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Sovereign Pharma unveils India’s first high-volume ampoule isolator line

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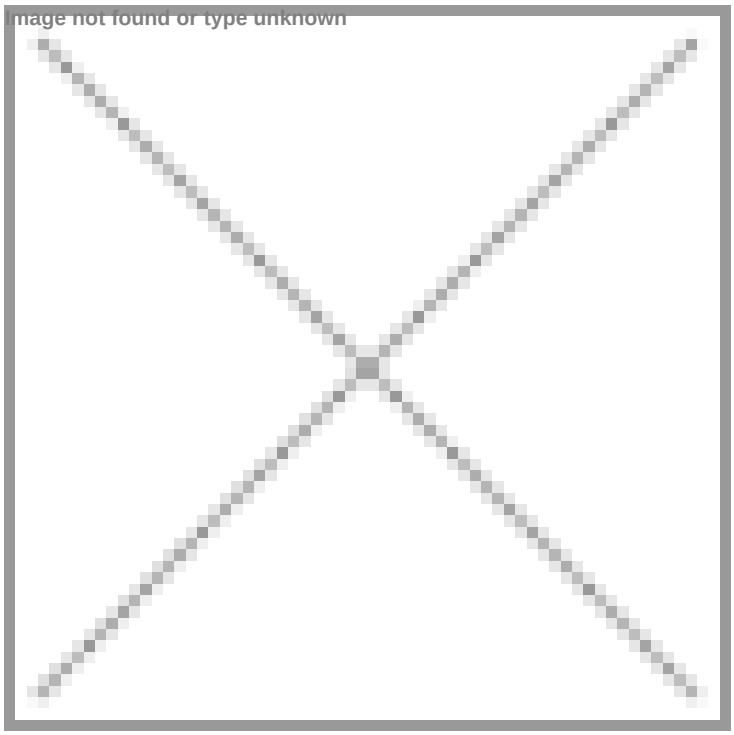
New advanced isolator-based filling line delivers higher sterility assurance



Sovereign Pharma has announced the successful commissioning of its new advanced isolator-based filling line, marking a major advancement in India’s sterile injectable manufacturing landscape.

As part of its long-term modernisation strategy, the company had planned to transition three of its filling lines to isolator-based systems. With this milestone, the first of these isolator lines is now fully commissioned and operational in production.

This cutting-edge system positions Sovereign Pharma among the select few globally operating fully contained isolator technology for high-volume ampoule manufacturing. The isolator creates a sealed aseptic environment through glove ports, HEPA-filtered air, positive pressure containment, and vaporized hydrogen peroxide (VHP) bio-decontamination. This significantly reduces human contact, responsible for nearly 80% of contamination risks in sterile processing, resulting in higher sterility assurance, improved consistency, and reduced human error.

The new isolator line also features online PUPSIT *(Pre-Use Post-Sterilisation Integrity Testing)*, making Sovereign Pharma among the very few companies capable of executing real-time, non-destructive verification of sterilised filters prior to use, significantly strengthening sterility assurance and product safety.

In a significant national milestone, Sovereign Pharma becomes the first manufacturer in India to introduce an isolator-based high-volume ampoule filling line. While isolators are globally mandated for aseptically filled products, the company is going

beyond compliance by deploying this technology even for terminally sterilized products, exceeding regulatory expectations and aligning with evolving EU Annex 1 and USFDA standards.

The line supports the filling of both aseptic and terminally sterilized injectables, expanding Sovereign Pharma’s capability and offering customers faster turnaround, enhanced sterility assurance, and globally benchmarked process control.?