India Pharma Outlook

Indoco Remedies Eyes European Entry After EU GMP Certification

India Pharma Outlook Team | Friday, 15 May 2026

Indoco Remedies Ltd. has announced that its manufacturing facility for solid oral dosage forms (Unit I) located at Baddi, Himachal Pradesh has received EU GMP (Good Manufacturing Practice) certificate from the Malta Medicines Authority, marking the company's first step to European entry.

Indoco gained the EU GMP certification after a successful inspection at its Baddi unit between January 29 and February 3, 2026. This certification confirms that the company solid oral dosage manufacturing meets the stringent quality and safety standards required under European Union regulations.

Aditi Panandikar, Managing Director of Indoco Remedies Ltd., said, "This approval from the Malta Medicine Authority further reflects Indoco's strong commitment to quality, compliance, and adherence to global regulatory standards. We are focused on maintaining the highest quality standards while catering to our customers in India and globally."

For a company like Indoco, looking to deepen its presence in European markets, the certification is a foundational requirement. The European generics market is highly competitive. It demands continuous innovation and cost management. Indoco will have to maintain strict adherence to the EU GMP standards to preserve its certification and avoid future compliance issues.

Selling Small for a Big Win

On April 30, the company has also transferred its ophthalmic business through an agreement to transfer business (ATB) Sunways Private Limited for a consideration of Rs 110 Cr. These moves are not just coincidental, it outlines the company's focus on European entry and international growth strategy.

This transaction covers the country's ophthalmic division across India and other international territories including, Benin, Burkina Faso, Ivory Coast, Mali, Niger, Mauritania, Senegal, Cameroon, Congo, Gabon, Kenya, Botswana, Tanzania, Zambia, Zimbabwe, and Namibia.

Aditi Panandikar commented on this deal as, "This divestment is an important step in sharpening our focus on core therapeutic areas with stronger potential. We are confident that Sunways will further build on the strengths of the ophthalmic division, leveraging its core competencies across markets. At Indoco, we will continue to invest in innovation, quality, and operational excellence, creating long-term value for our stakeholders and the communities we serve."

The company announced that the transaction is expected to be completed within three months. The buyer Sunways (India) Private Limited is a Mumbai based ophthalmic products manufacturer with consolidated revenue of Rs 135.59 Cr.

By exiting a low-contribution segment with niche geographic exposure, Indoco has freed up its management bandwidth and capital, which can be deployed towards higher margin segments.

What the Investors Will be Watching

As the EU GMP certification opens up the door to European export orders, the investors will be watching the company's export order wins, tracking product launches from the Baddi facility, further certifications for other Indoco units, and management's new strategic expansion plans post this certification. In February, the US FDA approved brivaracetam oral solution, a medicine used for treating partial-onset seizures, allowing Indoco Remedies Ltd. to sell brivaracetam oral solution in America.

Indoco Remedies is a Mumbai-headquartered research-oriented pharma company engaged in the manufacturing and marketing of formulations.