Govt intensifying focus on excipient manufacturing under PLI scheme to break import dependency

Aiming to drastically reduce the country's heavy reliance on imported pharmaceutical excipients and strengthen its global supply chain resilience, the Government of India is intensifying its focus on excipient manufacturing under the production linked incentive (PLI) scheme.

Excipients play a pivotal role in drug formulation, determining the quality, stability, and delivery of medicines.

India, despite being a global leader in pharmaceutical formulations and exports, imports nearly 90 per cent of its excipient needs from countries like the USA, China, Taiwan, Japan, and Europe, according to pharmaceutical experts and industry leaders. Adding to the challenge, major global acquisitions in the past of Indian excipient companies have led to a decline in domestic manufacturing.

With only 8 to 10 active players in the country, India's reliance on imports remains immensely high at 90 per cent. Experts are calling for domestic manufacturing of critical excipients like microcrystalline cellulose (MCC) used in 50% of oral dosage forms and magnesium stearate used in 90 per cent of oral dosage forms.

These are essential for tablet binding, stability, and dissolution, yet India remains largely dependent on global suppliers.

“By prioritizing excipient production and quality, we safeguard the future of pharmaceuticals, ensuring they are safe and effective for all,” says Ravleen Singh Khurana, Secretary of the International Pharmaceutical Excipients Council (IPEC) India.

Against this backdrop, the Technology Development Board (TDB) under the Department of Science and Technology (DST) recently announced support for a landmark initiative — the Complex Excipients Manufacturing Project by Nitika Pharmaceutical Specialties Pvt. Ltd., Nagpur.

The project is one of the world’s largest excipient facilities, projected to scale to 5,000 tons per month within 7 years. Nitika plans to manufacture 14 advanced excipients designed under the Quality by Design (QbD) framework, meeting rigorous global standards on particle size, surface area, and stability.

Founded in 1991 and incorporated in 2011, Nitika has grown into a trusted name in fine chemicals and specialty excipients, supplying to over 90 countries. Its in-house DSIR-recognized R&D capabilities and its selection as a Group C (MSME) beneficiary under the PLI scheme positions it as a torchbearer for India's journey towards excipient self-sufficiency.

“As global demand for complex excipients rises with the evolution of biopharmaceuticals and advanced drug delivery systems, India's ability to manufacture them domestically becomes critical to avoiding supply chain shocks (as seen during the Covid-19 pandemic), enhancing national drug security and bolstering India's role as a global pharma hub. Conclusion. India's bold step to incentivize domestic excipient production through strategic financial and policy support marks a pivotal moment in the country's pharmaceutical evolution," experts conclude.

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