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EXPRESS
PHARMA

Diversifying beyond the US market

On July 21, US President Trump unleashed uncertainty on the tariff front once again. Generics exported to the US will have zero tariff until August 1, 2028, after which tariffs are proposed to increase to 100 per cent from August 2028 and 200 per cent from August 2029.

However the two year interim period makes it seem like a negotiation tool.

As Bharat Celly, Equity Research Analyst at Equirus Securities points out, the proposal runs counter to the intent of the Hatch-Waxman framework, which was designed to reduce drug prices through greater generic competition. Imposing 100-200 per cent tariffs on imported generics could instead raise the cost of low-priced medicines and, in shortage-prone categories, increase the risk of supply disruptions rather than drive reshoring.

Param Desai, Research analyst - PL Capital points out that President Trump's term ends in January 2029, while the major tariff impact begins from August 2028, so the eventual implementation remains uncertain if there is a change in administration.

An Ind-Ra analysis believes that the evolving tariff environment could accelerate consolidation across the generic pharma industry, strengthening the market position of larger and better-capitalised companies. As operating challenges increase, small generic companies may find it difficult to remain competitive due to weaker balance sheets, lower pricing flexibility, and limited ability to undertake significant greenfield investments in the US, particularly where investment paybacks remain unattractive.

The Ind-Ra report posits that tariff-driven disruptions could create opportunities for partnerships, acquisitions, and strategic investments. Distressed generic assets may become attractive acquisition targets, while Indian pharma companies could increasingly collaborate with US contract manufacturing organisations to establish domestic manufacturing capabilities in a capital-efficient manner and meet local sourcing requirements where necessary.

India has already diversified beyond the US market, through numerous free trade agreements (FTAs). India's FTA network now includes 15 agreements covering 27 countries, and counting. Though we still haven't been able to make a trade deal with the US, which is the world's biggest pharma market, 6Wresearch's recently released India Export Attractiveness Tracker 2026 makes the point that India's next export wave will not be



India's next export wave will not be won on tariff advantage alone; mutual recognition of standards and regulatory cooperation will play vital roles

won on tariff advantage alone — most of the frictionless doors (Japan, Egypt, Mexico) are already open, and most of the mature markets (US, China, UAE) are now regulatory contests rather than tariff contests.

For instance, the report points out that the US applies 213 regulatory measures whereas China applies 148 measures on medicines. Both large pharma export markets thus come with a dense regulatory architecture.

The playbook is therefore twofold: scale fast in the zero-tariff corridors while capacity is uncontested, and invest early in regulatory and standards compliance in the high-value, high-friction markets — because that is where the next \$30.1 billion in untapped potential will actually be won.

According to 6Wresearch's report, built on UN Comtrade data, generic medicines are the fourth anchor of India's highest-value future export potential by 2031. Smartphones, polished diamonds, and refined petroleum, lead the list.

Pharma exports currently make up \$39.45 billion, of which medicines make up 44.7 per cent. By 2031, the report projects that medicines alone carry export potential of \$23.30 billion, led by the US (\$8.67 billion), Switzerland (\$3.15 billion), China (\$1.81 billion), Japan (\$1.45 billion) and Canada (\$758.62 million). Human vaccines have an export potential of \$209 billion. Within the exports to the US, medicines lead with 9.6 per cent share followed by smartphones (8.8 per cent).

The pharma sector could scale this to \$66.81 billion, with the US alone accounting for \$20.13 billion — nearly a third of the total — followed by China (\$ 8.79B), Switzerland (\$ 5.68B), Japan (\$4.23B) and Brazil (\$3.36B).

But the July 21 tariff announcement put this at risk. As the cover story in the August 2026 *Express Pharma* edition analyses, in a world shaped by geopolitics, economic nationalism and heightened scrutiny on quality and resilience, India's next phase of growth will depend on trust, innovation and strategic agility. (*See story, Power, politics and pharma*).

India will have to work on deepening and expanding current FTAs to increase our export competitiveness. A key part of these measures is mutual recognition of standards and regulatory cooperation. The US tariffs could well be a blessing in disguise if we can look beyond the US and achieve these wins.

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INTERVIEW

Why India's medicines need integrated authentication, enforceable standards

Triggered by recent high profile operations involving counterfeit semaglutide in the domestic markets and anti-rabies vaccines exported to various countries, India's regulators are plugging the gaps by expanding the existing QR code mandate and may next require online registration of manufacturers and suppliers of printed pharma packaging materials. However, **Ankit Gupta**, President, ASPA explains to **Viveka Rychowdhury**, that as counterfeiters evolve, isolated security measures should be replaced with integrated authentication ecosystems and enforceable standards

What is the extent of counterfeiting in India's pharma supply chain?

Counterfeit medicines continue to pose a significant risk to patient safety and the integrity of India's pharmaceutical supply chain. According to the CRISIL-ASPA State of Counterfeiting in India 2025 Report, 28 per cent of consumers reported encountering a counterfeit healthcare product at least once during the last 12 months. The report uses the broader category "healthcare products," which includes pharmaceuticals, OTC medicines, nutraceuticals, and medical devices following a nomenclature update.

ASPA believes the threat extends beyond economic losses. Counterfeit medicines directly endanger patient safety, undermine treatment outcomes, erode consumer confidence, and damage the reputation of legitimate pharmaceutical manufacturers.

What are the common modus operandi of such counterfeit operations?

ASPA observes that counterfeiters have become increasingly sophisticated. Rather than producing obvious imitations, they now:

- Closely replicate genuine packaging and labels.
- Attempt to imitate certain security features.
- Exploit fragmented distribution networks.



- Use online marketplaces and e-pharmacies to reach consumers.

- Introduce products containing incorrect ingredients, substandard formulations, harmful substances, or sometimes no active pharmaceutical ingredient at all.

These evolving tactics make visual inspection alone insufficient and reinforce the need for authentication combined with end-to-end traceability.

What has been the reaction of pharma companies to such incidents? Has it been adequately addressed to prevent future incidents? Pharma companies are

increasingly strengthening their anti-counterfeiting efforts. ASPA cites examples such as Mankind Pharma, which has adopted authentication and traceability solutions to enhance product security and consumer trust. Manufacturers are increasingly viewing authentication not merely as a compliance requirement but as a strategic investment in patient safety and brand protection.

That said, ASPA's position is that more needs to be done. Counterfeiters continue to evolve, making isolated security measures insufficient. The association advocates integrated

authentication ecosystems combining serialisation, traceability, physical security features, digital verification, and stakeholder collaboration.

What has been the reaction from policymakers like the CDSCO?

ASPA welcomes the Government of India's efforts to strengthen oversight within the pharma packaging ecosystem, including initiatives aimed at improving accountability and traceability. This is a step in the right direction and reflects growing regulatory recognition of the problem.

At the same time, ASPA believes oversight measures need to evolve into

enforceable standards. The association is advocating for the next phase of policy to include mandatory adoption of multi-layered Authentication and Traceability Solutions (ATS) for high-risk drug categories, stricter penal action against counterfeiters and those enabling them, and a national track-and-trace mandate that gives visibility across the entire supply chain, not just at the point of packaging.

The CDSCO has mandated expansion of QR codes to vaccines. What are ASPA's views, given that QR codes have proven unsuccessful in preventing counterfeiting?

ASPA welcomes this as a step in the right direction. Extending QR code requirements to vaccines shows the regulator's intent to improve traceability in a high-stakes category.

However, the solution is complete only when QR codes are combined with other visible and invisible security features. A standard QR code, on its own, carries the risk of being copied or reprinted by counterfeiters just as easily as the genuine one, since it does not by itself authenticate the product. Layering it with tamper-evident features, holograms, and covert or non-clonable markers is what actually closes that gap and gives both regulators and consumers a way to verify authenticity with confidence.

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INTERVIEW

At the 69th Drugs Consultative Committee (DCC) meeting, held virtually on last month on June 24, it was recommended to constitute a subcommittee to evaluate the feasibility of the proposal to introduce an online registration framework for manufacturers/suppliers of printed pharma packaging materials used for drugs. Why does ASPA feel that the printer registration initiative is a meaningful first step, but insufficient on its own?

ASPA sees printer registration as a welcome and meaningful first step. It strengthens oversight, accountability, and transparency at the packaging stage of the supply chain, an area that has traditionally seen limited scrutiny.

However, registration of printers does not, by itself, authenticate a product or

track it once it leaves the printing facility. Counterfeiters operating outside registered networks can still replicate packaging design. ASPA's ask is for this initiative to be paired with clear enforcement mechanisms, such as periodic audits of registered printers and a defined compliance timeline, alongside a broader push for product-level authentication so that oversight extends beyond who printed the packaging to whether the product itself can be verified as genuine.

Where are the gaps even after printer registration is in place?

The real gap lies beyond the printing stage. Once a product moves through manufacturing, warehousing, distribution, and retail, visibility drops sharply. There

is currently no reliable way to confirm that the medicine reaching a patient at the last mile is the same one that left the manufacturing facility.

This is a supply chain visibility problem as much as a packaging problem. Diverted stock, parallel distribution channels, and unregulated online sellers can all introduce counterfeit or tampered products at any point after packaging, well outside the reach of printer oversight. Closing this gap requires giving every product a verifiable identity that can be checked at each handoff, not just at the point of origin.

What kind of authentication technology is essential to close those gaps?

ASPA's position is that no single technology can eliminate pharma counterfeiting on its own.

What is needed is a multi-layered Authentication and Traceability Solution (ATS): serialisation for unique product identity, secure or non-clonable QR codes, tamper-evident packaging, holograms and covert security features, RFID/NFC for automated tracking, cloud-based verification, and AI-enabled monitoring for anomaly detection.

This "phygital" approach, combining physical security with digital verification, is what allows a product to be authenticated and tracked through its entire lifecycle, rather than relying on any single checkpoint.

What do such counterfeiting operations mean for India's credibility as a global pharma exporter?

Counterfeiting poses a serious threat to India's reputation as

one of the world's largest pharmaceutical manufacturers and exporters. Even isolated incidents can undermine confidence among international regulators, healthcare providers, and global buyers, leading to increased scrutiny and affecting trust in the country's pharmaceutical supply chain.

As the Pharmacy of the World, India must continue strengthening supply chain integrity through robust product authentication, end-to-end traceability, and advanced anti-counterfeiting technologies. These measures will not only safeguard patient safety but also reinforce India's credibility as a trusted global supplier of high-quality medicines and support seamless international trade.

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Inside Shilpa Medicare's growth strategy: Quality, digital and global ambitions

Dr Vellaian Karuppiyah, COO-Management, Shilpa Medicare shares his vision for building a future-ready organisation powered by quality, digital transformation, and operational excellence. In this conversation, he discusses leadership, biosimilars, global markets, and what it takes to earn lasting regulatory trust, in an exclusive interaction with **Lakshmipriya Nair**

You have recently stepped into a new role as COO of Shilpa Medicare - Formulations. What excites you the most, and what are you most careful about? Joining Shilpa Medicare at this stage of its evolution is both an exciting opportunity and a significant responsibility. What excites me most is the opportunity to contribute to an organisation that has already established strong scientific capabilities and a differentiated position in oncology and specialty pharma. The global pharma landscape is evolving rapidly, and companies that can consistently combine scientific innovation, manufacturing excellence, and regulatory credibility will emerge as long-term leaders.

I believe there is tremendous opportunity to further strengthen operational excellence, accelerate commercialisation, improve execution speed, and build an integrated quality culture across the organisation. My focus will be on creating sustainable systems rather than short-term achievements.

At the same time, I am very conscious that growth should never compromise quality or patient safety. The pharma industry operates on trust. Every product we manufacture ultimately reaches patients whose lives depend on our commitment to quality. Therefore, maintaining regulatory compliance, strengthening our pharma quality system, developing our people, and ensuring robust governance



I also believe innovation should not be confined to drug discovery. Process innovation, manufacturing innovation, quality innovation, and digital innovation often generate equally significant competitive advantages

will remain non-negotiable priorities.

For me, sustainable growth is achieved when scientific excellence, operational excellence, and quality excellence progress together.

You've spent much of your career building scale, strengthening operations,

and navigating global regulatory environments. How will that experience shape your leadership approach at Shilpa Medicare - Formulations?

Throughout my career, I have learned that successful pharma organisations are built on systems rather than individuals. My leadership

philosophy has always centered around creating processes that are scalable, predictable, compliant, and continuously improving.

