significant improvement in fatty liver stage. 83.3% of participants showed fibrosis reversal, with stabilization in the rest. Elevated alanine transaminase (ALT) levels, a key NAFLD marker, normalized in ~90% of participants within 12 weeks.

These results position Nor UDCA as a breakthrough therapy for NAFLD, offering advantages over conventional UDCA, including enhanced choleretic effect, resistance to amidation, anti-inflammatory properties, and fibrosis reduction.