Global regulatory inspections have taught me that compliance cannot be prepared for just before an inspection—it must be embedded into daily operations. This requires cross-functional collaboration where quality, manufacturing, engineering, supply chain, R&D, regulatory affairs, and commercial teams work towards common objectives.

My approach will emphasise three pillars:

● **Operational excellence:** Building highly efficient, data-driven manufacturing systems that improve productivity while maintaining the highest quality standards.

● **Quality culture:** Moving beyond documentation-driven compliance toward a culture where every employee understands their responsibility toward patient safety and product quality.

● **People development:** Investing in leadership development, technical competency, and empowering teams to make scientific, evidence-based decisions.

Ultimately, my objective is to create an organisation where operational discipline and innovation complement each other rather than compete.

Biosimilars are getting more competitive. Where do you see real room to differentiate today?

The biosimilar industry has

evolved significantly. Price alone is no longer a sustainable differentiator. True differentiation now lies in delivering consistent quality, regulatory confidence, supply reliability, and patient-centric solutions.

Manufacturing excellence has become a strategic advantage. Companies that demonstrate robust process controls, strong analytical capabilities, and reliable commercial supply will gain greater confidence from regulators and healthcare providers.

Another important differentiator is lifecycle management. Developing improved formulations, convenient delivery systems, patient support services, and digital health integration can significantly enhance value beyond the molecule itself.

Global partnerships will also play an increasingly important role. Collaborations that combine scientific expertise, manufacturing capability, and commercial reach can accelerate market access while reducing development risks.

Finally, digital manufacturing, artificial intelligence, advanced analytics, and continuous manufacturing technologies will become increasingly important in improving efficiency, reducing costs, and ensuring product consistency.

When you look at Shilpa Medicare - Formulations three years from now, what do you want it to be known for? What is the one big bet you think will define

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whether you get there or not?

Three years from now, I would like Shilpa Medicare Formulations to be recognised globally for three attributes: uncompromising quality, execution excellence, and scientific innovation.

I envision an organisation known for consistently delivering high-quality oncology and specialty medicines across global markets while maintaining strong regulatory credibility.

The one strategic bet that will define this journey is building an integrated culture of operational excellence supported by digital transformation.

Digital technologies—including electronic quality systems, advanced manufacturing analytics, predictive maintenance, automation, and real-time process monitoring—can transform both compliance and operational performance. However, technology alone is insufficient. Success depends on developing people who understand how to leverage these tools effectively.

Organisations that successfully combine digital capabilities with strong quality culture will be best positioned for sustainable growth.

There's a lot happening in science, be it new therapies or new technologies. How do

you decide what is worth investing in and what is just noise?

Every innovation should ultimately answer one question: Does it create meaningful value for patients, healthcare systems, and the organisation?

I generally evaluate investments across five dimensions: Scientific differentiation, Unmet medical need, Regulatory feasibility, Commercial sustainability and Operational scalability.

Not every emerging technology requires immediate adoption. Some technologies generate excitement but lack commercial maturity or practical application.

Conversely, technologies that improve product quality, manufacturing robustness, regulatory compliance, data integrity, supply reliability, or patient outcomes deserve serious consideration.

I also believe innovation should not be confined to drug discovery. Process innovation, manufacturing innovation, quality innovation, and digital innovation often generate equally significant competitive advantages.

Balanced investment decisions require scientific rigor, business discipline, and long-term strategic thinking.

As regulatory expectations for oncology and other niche

formulations like TDS and ODG rise globally, credibility is becoming a business moat. How do you plan to build that at Shilpa Medicare - Formulations?

Credibility cannot be built during inspections—it is built every day through disciplined execution.

My approach focuses on strengthening the entire Pharmaceutical Quality System rather than isolated compliance initiatives.

This includes:

- Robust quality risk management
- Strong contamination control strategies
- Advanced data integrity practices
- Effective deviation and CAPA systems
- Scientific process validation
- Comprehensive training and competency development
- Continuous process verification
- Transparent quality governance

For specialised formulations such as oncology products, transdermal systems (TDS), and orally disintegrating dosage forms (ODG), manufacturing complexity demands even greater process understanding and contamination control.

Equally important is leadership behavior. Quality should never be viewed as the responsibility of the QA department alone. Every

function—from R&D to Engineering to Manufacturing—must own quality.

When this culture becomes embedded throughout the organisation, regulatory confidence naturally follows.

Which markets are you most focused on right now, and why?

Our focus should remain balanced between highly regulated markets and high-growth emerging markets.

Highly regulated markets such as the US, Europe, Canada, Australia, Japan, and the UK continue to represent significant opportunities because they reward companies with strong quality systems and regulatory excellence.

At the same time, emerging markets across Asia, Latin America, Africa, and the Middle East continue to experience increasing demand for high-quality, affordable specialty medicines.

A diversified global presence reduces business risk while creating sustainable long-term growth.

Success in these markets will depend not only on obtaining approvals but also on ensuring reliable supply, maintaining regulatory compliance, understanding local healthcare needs, and building long-term partnerships.

At a strategic level, what do you believe companies like yours should focus on: innovation, partnerships or scale? Why?

I do not view innovation, partnerships and scale as competing priorities—they are mutually reinforcing.

Innovation creates differentiated products and technologies.

Partnerships accelerate development, expand market access, and bring complementary capabilities.

Scale enables affordability, operational efficiency, and global competitiveness.

The companies that will lead the next decade are those capable of integrating all three.

However, if I had to identify the foundational element, I would say quality-driven innovation. Innovation without quality cannot reach patients. Scale without quality is unsustainable. Partnerships succeed only when built on trust and credibility.

Ultimately, pharma success is built on a simple principle: delivering safe, effective, high-quality medicines to patients consistently. Everything else—innovation, partnerships, and scale—should strengthen that mission.

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Interview
Nandakumar Kalathil
Country General Manager - India, Argent Technologies
Chief Operating Officer (APN Holdings), Chief Business Officer (CBF)

FRIENDSHORING PHARMA'S NEXT SUPPLY CHAIN BET?

With friendshoring gaining attention in global supply chain conversations, this story looks at what it could mean for the India pharma inc.

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Major Machinery/Equipment

Machine	Brief Specification
STEAM STERILISER / BUNG PROCESSOR (01 brand new unopened box, 01 old)	Capacity 432lt, Pharmalab 600 mm (W) X 600 mm (H) X 1200 mm (D) PSSD224AB (V)
Parenteral: 20 sqm API Lyo with powder processing and canister packing system under cRAB microenvironment (installed but never used).	Tofflon make 20 sqm Lyophilizer of Shelf surface area: 17.01 m ² - Condenser capacity: 400 kg, 7 Shelves + 1 Thermal, Auto loading/unloading arm, SIP and CIP. Model No. LYO-20 (SIP, CIP) Powder transfer with Sifter, mill, cone blender 200L, Automatic canister filling, weighing and capping under cRAB microenvironment
Parenteral: 3 sqm API Lyo with powder processing and canister packing system under cRAB microenvironment (installed but never used).	Tofflon make 3 sqm Lyophilizer of Condenser capacity: 60 kg, 5 Shelves + 1 radiant, Auto loading/unloading arm, SIP and CIP. Model No. LYO-3 (SIP, CIP) Powder transfer with Sifter, mill, cone blender 5L unloading system under cRAB microenvironment
Parenteral Vial Filling Line with LAF and Barrier, 2-100ml (fully operational till May 26)	Vial Washing m/c, Depyrogenation Tunnel, Vial Filling Line (120 VPM) with Sealing/Capping m/c.
Parenteral combined Liquid and Powder filling Line, COMAS, Italy (installed but never used)	Liquid Mfg vessel Liquid Filling station (IPEC 450lt) and capping m/c (50pcs) and powder filling with capping (50pcs) with line machine
Oncology – Ointment Skid	Micro Fluidizer Processor Manufacturing Tank 3 lts/minute, Model M700, IUS manufacturing tank 150lts with 63lt Glass Reactor
Ointment skid 150lt, (never used)	150lt mfg skid with 3 sets of manufacturing vessels
Granulation area 150lt (fully operational to date)	Complete granulation area with RMG (150lt), FBD (60kg) and OG
Ganscoater GAC900 (fully operational to date)	Gansons autocoater GAC900 21CFR upgraded

Interested parties and companies are invited in person for physical inspection, to review detailed technical specifications, and engage in further techno-commercial discussions.

To schedule an inspection appointment or request technical data sheets, please contact:

Mr. Shrutal Shah - 8000776967 | shrutal_shah@intaspharma.com

Mr. Mahesh Iyer - 9825900293 | Mahesh_Iyer@intaspharma.com

Protecting domestic stainless steel is vital for pharma manufacturing

Rajamani Krishnamurti, President, Indian Stainless Steel Development Association (ISSDA) discusses the role of stainless steel in supporting pharma infrastructure, the need for a dedicated stainless steel policy, concerns over low-cost imports, procurement reforms, and the policy measures required to strengthen domestic manufacturing and enhance India's global competitiveness, in an interaction with **Kalyani Sharma**

India aims to become a global leader in pharmaceuticals, medical devices and healthcare manufacturing. What role do you envision the ISSDA playing over the next decade in enabling this vision, particularly through innovation, standards and industry partnerships?

Stainless steel is already the preferred material for pharmaceutical processing equipment because health and hygiene standards leave no room for compromise. The pharma industry relies almost entirely on stainless steel in processing applications, and our role is to further strengthen this ecosystem by promoting the latest technologies and global best practices. We want Indian manufacturers to adopt internationally accepted standards so that the country remains globally competitive.

However, one major concern is the recent suspension of the Quality Control Order (QCO). This creates uncertainty because substandard stainless steel imports, particularly from China, can enter the Indian market at predatory prices. Investigations by the Directorate General of Trade Remedies (DGTR) have already established that Chinese producers receive significant subsidies, making it difficult for Indian MSMEs to compete. If domestic manufacturers are expected to compete against heavily subsidised imports without adequate policy support, it will become increasingly difficult for them to survive.

Globally, countries such as the US, the UK, Canada and



those in Europe are strengthening their domestic manufacturing ecosystems through tariffs, quotas and non-tariff barriers. India must also create a level playing field if it wants to achieve its manufacturing ambitions.

What role will stainless steel play in achieving the Viksit Bharat vision for India's healthcare and pharmaceutical sectors?

Stainless steel will remain a critical material for nation building. We prepared a Vision 2047 document for the stainless steel sector in 2022, and the projections have largely remained on track.

One of our key recommendations is the creation of a dedicated National Stainless Steel Policy because

stainless steel manufacturing is fundamentally different from carbon steel production. Unlike carbon steel, stainless steel relies primarily on scrap and alloying materials rather than iron ore and coal. Recognising these differences, the Ministry of Steel has accepted the proposal, and work on such a policy is underway.

A dedicated policy can improve raw material security through government-to-government arrangements and help strengthen India's manufacturing ecosystem, including healthcare and pharmaceuticals.

What policy reforms would help improve quality and compliance in infrastructure and healthcare projects?

One important reform would be

to revisit the L1 (lowest bidder) procurement model. Either the L1 concept should be abolished or contractors awarded projects under L1 should be held accountable for the long-term performance of the infrastructure they build.

Quality should not be judged only by the lowest initial cost but also by durability and lifecycle performance. There are examples where stainless steel infrastructure has performed efficiently for over 50 years without recurring maintenance issues. Such long-term thinking should guide procurement policies.

Diagnostics centres and hospitals are expanding rapidly in India. Do you see sufficient collaboration between the stainless steel industry and the healthcare sector?

Healthcare already depends extensively on stainless steel. Hospital furniture, operating tables, handrails, gates and numerous critical applications use stainless steel because of its hygiene advantages. Bacteria do not survive on stainless steel surfaces for long, and the material is easy to clean and disinfect. During the COVID-19 pandemic, these qualities made stainless steel the preferred material for many healthcare applications.

Beyond hygiene, stainless steel is also highly durable and 100 per cent recyclable. It is a long-term investment because it retains value throughout its lifecycle while supporting sustainable infrastructure.

What policy measures would

accelerate collaboration between the stainless steel industry and the pharmaceutical and healthcare sectors?

India already has the capability to manufacture almost every grade of stainless steel required by the healthcare and pharmaceutical industries. Only a few niche grades are still imported because domestic demand is relatively small.

The larger concern is unrestricted imports. India remains one of the fastest-growing markets, making it an attractive destination for dumped products. Appropriate measures to regulate unfair imports would encourage greater domestic production and strengthen the entire value chain.

How do geopolitical developments and rising tariffs globally affect India's manufacturing ambitions?

The changing geopolitical landscape reinforces the importance of the Make in India initiative. Several countries have imposed significant tariffs and other trade restrictions to protect their domestic industries. India must also carefully evaluate its trade policies to ensure that domestic manufacturers are not placed at a disadvantage while competing with heavily subsidised imports. Strengthening domestic manufacturing capacity is essential for long-term industrial growth.

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Why Rashida Najmi believes in running quality on trust, not vigilance

Rashida Najmi, Chief Quality Officer, Piramal Pharma, believes that while her department may be the torchbearer, quality is everyone's responsibility. In a free-flowing discussion with **Viveka Roychowdhury**, she explains how the company's Quality Intelligence Platform, QUENCH, keeps it inspection-ready at all times, helping maintain an enviable record of no adverse regulatory action across its 17 sites in the US, Europe and Asia for the past 15 years. She also discusses investments in strengthening the company's quality-first manufacturing and compliance ecosystem, and the importance of building future-ready teams rooted in a culture of trust, not just compliance

In your article for Express Pharma in April 2019, you mentioned that quality needs to be part of culture, beyond compliance. ([https://www.expresspharma.in/quality-from-](https://www.expresspharma.in/quality-from-compliance-to-culture/)

[compliance-to-culture/](https://www.expresspharma.in/quality-from-compliance-to-culture/)) Can you give practical examples of how Piramal Pharma has implemented this? What's been the stance of the pharma industry, given the growing importance of

quality culture and compliance in global pharma manufacturing, backed by increasing regulatory rigour?

I will take your second question first. Across the industry,

quality is no longer a choice; it is a necessity. Quality cannot be confined to a department—it has to be embedded in the culture. Whether it is manufacturing, clinical research or any other life

sciences function, we are dealing with people's lives. So quality cannot be optional; it has to be integral to everything we do.

At Piramal Pharma, one of the most important steps we



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INTERVIEW

have taken is building future-ready teams—not just within quality, but across all associated functions. We already had a strong quality foundation, but we have significantly strengthened our teams to make them high-performing and future ready. We also launched our own internal Quality Academy to build what we call our quality DNA. It is a 20-month programme that takes employees through every aspect of quality at Piramal Pharma. Since we operate with harmonised quality standards across all our geographies and sites, the academy helps employees understand our quality philosophy, systems and expectations. More than 200 employees have graduated from the programme, and after completing Phases One and Two, we are preparing to launch the next phase.

Continuous learning is critical because regulations evolve rapidly.

We also restructured our quality organisation at the global, regional and site levels to ensure the right balance between strategy and execution. The global team focuses primarily on strategy, regional teams balance strategy and execution, while site teams focus largely on execution with site-specific strategic responsibilities. Strategic direction flows from the global team, while regular quality town halls ensure alignment across the organisation. These sessions help everyone stay updated on evolving regulations, standards and expectations.

Another important initiative has been strengthening regulatory compliance across every business and site. As data integrity became increasingly important, we established a dedicated Data Integrity Coordinating Officer (DICO) structure. Every site has its own DICO, reporting to a central DICO, who in turn reports directly to me. Any data integrity event is escalated to me within 24 hours. We also have a defined white paper outlining how such



events are handled. Our teams are empowered to make decisions within their responsibilities, supported by a robust escalation framework. This balances operational autonomy with strong governance, ensuring that critical issues receive timely attention at the global level.

Customer engagement has also become an important part of our quality culture. We conduct regular Quality Steering Committee meetings with customers, bringing together both quality teams to align expectations, review performance and strengthen collaboration.

We have also built a sustainable, scalable and quality-led global supply chain. Consistent quality depends on consistent availability of materials, supported by clearly defined assets and capable teams across our global network. Digitisation has been another major focus area. We have significantly expanded automation across our quality systems, and my goal is to make our shop floors completely paperless over time. Today, digitisation is no longer optional—it is as essential as quality culture itself.

In addition, we established a

central governance and compliance cell that works closely with every business and site to continuously strengthen compliance. We have also moved high-volume, low-complexity compliance activities from international sites to our central shared services team in India. This gives us economies of scale, enables 24x7 operations across time zones and allows site teams to focus on higher-value activities. Ultimately, the most important message remains the same: quality is everyone's responsibility. My team may be the torchbearers and custodians of quality, but every employee owns it. This philosophy has enabled us to maintain perpetual audit readiness. You cannot become inspection-ready only when an audit is announced—you have to be ready every single day. Our quality track record reflects that commitment.

When we talk about the company's quality track record, what has been Piramal Pharma's history with 483s, warning letters and other regulatory actions?

Our track record speaks for itself. Over the past 15 years, across our 17 manufacturing

sites, the majority of which are regulated by the US FDA, European, UK, Japanese and Australian authorities, we have not received a single Official Action Indicated (OAI).

During this period, we have successfully undergone more than 200 regulatory inspections, over 2,000 customer inspections and more than 50 US FDA inspections. We have not received a warning letter, consent decree, letter of non-compliance or any major regulatory non-compliance from the US, Europe, UK or any other regulatory agency.

That reflects both the strength of our quality systems and the consistency of our execution. Across the organisation, we undergo around 150-160 inspections every year when regulatory and customer audits are combined. In effect, almost every other day is an inspection somewhere within the company. That is why we maintain continuous inspection readiness.

For us, compliance is not about meeting regulations because we have to—it is about doing the right thing. I always tell my teams not to begin with the regulations during execution. Instead, ask what is right for the patient. If you do what is right for the patient, you will naturally meet regulatory requirements.

That is also why I say we run quality through trust, not vigilance. Regulations are important, but simply telling people to comply because of regulation is not enough. We want people to understand why quality matters and why doing the right thing is important. When people are guided by that mindset, regulatory compliance follows naturally.

How are pharma companies adapting to evolving regulatory expectations, especially global CDMOs like Piramal Pharma operating across multiple geographies? Does biologics manufacturing add further complexity?

A patient is a patient, whether the medicine is a small

molecule or a biologic.

Every molecule has different characteristics, therapeutic effects and potential adverse effects. Naturally, biologics—including mRNA therapies, RNA vaccines, gene therapies, antibody-drug conjugates (ADCs) and injectable biologics—bring additional complexity. We manufacture biologic injectables and ADCs ourselves. The key is to develop quality systems that are appropriate for each molecule and ensure patient safety and efficacy. As complexity increases, your quality systems, processes, mindset and, most importantly, your teams must evolve accordingly.

Regarding changing regulations, I do not see regulators simply as regulators. I see them as an extension of my own quality organisation, helping us make the right decisions for patients. Their role is to ensure patient safety, and if they identify something we have missed, we welcome that feedback. To manage evolving global standards, we have a robust global quality risk management system. If an issue arises at one site, it is immediately communicated across our global network so that similar risks can be identified and addressed proactively elsewhere.

Within our central quality organisation, we also have a team that continuously monitors warning letters, emerging regulatory expectations and developments across global regulatory agencies. Relevant updates are shared across the organisation through our Quality Intelligence Platform, QUENCH.

QUENCH allows us to proactively monitor regulatory developments and prepare well before new requirements become mandatory. For example, we tracked the nitrosamine issue from the very beginning and achieved full compliance within the August 2025 regulatory timeline.

As a CDMO, staying ahead of regulatory changes is

INTERVIEW

critical. While some companies struggle to be ready when new expectations emerge, our tracking systems, structured reviews and cross-learning sessions help us respond proactively. Regulatory expectations will continue to evolve, and the industry must evolve with them. Rather than resisting these changes, we should embrace them. I have personally participated in working groups that helped develop several global standards, including those relating to particulate matter in injectables, non-antibacterial beta-lactams and nitrosamines.

Ultimately, technology and systems are important, but future-ready teams remain equally critical. Strong quality culture, automation and capable people must all work together.

What technologies are helping pharma companies meet the rising regulatory bar? How close are you to your goal of becoming paperless, and how much is Piramal Pharma investing in these technologies?

We are very close to achieving a paperless environment at our regulated sites.

Automation has been part of our quality strategy for many years—it is not something we adopted recently. Our quality management systems and document management systems have long been digitised, significantly

strengthening compliance.

We are now expanding several additional digital platforms. One of our biggest initiatives is migrating from SAP to SAP S/4HANA. The rollout has already been completed across our India sites and will be completed across the organisation next year.

SAP S/4HANA will become a major data lake for quality information, supporting every stage from vendor qualification through product delivery. There are around 15-16 quality intervention points across that lifecycle, all of which are integrated into the system. While these processes were already managed digitally, we are now scaling them through a much more robust platform.

Our digitalisation journey, however, will never really end because technology keeps evolving. We have also begun our AI journey within quality. AI is advancing rapidly, and we need to keep pace with new developments so that we can continue strengthening our quality systems. We are embarking on an AI journey in GxP processes keeping human in the loop and working with a partner who understands the life science space well.

We have made significant investments in automation, with a significant percentage of our infrastructure-related spend currently directed towards automation and digital technologies. This proportion is expected to increase as

automation becomes central to our capital expenditure planning. Every new manufacturing facility is designed with automation built in from the outset, whether through SCADA, MES, LIMS or other digital systems. Alongside expanding our facilities, we are also upgrading existing plants with newer technologies. Automation is becoming central not only to our operations, but also to our long-term investment strategy.

What would you estimate as the industry benchmark for technology investment?

It varies significantly from company to company because it depends on each organisation's priorities and mindset towards automation. For companies that are serious about quality, I would estimate that around 30 per cent of infrastructure-related investment could be directed towards automation, although that is only my personal estimate. What is clear is that the industry is investing far more in automation today than it did in the past. One of the drivers has been the increased focus on data integrity.

Technology alone cannot guarantee data integrity—that ultimately depends on an organisation's culture and values—but automation provides built-in controls that greatly strengthen compliance.

Beyond compliance, digitisation improves efficiency

and gives leaders immediate access to data for faster decision-making. It therefore delivers both operational benefits and stronger regulatory compliance.

Geopolitical disruptions have repeatedly tested global pharma supply chains. How is Piramal Pharma building resilience and maintaining customer trust?

Recent geopolitical developments—including the Red Sea disruptions, tariffs and ongoing conflicts—have certainly created challenges.

In such an environment, the strength of a company's supply chain becomes extremely important.

Our vendor management network is quality driven, and our global footprint gives us significant flexibility. Because we operate across multiple geographies, we can source materials closer to individual manufacturing locations while also supporting sites in other regions whenever required.

Our global presence also allows us to leverage local expertise. For example, if a supplier in the UK needs to be qualified for one of our India sites, our UK quality team can conduct the vendor audit rather than sending a team from India. This improves efficiency and responsiveness.

Our supply chain, quality and manufacturing teams work very closely together, and we continuously monitor geopolitical developments so

that we can take risk-based decisions early. That may include building inventory, securing alternate supplies or advancing shipments before disruptions occur.

So far, we have been able to maintain reliable supplies for our customers, and we have not faced situations where customer commitments could not be fulfilled because materials were unavailable.

When you talk about future-proofing quality systems and building future-ready teams, what would be your key message for pharma quality professionals?

My message remains the same: quality is not a department—it is a commitment.

You have to build quality on trust, not vigilance. Oversight will always be necessary, but vigilance alone cannot sustain quality. If people only do the right thing when someone is watching, the system will eventually fail.

Every tablet we manufacture, every grain of API we produce and every vial we fill must meet the highest quality standards—not only during an inspection, but every single day.

That is why culture remains the foundation of everything we do. Quality must become part of how people think and work, not simply a compliance requirement.

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The digital twin revolution: Modernising the pharma industry

Amit Malviya, VP-QA, Zest Pharma highlights that from testing quality after production to designing it digitally from the outset, pharma manufacturing is undergoing a fundamental transformation. Digital twins are at the heart of this shift, enabling smarter, faster, and more sustainable drug manufacturing

In the traditional landscape of pharma manufacturing, we relied on Quality by Design (QbD). This science-based approach was a significant step forward, aiming to build quality into the product from the start by defining the Quality Target Product Profile (QTPP)—the essential characteristics that ensure safety and efficacy. However, traditional QbD often remains "manual," tethered to physical experiments and retrospective batch testing.

As we look toward the future of Industry 4.0, we are transitioning to Quality by Digital Design (QbDD). This evolution moves the laboratory into a virtual environment, using Artificial Intelligence (AI) and high-fidelity simulations to predict outcomes before a single molecule is processed. By shifting from physical trials to digital simulations, we can explore thousands of scenarios instantly, ensuring that we meet Critical Quality Attributes (CQAs) like purity and dissolution rates with unprecedented precision.

2. Digital twin: The virtual mirror of medicine

In my role as an innovation lead, I often describe a Digital Twin (DT) as the factory's "virtual mirror." It is not merely a static 3D model; it is a dynamic, living replica of a physical system—from a single machine to an entire production line—that evolves in real-time.

"A Digital Twin is a virtual replica of a physical system or process... constantly updated with real-time data from its physical counterpart, allowing for simulation, analysis, and optimisation throughout the product's lifecycle."

A Digital Twin serves three vital functions in a modern pharmaceutical facility:



its "Design Space," maintaining the consistency required for complex medicines.

These virtual models stay "smart" by listening to the digital heartbeat of the physical factory through a sophisticated nervous system of real-time sensors.

The factory's nervous system: Real-time monitoring and adaptive control

To keep the Digital Twin updated, the factory employs Process Analytical Technology (PAT). Think of PAT as the "eyes and ears" of the system. Advanced sensors, such as Near-Infrared (NIR) and Raman spectroscopy, act as high-tech observers that detect chemical and physical changes at the molecular level during production.

When these sensors detect a deviation from the ideal state, the system initiates an Adap-

lates how this deviation will impact the final CQAs, such as how fast a tablet will dissolve in a patient's body.

3. Adjust: The system automatically modifies a CPP, such as increasing the drying speed or adjusting the granulation temperature, to correct the error before it can compromise the batch.

This constant, invisible calibration leads to a breakthrough in how we finally test and release medicine to the public.

4. The "Why": Why real-time testing beats the old way

In a traditional factory, finished medicine sits in a warehouse for days or weeks while scientists perform "old-fashioned batch testing" in a lab. This delay is not just an efficiency issue; it is a clinical risk. Real-Time Release Testing (RTRT) changes the game by using AI-enhanced continuous testing during production.

RTRT is a critical advancement for Biopharmaceuticals and Narrow Therapeutic Index (NTI) drugs, where even minor deviations in concentration can lead to significant therapeutic failure. The system "knows" the quality is perfect the moment the process ends.

The primary "wins" of RTRT include:

- **Speed to market:** Accelerated release timelines mean life-saving medicines reach hospitals and patients faster.

- **Reduced costs:** By eliminating the need for massive storage and repetitive post-production lab work, the cost of manufacturing drops significantly.

This digital shift does more than just increase speed; it allows us to address the "sustainability paradox"—the challenge of using energy-intensive AI to ultimately create

THE QUALITY EVOLUTION

Dimension	Traditional QbD	AI-integrated QbDD
Process understanding	Gained through labor-intensive physical experiments and risk assessments.	Enhanced by digital simulations, molecular modeling, and predictive analytics.
Data usage	Relies on historical batch data and results from limited designed experiments.	Processes massive volumes of real-time data from IoT sensors and AI-driven insights.
Control strategy	Dependent on predefined rules and testing the final product (Batch Testing).	Utilises Process Analytical Technology (PAT) for real-time monitoring and adaptive adjustments.
This shift allows us to move beyond the limitations of physical experimentation to a more sophisticated tool: The Digital Twin.		

- **Predictive maintenance:** By analysing historical equipment data, the twin predicts machinery failures before they occur. This reduces unplanned downtime and prevents the loss of expensive batches.

- **Process optimisation:** The twin can simulate "what-if" scenarios for Critical Process

Parameters (CPPs)—such as mixing speed, humidity, and reaction kinetics—to find the most efficient manufacturing path without wasting physical raw materials.

- **Quality assurance:** By continuously monitoring the virtual process, the twin ensures that every batch stays within

tive Control loop. Instead of a manual shutdown, the AI handles adjustments through a "Sense-Analyse-Adjust" cycle:

- 1. Sense:** Sensors like NIR detect a tiny anomaly, such as a shift in moisture levels or a change in the chemical composition of a blend.

- 2. Analyze:** AI instantly calcu-

a more efficient, greener industry.

Protecting the planet while making medicine

The pharma sector is responsible for a significant environmental footprint, but digital twins and AI are making "green manufacturing" a reality. While model training consumes significant computational energy, we mitigate this through "Green Simulations" which reuse previously processed data rather than starting every simulation from scratch, drastically reducing the carbon footprint of R&D.

Sustainability spotlight

- **Energy efficiency:** Industrial projects integrating these digital groups have demonstrated a 15–25 per cent increase in energy efficiency.
- **Waste reduction:** AI-based quality control can identify



defective batches early, reducing material waste by up to 25 per cent.

- **Emission control:** Advanced analytics in the supply chain significantly lower greenhouse gas emissions by optimising logistics and reducing overproduction.

These concepts are being successfully deployed by the industry's most recognisable names to transform how medicine is made.

Science in action: Real-world success stories

The Digital Twin Revolution is

no longer a theoretical exercise. Leading companies are currently utilising AI-integrated QbDD to achieve remarkable results:

- **GSK (GlaxoSmithKline):** By employing real-time energy and sensor monitoring, they achieved a 34 per cent re-

duction in waste generation and identified errors up to 35 days early.

- **Merck:** Launched the AIDDI-SON™ platform, which integrates virtual molecule design to potentially reduce the design cost of drugs and manufacturing by 70 per cent.

- **Johnson & Johnson:** Their Xi'an facility utilised AI and IoT for a "Smart Supply Chain," resulting in a 47 per cent drop in material waste, a 26 per cent reduction in greenhouse gas emissions, and a 23 per cent cut in energy use.

The future of pharma manufacturing requires us to move beyond checking for quality after a product is made. We must embrace the shift to building quality digitally at the molecular level. By creating virtual mirrors of our factories, we ensure that medicine is higher quality, more accessible, and kinder to our planet.

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Digital Twin- Transformative role in pharma technology transfer

Digital twins are transforming pharma technology transfer by enabling virtual process simulation and real-time decision-making. The technology is driving faster scale-up, better quality, and more efficient manufacturing in the Industry 4.0 era, explains **Rakesh Goswami**, Sr Manager, MS&T, Zydus Life Science

As the pharma industry advances toward Industry 4.0, digital twin technology is emerging as a key enabler of data-driven innovation. A digital twin serves as a dynamic virtual model of a physical process, asset, or system, enabling real-time simulation, predictive analytics, and continuous process optimisation. Digital Twins (DTs) represent a groundbreaking development tool in the pharmaceutical industry providing virtual representations of physical entities, processes, or systems.

Its adoption across pharma research, development, and manufacturing is facilitating accelerated drug development timelines, enhanced operational efficiency, improved product quality, and ultimately better patient outcomes. Digital twin technology is rapidly gaining prominence as a transformative innovation within the pharma industry. Defined as a virtual representation of a physical asset, process, or system, a digital twin enables real-time simulation, monitoring, and optimisation of its real-world counterpart.

Digital Twins: From initial formulation development to continuous manufacturing

Digital twin technology is increasingly being adopted across the pharmaceutical product lifecycle, from formulation development to continuous manufacturing, delivering significant improvements in process understanding, efficiency, and product quality.

During formulation development, digital twins enable the virtual modelling of critical material attributes (CMAs) and



critical process parameters (CPPs), facilitating rapid optimisation of formulation composition and process conditions while reducing experimental burden. As development progresses to scale-up and commercial manufacturing, digital twins support real-time process monitoring, predictive analytics, and advanced process control, enabling robust and efficient continuous manufacturing operations.

By integrating mechanistic models with real-time manufacturing data in a closed-loop framework, digital twins enhance process performance, improve product consistency, and enable proactive decision-making throughout the product lifecycle.

Furthermore, the integration of artificial intelligence and machine learning with digital twin platforms has the potential to accelerate pharmaceutical development, optimise clinical trial design through virtual patient modelling, and support the advancement of precision medicine. Leveraging patient-specific genetic, physiological, and lifestyle information, digital twins can facilitate the development of personalised therapeutic strategies, ultimately improving treatment efficacy,

patient outcomes, and overall healthcare delivery.

Need for an Industry 4.0-ready pharma manufacturing ecosystem

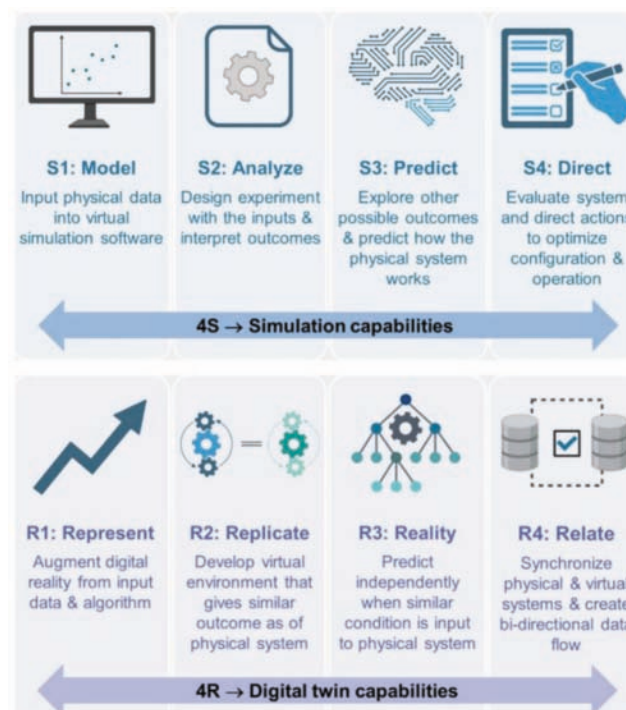
The transition toward Industry 4.0 necessitates the adoption of advanced digital technologies capable of enabling intelligent, connected, and resilient pharmaceutical manufacturing. Digital twin technology provides a virtual representation of pharmaceutical products, processes, and manufacturing systems, facilitating real-time monitoring, predictive analytics, process optimisation, and advanced control. Its implementation supports accelerated development, enhanced product quality, regulatory compliance, reduced operational costs, improved sustainability, and seamless integration with continuous manufacturing platforms. Combined with AI, IoT, and cloud-based infrastructure, digital twins represent a foundational technology for the next generation of smart pharmaceutical manufacturing.

Digital twins further support Quality by Design (QbD) and Process Analytical Technology (PAT) frameworks by enabling virtual experimentation, process optimisation, and risk assessment throughout the product lifecycle. Their ability to simulate manufacturing scenarios facilitates regulatory compliance with FDA, ICH, and GMP requirements, while strengthening data integrity, process traceability, and inspection readiness.

From formulation development through scale-up and continuous manufacturing, digital twins accelerate process devel-

opment, reduce the need for extensive qualification and validation runs, and shorten time-to-market. By optimising resource utilisation, minimising material waste, and supporting sustainable manufacturing practices, they contribute to both opera-

tion. In pharmaceutical manufacturing, digital twins improve process understanding, enhance operational efficiency, support quality assurance, and enable proactive decision-making throughout the product lifecycle.



tional efficiency and environmental stewardship.

How the digital twins work

A digital twin comprises a physical system and a virtual representation of that system. The physical component generates real-time data through sensors and manufacturing equipment, while the virtual component continuously updates its models using historical and real-time information. This closed-loop connection enables real-time monitoring, predictive insights, and process optimisa-

Regulatory challenges

Despite their significant potential, the adoption of digital twins in pharmaceutical applications is constrained by regulatory considerations. Regulatory authorities require robust model validation, verification, and documentation to establish the accuracy, reliability, and intended use of digital twin systems. The extensive effort needed to generate sufficient evidence for regulatory acceptance can increase implementation complexity and represent a barrier to broader industrial adoption.

How AI is redefining India's pharma export edge

Sunil Kharbanda, Co-founder and COO, Trezix explains how global pharma trade is evolving rapidly, demanding greater precision, transparency, and regulatory agility. He finds that the industry's next competitive advantage will lie in its ability to turn data into smarter decisions

India's pharma industry has gained an international reputation due to its large-scale production, advanced scientific knowledge, and competitive pricing. The sector supplies various highly regulated markets worldwide with generics, APIs, biologics, vaccines, and specialised formulations, which play a crucial role in supporting the country's export economy. However, focusing solely on the quality of products is no longer enough. In today's competitive landscape, exporters must deal with a complex global trade environment that requires regulatory flexibility, accurate documentation, and transparent supply chains to stand out from their competitors. Artificial intelligence is now being recognised as the key tool to help businesses navigate through these challenges.

A more demanding trade world

The trade environment is becoming more challenging. Different markets such as the US, EU, UK, Middle East, Africa, and Southeast Asia have their unique requirements for labeling, serialisation, quality certifications, and pharmacovigilance responsibilities. Moreover, the unpredictability of global supply chains, including shipping interruptions, export restrictions, reliance on raw materials, and sudden regulatory changes, adds to the operational complexities rapidly.

Failing to meet these requirements can have serious consequences. For instance, a missing document, an incorrect HS code, an expired permit, or a discrepancy in paperwork can lead to shipment holds, fines, and harm to reputation. In an industry where the quality of products directly impacts patients, these risks are



India already holds the foundational strengths: manufacturing depth, scientific talent and established global market access. Layering AI-driven trade and compliance infrastructure onto these strengths positions Indian exporters to move further up the value chain from reliable suppliers to indispensable, digitally mature partners

tangible and not merely theoretical.

The question has shifted from whether exporters need technology to whether their technology is intelligent enough to anticipate problems before they escalate.

From compliance burden to regulatory intelligence

Export documentation in the pharma industry is known for being complex within the realm

of global trade. This includes a variety of paperwork such as invoices, certificates, quality records, customs forms, and logistics paperwork, which have traditionally been managed using manual lists and fragmented systems. The use of AI technology is changing this situation by streamlining processes. Advanced systems can analyse product-market pairs, identify the necessary documentation for each spe-

cific destination, and keep track of any regulatory changes in real time. This allows teams to be notified of any missing documents well before a shipment's departure, enabling them to proactively address compliance issues. It's important to note that AI doesn't replace the need for regulatory experts in the pharma field. Human judgement remains a critical aspect in this industry. However, AI can reduce repetitive tasks, identify potential risks early on, and empower skilled professionals to concentrate on strategic decision-making and handling exceptional cases.

Supply chain visibility that goes deeper

The global health crisis revealed a stark reality: having a robust manufacturing sector is insufficient if there is a lack of transparency in the supply chain. In the realm of pharma exports, having meaningful transparency involves more than just monitoring the whereabouts of shipments. It necessitates finding solutions to more challenging inquiries such as the origin of raw materials, the approval status of suppliers for the target market, the alignment of batch records with export paperwork, and the ability of the company to demonstrate the integrity of its supply chain to regulators or overseas buyers.

Artificial intelligence integrates information from procurement, manufacturing, quality control, storage, and transportation to create a unified, up-to-date overview. It predicts the potential consequences of delays in shipments, identifies suppliers with repeated quality issues, and promptly locates affected products when a country revises its import regulations. In an industry where delays can hinder patient access, this intelli-

gence provides a direct competitive edge.

Documentation accuracy at scale

Pharma export documentation demands exactness. Product names, batch numbers, invoice values, licence references and country-specific declarations must align precisely across every document. A single inconsistency between an invoice and a certificate of analysis can stall customs clearance. AI extracts data from source systems, validates it against regulatory rules and detects inconsistencies before submission. Machine learning identifies recurring error patterns and recommends corrections. For exporters managing high volumes across multiple markets, the result is faster processing, fewer errors and stronger audit readiness.

Competing on trust

The next frontier of competitiveness will be defined by trust: the ability to demonstrate compliance, respond swiftly to regulator queries, trace materials end to end and maintain transparency across markets simultaneously. India already holds the foundational strengths: manufacturing depth, scientific talent and established global market access. Layering AI-driven trade and compliance infrastructure onto these strengths positions Indian exporters to move further up the value chain from reliable suppliers to indispensable, digitally mature partners.

AI will not eliminate pharma export complexity. It will make that complexity manageable by converting reactive firefighting into proactive intelligence, and fragmented data into strategic clarity. For a sector that has already earned the title of pharmacy to the world, that shift may prove decisive.

POWER POLITICS AND PHARMA

In a world shaped by geopolitics, economic nationalism and heightened scrutiny on quality and resilience, India's next phase of growth will depend on trust, innovation and strategic agility

By **Lakshmipriya Nair**



TRUST



INNOVATION



**STRATEGIC
AGILITY**





India must push for regulatory convergence to remain globally competitive, as non-tariff barriers could outweigh the impact of tariffs

Sudarshan Jain
Secretary General,
IPA



Global pharma supply chains are too interconnected to be reshaped by geopolitical decisions alone

Dr TS Parmar
Secretary General,
IDMA



Supply chain strategy must shift from cost optimisation to resilience through stronger supplier partnerships

Saurabh Sharma
GM – Supply Chain,
Sentiss Pharma



The ability to make rapid, cross-functional decisions has become a decisive competitive advantage.

Vishnu Mirge
AVP – Site Head, Sun
Pharmaceutical Industries



Continuous Vendor Verification (CVV) should become the new quality benchmark for resilient supply chains

Dr Sanjit Singh Lamba
Managing Partner,
Trillyum Consulting

On July 21, 2026, US President Donald Trump announced a three-phase tariff regime on generic medicines entering the US, with zero duty until August 2028, a 100 per cent tariff for the following year, and a 200 per cent tariff from 2029 onwards. The announcement sparked immediate concern across India's pharma industry. Markets reacted swiftly, with stocks such as Dr Reddy's and Cipla coming under pressure. SBI Research estimated that, with nearly 40 per cent of India's pharma exports headed to the US, steep tariffs could dent sector earnings in FY26. Dr Reddy's CEO Erez Israeli reminded investors that shifting generic manufacturing to the US was "a four-to-seven-year industrial undertaking," not a quick fix. A day later, India's External Affairs Minister S Jaishankar met US Secretary of State Marco Rubio in Manila as both countries worked towards an interim trade agreement.

But tariffs are only the trigger. Indian pharma is now operating in a world where geopolitics, trade policy, regulation and supply chain resilience

are becoming as important as manufacturing capabilities. The question is no longer whether India can produce medicines at scale. It is whether it can remain competitive in an increasingly volatile global landscape.

This question formed the backdrop to two recent discussions organised by *Express Pharma*: the inaugural edition of its virtual thought leadership series, *Pharma Frontlines*, and a panel discussion on Geopolitics, Trade and Trust at the *Chandigarh Pharma Summit*. Bringing together industry association leaders, manufacturing heads, supply chain experts, quality professionals and regulatory specialists, the discussions explored how Indian pharma is responding to a rapidly changing global environment. While each conversation approached the issue from a different perspective, both pointed to the same conclusion: the industry's future will depend not just on what it manufactures, but on how well it manages uncertainty.

A trade weapon India has faced before

Pharma and geopolitics have always gone hand in hand, but

India has often managed to transform challenges into opportunities. There are several cases in point.

In 2001, Cipla's Yusuf Hamied changed the conversation around access to medicines. He offered a triple-antiretroviral cocktail to *Médecins Sans Frontières* for \$350 per patient a year, compared to an originator price of more than \$10,000. The move challenged the global patent system and helped shape the WTO's Doha Declaration. More importantly, it established India as a trusted supplier of affordable medicines.

India reinforced that trust during the COVID-19 pandemic through the *Vaccine Maitri* initiative, launched in January 2021, supplying vaccine doses to 94 countries and two UN agencies. The initiative strengthened India's reputation as a reliable manufacturing partner for the world.

Today's challenge, however, is very different. In 2001 and again in 2021, India's manufacturing strength helped expand access to medicines. Now, that same strength is being tested as countries seek to bring manufacturing closer to home.

Trade policies are shifting, regulations are becoming more complex, and supply chains are increasingly vulnerable to geopolitical shocks.

India can still manufacture at scale. But the next phase of growth will depend on how well the industry adapts to this new reality.

Leadership in an era of uncertainty

Tariffs dominate the headlines, but industry leaders believe they are only one part of a much larger shift. The bigger question is not whether Indian pharma can absorb higher duties, but how it prepares for a world where trade rules, regulations and geopolitical priorities are constantly evolving.

For Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA), understanding the India-US pharma relationship is the starting point.

India exports over \$12 billion worth of medicines to the US, accounting for nearly one-third of its pharma exports. Indian companies also supply almost half of the generic medicines used by American patients. This

dependence, Jain says, is often overlooked. "There is a tremendous reliance on the generic drugs, because they ensure accessibility, affordability, and they have played a very important role to improve healthcare outcomes in the US."

In other words, the relationship is not one-sided. While India depends on the US as its largest export market, the US healthcare system also depends heavily on Indian manufacturers to keep medicines affordable and accessible.

Jain also pointed out that Indian companies have not waited for policy changes to strengthen their US presence. Companies such as Sun Pharma, Zydus and Lupin already operate more than 40 manufacturing facilities across 12 US states, reflecting a long-term commitment to the market rather than a short-term response to tariffs.

Dr TS Parmar, Secretary General, Indian Drug Manufacturers Association (IDMA), widened the discussion beyond bilateral trade. Healthcare, he argues, cannot be viewed through the lens of one country alone. It is, as he describes it, "a



Reducing dependence on China demands continuous supplier qualification and disciplined risk management—not just alternate sourcing.

Ravi Bhavadwaj

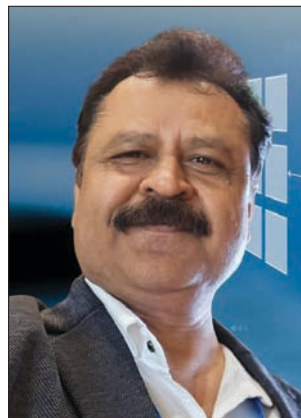
Corporate Quality Head,
Ind Swift Laboratories



Building domestic API capabilities is critical to reducing geopolitical and pricing risks

Dr Saurabh Pandey

Cluster Lead – API
Manufacturing,
Toansa (Punjab), Sun
Pharmaceutical Industries



Quality is evolving from a compliance function into a strategic business enabler

Yogesh Sharma

Head – Quality & Compliance,
Sun Pharmaceutical
Industries



Future competitiveness will depend on embedding science-based, risk-based and data- quality systems across operations

Dr Pardeep Agnihotri

Sr GM – Corporate
Regulatory Affairs,
CEPH Lifesciences



India's next phase of growth will depend on strengthening every link in the pharma value chain, from innovation to indigenous manufacturing

Prafulla Padhy

Head – Supply Chain
Management,
Fresenius Kabi Oncology

composite partnership." While governments may seek to bring manufacturing back home, globally integrated pharma supply chains cannot be rebuilt overnight.

For both Jain and Parmar, tariffs are only one part of the challenge. The more significant concern lies in the growing complexity of doing business across multiple regulatory jurisdictions.

Jain believes non-tariff barriers are likely to become a greater obstacle than tariffs themselves. Indian manufacturing sites continue to undergo separate inspections by regulators in the US, Europe, the UK and Africa, even though many of the requirements overlap. Greater regulatory convergence, he argues, would reduce duplication, lower costs and improve the efficiency of global supply chains. He says, "If there is a regulatory convergence, it would become very, very important."

The discussion points to a broader shift in the industry's priorities. Competitiveness is no longer determined solely by manufacturing efficiency or cost. It increasingly depends on a company's ability to navigate a

complex web of regulations, trade policies and international partnerships. For today's pharma leaders, managing uncertainty is becoming as important as managing operations.

When geopolitics reaches the factory floor

Geopolitical events are now influencing day-to-day operations in ways that would have been difficult to imagine a few years ago.

Saurabh Sharma, GM-Supply Chain, Sentiss Pharma, describes the shift and says what was once a purely operational function has been pulled into the centre of business strategy.

He shares how the recent US-Iran conflict disrupted pharma logistics almost overnight. Air cargo operations through Dubai were affected for nearly two weeks, delaying temperature-controlled pharma shipments. He informs that their shipments were stuck for almost two weeks because the flights were not allowed and even a one-degree temperature excursion recorded by data loggers triggered a compliance investigation.

The experience fundamen-

tally changed the way his company evaluates suppliers. He states, "Choosing the partner is also now becoming very critical."

For Sharma, procurement is no longer about securing the lowest price. Companies are evaluating suppliers on the total cost of ownership. As he explains, "It comprises of many things like quality, cost, of course, one factor, then delivery is another factor. Then the compliance is what is the business continuity? What is the financial strength of the supplier?" Thus, compliance history, delivery reliability, financial stability and operational capability have become key metrics.

His experience reflects a wider transformation across the industry. Supply chains are no longer just sourcing and logistics functions. They have become vital for business continuity, regulatory compliance and an organisation's ability to respond to disruption. In an era of geopolitical uncertainty, resilience has become as valuable as efficiency.

The business of being ready

The growing uncertainty in

global trade is forcing pharma companies to make decisions faster than ever before. What once unfolded over months now demands action within days, often based on incomplete information and with significant financial implications.

Vishnu Mirge, AVP - Site Head, Sun Pharmaceutical Industries, offers a glimpse into how quickly companies now have to respond. Following the US announcement of a 100 per cent tariff on branded formulations, his team took the unusual decision to double production over three months by securing six months' worth of input-material inventory instead of the usual three.

This was far more than an operational adjustment. It required rapid financial approvals, close supplier coordination and the confidence to invest ahead of demand.

For Mirge, the experience reinforced a simple lesson. "If you are agile enough to respond to that demand positively, then that is the success mantra."

His example highlights that competitive advantage is no longer determined solely by

manufacturing capacity or cost efficiency. Increasingly, it depends on how quickly organisations can assess risks, align cross-functional teams and respond to changing market conditions.

But responding quickly is only one part of the equation. As supply chains grow more complex and regulatory expectations continue to rise, companies are also rethinking how they approach quality and compliance.

It is in this context that Dr Sanjit Singh Lamba, Managing Partner, Trillyum Consulting, challenges the industry's traditional approach to vendor qualification. He states, "We don't need just a vendor qualification. We need something called continuous vendor verification (CVV). This is something I am driving more and more in companies, that they don't treat vendor qualification as a paper exercise and then remain quiet for two to three years."

His argument reflects a wider industry reality. Nearly 20 per cent of cold-chain pharma material is wasted every year, while first-time-pass rates remain at around 80

per cent, Lamba pointed out. As biologics account for a growing share of the industry's pipeline, these inefficiencies will become even more critical to address.

Addressing these challenges will require more than stronger processes alone. Technology has an increasingly important role to play but as an enabler rather than a substitute for robust quality systems.

Taken together, these perspectives reveal how leadership priorities are evolving. Companies are no longer preparing only for the next regulatory inspection or market opportunity. They are building organisations that can anticipate disruption, respond with speed and embed quality across every stage of manufacturing and supply chain operations.

Reducing dependence, building resilience

While companies are strengthening agility and quality systems, another strategic priority continues to dominate boardroom discussions, i.e. reducing dependence on China.

Progress is visible, but industry leaders agree that self-reliance remains a long-term journey rather than an immediate destination. Achieving it will require more than identifying alternate suppliers; it demands a systematic approach to qualification, risk management and long-term partnerships.

Ravi Bharadwaj, Corporate Quality Head, Ind Swift Laboratories, believes diversifying away from China is achievable, but only with discipline. He opines that successful diversification requires good planning and change management, with supplier qualification backed by comprehensive audits that evaluate suppliers' capabilities and compliance levels. He cautions that supplier qualification cannot be treated as a one-time exercise, as a supplier that has successfully completed process validation and stability studies may later receive an FDA warning letter, forcing

FIVE FORCES RESHAPING INDIAN PHARMA

- ◆ **Geopolitics:** Trade policies are reshaping global manufacturing decisions.
- ◆ **Supply chains:** Resilience is replacing cost as the primary metric.
- ◆ **Quality:** Compliance is evolving into a strategic differentiator.
- ◆ **Technology:** Digitalisation is enabling smarter quality and manufacturing systems.
- ◆ **Innovation:** Future growth depends on moving beyond volume-led manufacturing.

THE NEW RULES OF INDIA PHARMA INC

Yesterday	Tomorrow
Cost advantage	Strategic resilience
Lowest-cost supplier	Trusted partner
Vendor qualification	Continuous Vendor Verification
Reactive quality	Continuous inspection readiness
Volume-led manufacturing	Innovation-led growth
Compliance function	Business partner
China dependence	Supply diversification
Responding to disruption	Preparing for disruption

companies to start the qualification process all over again.

Moreover, supplier qualification is only one part of the challenge. The industry's continued reliance on China for critical raw materials remains a structural vulnerability with far-reaching implications for cost and supply continuity.

Dr Saurabh Pandey, Cluster Lead-API Manufacturing-Toansa-Punjab, Sun Pharmaceutical Industries, points to the scale of the challenge and informs, "Currently, we have around 65 per cent to 70 per cent of the APIs getting imported from China based on the cost pricing. With the recent geopolitical changes, we have seen a 40 per cent increase in the pricing of drugs like paracetamol and azithromycin". He notes the price shocks this dependence has already produced and cautions that prolonged reliance on a single source "will certainly set up a monopoly in the market, and any amount of instability in China will lead to disruptions, not only in the supplies, but to an increase in

the pricing."

Trust becomes the new currency

Yet resilience is not built through supply chain diversification alone. In an increasingly regulated global market, trust is as an equally key differentiator.

If cost and scale defined Indian pharma's last decade, trust may define its next one, and that trust is often built or broken in the quality function.

As a result, the role of quality leaders are also being reshaped. Yogesh Sharma, Head-Quality & Compliance, Sun Pharmaceutical Industries, describes how the job itself has been redefined. Five years ago, quality was reactive, teams scrambled only when an inspection was announced, pulling together data to prove there was nothing non-compliant. He explains that today, quality leaders are now measured not only on compliance but also on their ability to act as business partners. Their KPIs reflect their contribution to business deliveries and

organisational commitments because the cost of a lapse is no longer just a regulatory problem; it is a commercial one.

The shift is being reinforced by a regulatory landscape that is evolving just as rapidly. Dr Dr Pardeep Agnihotri, Sr GM - Corporate Regulatory Affairs, CEPH Lifesciences notes that global regulators have raised the bar considerably over the same period, pushing manufacturers toward "a science-based, risk-based, and data-centric approach." He explains that companies are expected to adopt the ALCOA principles, strengthen data integrity and digitalisation, implement comprehensive contamination control strategies (CCS), and ensure facilities remain inspection-ready at all times rather than preparing only for scheduled audits.

While these expectations have become more demanding, they have also highlighted where India's strengths and its challenges, lie. Agnihotri argues that India has built genuine strength in cost-competitive manufacturing, API

exports, regulatory dossier preparation and CDMO services. At the same time, he points out that gaps remain in data integrity and compliance with evolving regulations. He underscores that quality excellence is an ongoing process, not a one-time milestone.

The road to 2030

As the discussion turned from today's challenges to tomorrow's priorities, Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology, laid out a vision for where Indian pharma needs to go. He said the industry must move from volume-led manufacturing to innovation, supported by stronger intellectual property protection. He also highlighted the need to strengthen supply chain resilience through indigenous API and KSM manufacturing, improve end-to-end visibility across the supply chain, build quality and compliance so India is recognised as a trusted and reliable partner, adopt more sustainable practices, and make medicines more accessible by reaching tier II and tier III cities as well as rural areas.

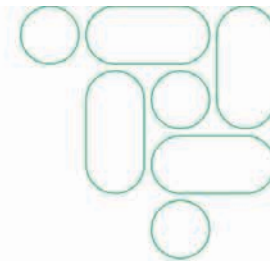
"It's time for India to move forward in its innovation journey," he said, "and that's possible only if we fortify each link in this pharma value chain."

His vision brought together many of the themes that had emerged throughout the discussion. Whether it was building resilient supply chains, strengthening quality systems, embracing innovation or expanding access, the underlying message was clear. The pharma value chain is only as strong as its weakest link.

That is perhaps the defining challenge and opportunity for Indian pharma today. As global trade dynamics shift, the industry's ability to anticipate change will matter more than ever.

Thum, success by 2030 will not be determined by how companies respond to disruption, but by how well they prepare for it.

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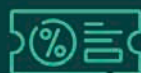
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EXPRESS PHARMA WORLD EXPO

The platform for India Pharma Inc's next leap

Scheduled as a three-day event (**March 3-5, 2027**), the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem

India's pharma industry is at a turning point. Long defined by its scale and cost advantage, the sector is now being reshaped by more complex forces like biologics, stricter regulatory expectations, shifting global supply chains, and the growing importance of innovation-led growth. The next phase will demand not just capacity, but capability.

Recognising this shift, Express Pharma is launching Express Pharma World Expo, a new industry platform designed to bring together the people, ideas and technologies that will define the future of Indian pharma.

Scheduled as a three-day event (March 3-5, 2027, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem.

Why this platform, why now

As regulatory scrutiny tightens and global competition intensifies, Indian pharma companies are being pushed to rethink manufacturing quality, compliance readiness, and innovation strategies. At the same time, emerging areas such as biosimilars, specialty pharma and digital transformation are opening new opportunities.

What has been missing is a credible, neutral platform that can bring all stakeholders together, not just to showcase solutions, but to address the sector's most pressing chal-



lenges in a structured, outcome-driven manner.

This is what *Express Pharma* aims to build. A space where industry dialogue translates into business action.

Who will attend

The expo is expected to attract over 10,000 professionals from across India's major pharma hubs, including Mumbai, Hyderabad, Ahmedabad, Pune, Bengaluru, Chennai, and Baddi.

Attendees will include:

- CXOs and business leaders from pharma and biopharma companies
- R&D, manufacturing, plant, and operations heads
- Quality, regulatory, and compliance leaders
- Engineering, technical services, and project heads
- Packaging, validation, and cleanroom specialists
- EHS and sustainability leaders
- Supply chain and procure-

ment strategists

- CDMO and contract manufacturing leaders
- Digital and technology transformation heads

Alongside them will be regulators, policymakers, investors, and solution providers, enabling a cross-functional, decision-making ecosystem under one roof.

The expo floor

The exhibition floor is designed to reflect the full pharma value chain, with participation from:

- API, excipients and KSM manufacturers
- Processing and manufacturing equipment providers
- Packaging solution companies
- Quality, validation, and analytical technology firms
- Engineering, project, and infrastructure specialists
- Cleanroom and controlled environment providers
- Utilities, water, and waste management solution c

ompanies

- EHS and sustainability solution providers
- Digital, automation, and Pharma 4.0 technology companies
- Supply chain and contract service organisations

This breadth ensures that the expo is not limited to one segment, but captures the interconnected nature of modern pharma manufacturing and operations.

Turning presence into progress

The focus here is on structured engagement, ensuring that interactions are relevant and outcome-oriented.

Attendees can expect to:

- Gain insights into regulatory trends, global market access, and emerging technologies
- Discover cutting-edge solutions across manufacturing, packaging, and digital transformation
- Engage directly with decision-makers and industry leaders
- Identify new partnerships and business opportunities
- Benchmark their operations against industry best practices
- Stay ahead of shifts shaping the future of pharma

Conversations that matter

At the heart of the event is a leadership conference curated to address the most critical issues facing the industry.

Key themes include:

- Regulatory intelligence and global compliance readiness
- Strategies for global market access

- Innovation in biosimilars, specialty pharma, and advanced therapies
- Manufacturing excellence and scale-up capabilities
- Pharma 4.0, AI, and digital transformation
- Supply chain resilience and risk management
- Investment, partnerships, and growth opportunities
- The future positioning of Indian pharma on the global stage

These discussions signal a broader shift, from volume-driven growth to quality, innovation and reliability as differentiators.

Beyond an event: Building an ecosystem

Backed by Express Pharma's editorial, digital, and events ecosystem, the platform is designed to enable year-round engagement, extending conversations, insights, and business connections well beyond the event itself.

The launch of this platform is tied to a larger industry question: how can India move from being the 'pharmacy of the world' to becoming a global hub for innovation, quality, and advanced manufacturing?

By convening the right stakeholders and focusing on actionable outcomes, Express Pharma World Expo seeks to play a catalytic role in that transition.

In an industry where the next leap will be defined by collaboration as much as competition, the value of such a platform lies not just in who attends, but in what emerges from the conversations it enables.

CHANDIGARH PHARMA SUMMIT 2026

Building a future ready pharma ecosystem

Industry leaders, policymakers, technology providers, and academia came together at the Chandigarh Pharma Summit to deliberate on the evolving landscape of the Indian pharma industry, reports **Swati Rana**

India's pharma industry, has established itself as the world's largest supplier of generic medicines. But, the industry's next challenge is no longer about scale alone. The focus is now shifting towards resilient supply chains, digital technologies, regulatory excellence and innovation.

Global geopolitical tensions, changing trade dynamics, increasing regulatory scrutiny and rapid advances in artificial intelligence are reshaping how pharma companies manufacture medicines, manage quality and invest in research. At the same time, emerging opportunities in biologics, biosimilars, peptides and advanced therapies are creating new avenues for growth, provided companies can develop the talent and infrastructure needed to support them.

These themes formed the backbone of Chandigarh Pharma Summit 2026, organised by *Express Pharma* at Taj Chandigarh recently. Bringing together industry leaders, technology providers, academic experts and policymakers, the summit provided a platform for discussion on what it will take for India to strengthen its position as a global pharma powerhouse in an increasingly complex business environment.

The summit commenced with an auspicious lamp lighting ceremony, attended by Dr Sanjit Singh Lamba, Managing Partner, Trillyum Consulting; Prof. Krishan Gopal, NIPER-Mohali; Ravi Bhardwaj, Corporate Quality Head, Ind Swift Laboratories; Vishnu Mirge, AVP - Site Head, Sun Pharmaceutical Industries; Dr Pardeep Agnihotri, Sr GM - Corporate Regulatory Affairs, CEPH Lifesciences; Yogesh Sharma, Head-Quality & Compliance, Sun Pharmaceutical Industries; and Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology.



L-R: Vishnu Mirge, AVP - Site Head, Sun Pharmaceutical Industries; Yogesh Sharma, Head-Quality & Compliance, Sun Pharmaceutical Industries; Prof. Krishan Gopal, NIPER-Mohali; Ravi Bhardwaj, Corporate Quality Head, Ind Swift Laboratories; Dr Sanjit Singh Lamba, Managing Partner, Trillyum Consulting; Dr Pardeep Agnihotri, Sr GM - Corporate Regulatory Affairs, CEPH Lifesciences; Rajesh Kumar Chopra, Founder & CEO, RAJBIOTEC; Dr Saurabh Pandey, Cluster Lead-API Manufacturing-Toansa-Punjab, Sun Pharmaceutical Industries; Saurabh Sharma, GM-Supply Chain, Sentiss Pharma; and Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology

pliance, Sun Pharmaceutical Industries; Saurabh Sharma, GM-Supply Chain, Sentiss Pharma; Dr Saurabh Pandey, Cluster Lead-API Manufacturing-Toansa-Punjab, Sun Pharmaceutical Industries; and Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology.

AI as the next frontier in pharma quality

In a special address on 'Impact of AI in enhancing quality and compliance', Dr Sanjit Singh Lamba highlighted the transformative role of artificial intelligence in pharma quality and compliance.

"AI is not a replacement for pharma's quality systems. It is a layer of intelligence that unlocks step-change performance," he said.

Lamba explained that as regulatory expectations continue to increase alongside rapidly expanding volumes of manufacturing and quality data, AI has evolved from an optional technology into an operational necessity. Rather than replacing exist-

ing quality frameworks, AI enhances them by identifying hidden patterns, predicting potential deviations, and recommending corrective and preventive actions (CAPAs) before issues escalate into compliance risks.

"The future of compliance is predictive, not reactive," he noted, emphasising that intelligent systems will become central to inspection readiness, operational excellence, and sustainable quality management.

Manufacturing, supply chain and quality move to the boardroom

The first leadership panel discussion on 'Geopolitics, trade and trust: The forces reshaping India Pharma Inc' explored how manufacturing, supply chain management and quality have evolved into strategic business functions that directly influence organisational resilience and long-term growth.

Moderated by Lakshmi Priya Nair, Assistant Editor, *Express Pharma*, the panel featured Ravi

Bhardwaj, Corporate Quality Head, Ind Swift Laboratories; Vishnu Mirge, AVP - Site Head, Sun Pharmaceutical Industries; Dr Pardeep Agnihotri, Sr GM - Corporate Regulatory Affairs, CEPH Lifesciences; Yogesh Sharma, Head-Quality & Compliance, Sun Pharmaceutical Industries; Saurabh Sharma, GM-Supply Chain, Sentiss Pharma; Dr Saurabh Pandey, Cluster Lead-API Manufacturing-Toansa-Punjab, Sun Pharmaceutical Industries; and Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology.

Panelists discussed how geopolitical uncertainties, fluctuating trade policies and global supply disruptions have compelled pharma companies to rethink sourcing strategies and strengthen business continuity planning.

The discussion highlighted that quality and compliance are no longer operational responsibilities alone but boardroom priorities, with greater emphasis on data integrity, quality culture and inspection readiness.

Artificial intelligence, Industry 4.0 technologies and digital manufacturing platforms are enabling predictive decision-making across production and quality operations, improving efficiency while reducing operational risks.

The panel also stressed the importance of reducing dependence on China for active pharmaceutical ingredients (APIs) through stronger domestic manufacturing capabilities, supplier diversification and supportive government policies.

Looking ahead, experts agreed that innovation, environmental sustainability, workforce capability and operational resilience will shape India's next phase of pharma growth, while maintaining the delicate balance between affordability, compliance and innovation.

Building India's future biopharma workforce

The next session on 'Next generation of pharma leaders: Academia's role in bridging the talent gap' by Prof Krishan Gopal, NIPER-Mohali focused on one of the industry's most pressing challenges—developing skilled talent.

"Don't just hire talent—help create it. Stronger industry-academia partnerships will be key to keeping India's biopharma growth on track," he remarked.

He highlighted that India's expanding biopharma sector requires a significantly larger pool of industry-ready professionals equipped with practical skills.

Referring to the government's Biopharma SHAKTI Mission, Prof Krishan explained that investments in new NIPER institutions, campus expansion and enhanced training infrastructure are intended to strengthen India's future workforce.

CHANDIGARH PHARMA SUMMIT 2026



Dr Sanjit Singh Lamba, Managing Partner, Trillyum Consulting



Prof. Krishan Gopal, NIPER-Mohali



Priadarshan Singh, Sales Manager, ROMACO Group



Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India)



L-R: Lakshmi Priya Nair, Assistant Editor, Express Pharma (Moderator); Vishnu Mirge, AVP - Site Head, Sun Pharmaceutical Industries; Ravi Bhardwaj, Corporate Quality Head, Ind Swift Laboratories; Dr Saurabh Pandey, Cluster Lead-API Manufacturing-Toansa-Punjab, Sun Pharmaceutical Industries; Saurabh Sharma, GM-Supply Chain, Sentiss Pharma; Dr Pardeep Agnihotri, Sr GM - Corporate Regulatory Affairs, CEPH Lifesciences; Yogesh Sharma, Head-Quality & Compliance, Sun Pharmaceutical Industries; Prafulla Padhy, Head - Supply Chain Management, Fresenius Kabi Oncology



L-R: Rajesh Kumar Chopra, Founder & CEO, RAJBIOTEC (Moderator); Dr Sukhjeet Singh, CSO, Acme Formulations; Mr Anmol Aggarwal, Lead, R&D Strategy, Venus Remedies; Dr Pankaj Bhatt, AVP - Technical Operations, Piramal Consumer Healthcare; Bhupendra Pratap Singh Chauhan, Head CQA (Formulation), Morepen Laboratories; Bhupinder Singh Grover, Founder & CEO, BSG Pharmaconsult; and Gursharanjit Singh, GM-Operations, Gracure Pharmaceuticals

According to him, India's greatest challenge is no longer market demand but ensuring the availability of skilled professionals capable of supporting the country's ambitious biopharma growth trajectory.

Advances in controlled drug delivery

Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India), addressing the scientific session on 'Drug release modulation through DRUGCOAT RSPO/RLPO', discussed innovations in modified drug release technologies using DRUGCOAT RL and RS polymers.

He explained that RL and RS polymers serve as effective binding agents capable of modulating drug release profiles. Combining both polymers enables significantly better control over drug release compared to using either polymer independently.

The optimal RL-to-RS ratio

depends on the solubility and permeability characteristics of individual drug molecules, allowing formulation scientists to develop accelerated, sustained or near zero-order drug release profiles tailored to therapeutic requirements.

Innovation - India's next growth engine

The second panel discussion on 'From generic success to innovation leadership: What's next for Indian Pharma?', shifted the focus towards innovation-driven growth and India's aspirations to move beyond its long-established leadership in generic medicines.

The panel was moderated by Rajesh Kumar Chopra, Founder & CEO, RAJBIOTEC, while featuring the panelists - Dr Sukhjeet Singh, CSO, Acme Formulations; Anmol Aggarwal, Lead, R&D Strategy, Venus Remedies; Dr Pankaj Bhatt, AVP - Technical Operations, Pi-

ramal Consumer Healthcare; Bhupendra Pratap Singh Chauhan, Head CQA (Formulation), Morepen Laboratories; Bhupinder Singh Grover, Founder & CEO, BSG Pharmaconsult; and Gursharanjit Singh, GM-Operations, Gracure Pharmaceuticals.

Panelists agreed that sustained investment in research and development infrastructure, improved funding mechanisms and enabling policy frameworks are essential to accelerate pharmaceutical innovation.

Collaboration between industry, academia, regulators and global research partners was identified as a critical success factor for developing novel therapies and bringing innovative products to market.

The discussion also highlighted the growing role of AI, digitalisation and smart manufacturing in improving quality, productivity and regulatory compliance across pharmaceu-



Abhinav Vikash, Head Engineering, Sun Pharmaceutical Industries



Shivaji Chakraborty, Head – Packaging Development, Fresenius Kabi Oncology

tical operations.

Participants noted that mid-sized pharma companies require greater access to timely funding and strategic partnerships to commercialise innovative products successfully.

Looking ahead, India must expand its capabilities in biosimilars, biologics, peptides and novel therapies while simultaneously strengthening intellectual property strategies, specialised talent and globally recognised pharma brands.

Leadership begins with continuous learning

During an engaging leadership session on 'The talent challenge: Building pharma leaders for the next decade', Abhinav Vikash, Head Engineering, Sun Pharmaceutical Industries discussed the importance of developing future-ready leaders for the pharma industry.

"Great leaders aren't born. They're developed through continuous learning, exposure and experience," he said.

He emphasised that cross-functional exposure enables pro-

fessionals to make better strategic decisions by understanding business operations beyond their immediate functional expertise.

Highlighting the importance of mentorship, Vikash observed that while technical competence may drive career progression, emotional intelligence ultimately defines successful leadership.

Showcase of integrated manufacturing solutions

In the session on 'Pharma processing and packaging: From powder to patient', Priadarshan Singh, Sales Manager, ROMACO Group presented the company's evolving approach towards pharmaceutical manufacturing, moving beyond stand-alone equipment to integrated end-to-end manufacturing and packaging solutions.

The company highlighted innovations designed to improve operational efficiency through faster product changeovers, simplified cleaning processes, reduced product loss and energy-efficient technologies without compromising product quality.



L-R: Dr Govind S Pandey, CEO & MD, Gamp Technologies (Moderator); Jawaaid Imam, Sr VP - Works, Aristo Pharmaceuticals; Narender Pal Singh, VP & Site Head, Panacea Biotech; Abhay Inamdar, VP - Engineering & Projects, Immacule Lifesciences; Dr Pirthi Pal Singh, VP and Head - R&D, Tirupati Group; Narotam Kumar Juneja, Technical Advisor, Uniserum Lifesciences; Ravinder Pal Singh, Lead - CMO Quality (North & East India Region), Sun Pharma; Suman Sharma, DGM-Quality, Indchemie Health Specialities

Romaco also showcased its growing commitment to the Indian market through its Experience Centre in Hyderabad, where customers can evaluate technologies, optimise manufacturing processes and develop solutions closer to their production facilities.

Building resilient pharma supply chains

Speaking on 'Indian pharma in a geopolitical crossfire: Preparing to navigate the challenges', Shivaji Chakraborty, Head – Packaging Development, Fresenius Kabi Oncology highlighted how geopolitical instability continues to increase operational costs and disrupt global pharmaceutical supply networks.

He emphasised that diversified sourcing strategies, stronger domestic manufacturing, flexible logistics networks and intelligent packaging technologies are becoming increasingly important for ensuring uninterrupted supply.

Digital traceability, sustainability initiatives and supportive government policies were also identified as essential enablers for maintaining India's competitive position in global pharmaceutical markets.

North India as next pharma growth hub

The concluding panel discussion on 'India Pharma 2030: Can North India become the next global manufacturing powerhouse?' was moderated by Dr Govind S Pandey, CEO & MD, Gamp Technologies

The panel featured Jawaaid Imam, Sr VP - Works, Aristo Pharmaceuticals; Narender Pal

Singh, VP & Site Head, Panacea Biotech; Abhay Inamdar, VP - Engineering & Projects, Immacule Lifesciences; Dr Pirthi Pal Singh, VP and Head - R&D, Tirupati Group; Narotam Kumar Juneja, Technical Advisor, Uniserum Lifesciences; Ravinder Pal Singh, Lead - CMO Quality (North & East India Region), Sun Pharma; and Suman Sharma, DGM-Quality, Indchemie Health Specialities.

The discussion focused on North India's emerging role in the country's pharmaceutical ecosystem.

The industry experts on the panel agreed that Punjab, Haryana, Himachal Pradesh and Chandigarh possess the collective capability to evolve into a globally competitive pharma cluster by strengthening innovation, manufacturing excellence and quality systems.

Digitalisation, automation and artificial intelligence were identified as key technologies for improving compliance, productivity and operational excellence across manufacturing facilities.

The discussion also underscored the importance of developing and retaining skilled talent through stronger industry-academia collaboration while expanding advanced manufacturing and research capabilities to support complex generics, biologics and next-generation therapies.

Panelists concluded that industry-friendly government policies, robust infrastructure, faster regulatory approvals and a sustained focus on quality, compliance and sustainability will be critical to attracting investment and positioning

North India as a leading global pharma destination.

A shared vision for future

While the discussions at the Chandigarh Pharma Summit 2026 spanned diverse themes—from artificial intelligence and quality management to innovation, talent development and supply chain resilience—the industry leaders converged on a shared vision for the future of Indian pharma. The consensus was clear: sustaining India's global leadership will require the industry to move beyond its traditional strengths in generic manufacturing and embrace a more holistic approach that combines scientific innovation, digital transformation, operational resilience and collaborative growth.

As the pharma landscape continues to evolve, success will depend not only on adopting new technologies but also on fostering stronger partnerships between industry, academia, policymakers and technology providers. By investing in people, strengthening research capabilities and building globally competitive manufacturing ecosystems, India is well positioned to shape the next chapter of pharma innovation.

The Chandigarh Pharma Summit served as more than a forum for discussion—it reinforced a collective commitment to building a resilient, future-ready pharma ecosystem that can meet global healthcare needs while driving sustainable growth for the industry.

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How next-gen E&L strategies transform nitrosamine risk

Experts decode the evolving role of E&L studies in addressing nitrosamine risks, complex product challenges, and emerging regulatory expectations

The growing focus on nitrosamine impurities has fundamentally reshaped the role of Extractables & Leachables (E&L) studies in pharmaceutical development and manufacturing. Once considered a regulatory checkpoint primarily associated with packaging and device compatibility, E&L assessments have evolved into a proactive, science-driven approach for identifying, understanding, and mitigating contamination risks across the entire product lifecycle.

However, the path forward is not without challenges - complex generics, biologics, and combination products present significant analytical hurdles, including ultra-low detection requirements, matrix interference, compound recovery issues, and complex drug-device interactions. Addressing these challenges requires a deeper understanding of material chemistry, advanced analytical capabilities, and integrated E&L strategies aligned with global regulatory expectations.

Experts share how the convergence of regulatory science, analytical innovation, and risk-based decision-making is redefining E&L studies—enabling the pharmaceutical industry to move from reactive testing toward predictive quality management while ensuring product safety and patient protection.

The evolving intersection of nitrosamines and E&L studies

The discovery of nitrosamine impurities in common medications in 2018 triggered a paradigm shift in pharmaceutical quality control. Regulatory agencies like the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA) quickly established strict daily intake limits for these potent mutagenic carcinogens. This regulatory shift profoundly transformed the role of Extractables and Leachables (E&L) studies, elevating them from routine compliance checks to critical components of proactive risk management.

Traditionally, E&L studies focused primarily on assessing volatile, semi-volatile and non-volatile organic compounds originating from container closure systems and manufacturing equipment. However, nitrosamines introduced a new

layer of complexity. These impurities can form through interactions between secondary or tertiary amines and nitrites. Because processing materials, Active Pharmaceutical Ingredients, excipients and packaging components can all introduce these precursors, E&L studies must now evaluate the entire manufacturing ecosystem. Elastomeric closures, nitrocellulose-based blister packs and printing inks are now scrutinised as potential sources of nitrosamine contamination, requiring E&L programs to expand their analytical scope significantly.

Bridging compliance with a science-based strategy:

A science-based E&L strategy allows Pharmaceutical manufacturers to navigate these evolving regulatory expectations effectively, moving away



Sanjay K Rangadhol, Vice President, R&D, Qualigens Pharma

from reactive testing toward predictive risk mitigation.

Comprehensive Material Characterisation Manufacturers must initiate deep chemical characterisation of all contact

materials. This involves collaborating with suppliers to map out full material compositions, including trace catalysts and secondary stabilizers that might act as nitrosamine precursors.

Advanced Trace-Level Analysis Because regulatory thresholds for nitrosamines are exceptionally low (often in the parts-per-billion range), standard E&L screening methods are insufficient. A robust strategy deploys highly sensitive, specific hyphenated techniques. Coupling Gas Chromatography or Liquid Chromatography with High-Resolution Mass Spectrometry (GC-MS/MS and LC-MS/MS) ensures the reliable detection and quantification of trace impurities.

Toxicological risk assessments:

Evaluating data through a toxicological lens is essential. Using Structure-Activity Relationship models and Quantitative SAR tools helps predict the mutagenic potential of newly identified extractables, aligning with ICH M7 guidelines for controlling mutagenic impurities.

Conclusion:

Evolving global regulations have firmly intertwined nitrosamine risk management with E&L testing. By implementing a proactive, science-based E&L strategy, Pharmaceutical manufacturers do more than just check a regulatory box. They build a comprehensive understanding of their products and processes, ensuring robust compliance with the FDA and EMA while safeguarding global patient safety.

Advancements in E&L technologies to accelerate product development

Extractables and Leachables (E&L) testing have long been a critical, but often time-consuming, checkpoint in the development of pharmaceuticals, biologics, medical devices, and combination products. Historically, E&L studies were viewed as a late-stage bottleneck necessary for regulatory submission but disconnected from the earlier, faster-moving stages of formulation and packaging design. Today, that paradigm is shifting. A convergence of analytical, computational, and data-management innovations is transforming E&L testing from a reactive compliance exercise into a proactive, integrated part of the development lifecycle. These advancements are enabling companies to move products to market faster without compromising the rigorous safety and quality standards regulators demand.

Beyond the laboratory bench for organisational and process benefits:

Technological advancements are reshaping for organisations structure their development processes. E&L considerations are increasingly being incorporated during early formulation and packaging selection rather than treated as a late-stage gate. This "shift-left" approach, made possible by faster and more predictive tools, allows potential compatibility or safety issues to be identified and mitigated months earlier in the development cycle. The result is fewer late stage failures, more predictable regulatory timelines, and reduced overall development cost. Modern data platforms make E&L findings more accessible and interpretable, regulatory affairs teams can begin preparing submission documentation in parallel with ongoing studies rather than waiting for final reports. This parallel-path approach further compresses time-to-market without sacrificing the depth of safety evaluation



Dr Kashyap Nagariya, Asst. Division Head – PTD, Otsuka Pharmaceutical India

regulators requirement.

The trajectory of E&L technology suggests continued acceleration. Artificial intelligence is expected to play an even greater role in predictive toxicology, potentially reducing reliance on animal testing while improving the accuracy of early risk assessments. Advances in non targeted analysis workflows, combined with expanding reference li-

braries, will likely further reduce the time needed to characterize unknown compounds. Meanwhile, regulatory agencies are showing increasing openness to science and risk-based submissions supported by robust computational and analytical evidence, which should continue to reward companies that invest in these advanced capabilities.

Technological advancements that driving change:

- High-Resolution Analytical Instrumentation
- Automation and High-Throughput Screening
- Predictive Modelling and In Silico Toxicology
- Digital Data Platforms and AI-Assisted Interpretation
- Standardised Extractables Databases and Material Libraries

Balancing speed with safety and compliance:

A common misconception is that faster E&L testing necessarily

means cutting corners. In practice, the opposite is often true. Modern analytical and computational tools improve detection sensitivity and data quality simultaneously with speed. Regulatory bodies, including the FDA, EMA, and international bodies aligned with ICH guidelines, have also evolved their expectations, increasingly referencing harmonized frameworks such as USP <1663>/<1664> and PQRI recommendations for extractables and leachables assessment. These frameworks provide structured, risk-based approaches that align well with the capabilities of modern instrumentation and modelling tools. Modern E&L technologies are helping the industry move faster without compromising control: they reduce development uncertainty, support robust quality decisions, and create a clearer scientific bridge between product design, patient safety, and global regulatory expectations.

Overcoming matrix challenges and analytical barriers in E&L assessment

The biggest challenges while handling the complex generics is recovery of the standards from the matrix, we have encountered analytical hurdles due to high compound reactivity, and complex drug-device interactions. Key recovery difficulties include ultra-low detection limits, matrix interference, and lack of true blank controls.

Complex generics undergo intricate degradation pathways. Over time, excipients break down into a series of secondary byproducts that may share identical mass-to-charge (m/z) ratios or chemical structures with known packaging leachables—for example, fatty acids generated from polysorbate degradation that mimic plastic-derived components.

This baseline interference makes quantification and spike-recovery studies unreliable.

Biological products having High-concentration surfactants (e.g., Polysorbate 80, Koliphor), polymers (PEG), and complex excipients are difficult to separate from the analytes.

While using Liquid Chromatography-Mass Spectrometry (LC-MS), these co-eluting excipients dominate the ionization source. Causing ion suppression or ion enhancement. This masks the true signal of the target leachable and skews the recovery percentage calculation,

Achieving a low Analytical Evaluation Threshold (AET) remains a significant challenge. Since complex generics



are often administered

Dr Veena Shetty, Head Analytical Development, Reliance Life Sciences

Ultra-low detection limits, matrix interference, and complex drug-device interactions are making E&L analysis of complex generics more challenging than ever

through high-risk routes—such as ophthalmic solutions, inhalation devices, and long-acting parenterals—regulators mandate very low Safety Concern Thresholds (SCTs). It is also challenging to achieve linear recoveries at parts-per-billion (ppb) or parts-per-trillion (ppt) levels. Physical losses due to non-specific adsorp-

tion—where analytes bind to sample vials, pipettes, or filters during sample preparation and processing—can significantly reduce recovery rates and compromise analytical accuracy.

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The next move on India's trade chessboard

As tariffs dominate global trade discussions, India's expanding FTA network promises wider market access for Indian pharma. But will preferential trade agreements translate into sustained export competitiveness? examines **Neha Aathavale**

Few global leaders have kept the world of trade on its toes quite like the United States President Donald Trump. His latest announcement of a phased tariff regime on pharmaceutical imports into the US once again has sent ripples across the Indian pharma industry, triggering discussions

off. If tariffs represent one side of the trade equation, Free Trade Agreements (FTAs) represent the other.

Every Free Trade Agreement is, in essence, a wager: A wager that easier market access today will deliver economic gains years later. New Delhi has been placing that bet with increasing

That raises an important question. Can preferential trade agreements fundamentally alter the industry's competitive position, or do they merely provide an advantage that still has to be earned through quality systems, regulatory credibility, innovation and manufacturing excellence?

under existing WTO commitments. The latest generation of FTAs therefore offers value in a different way: by making trade more predictable, reducing operational friction and creating an environment that encourages long-term commercial relationships.

For businesses making in-

bring together interdependent economies, create greater predictability in commercial relationships and provide businesses with the confidence to make long-term investments."

That perspective is echoed by Neeraj Bansal, Partner and Head, India Global, KPMG in India, who argues that the real



FTAs can encourage investment, strengthen cross-border partnerships and build confidence for long-term manufacturing decisions. Ultimately, their success will be measured not just by trade flows, but by the investments they enable, the partnerships they foster and the resilience they bring to global pharmaceutical supply chains

Vivek Valsaraj
CFO,
Piramal Pharma



Tariff concessions are essentially a one-time reset; the durable advantage sits with the other three. Regulatory compliance and manufacturing excellence — data integrity, consistent GMP performance, the ability to clear stringent inspections and meet serialisation and traceability requirements — are what actually determine whether a company can hold shelf space in the EU or UK

Dr Vellaian Karupiah
COO,
Shilpa Medicare



The latest FTAs are encouraging because they send a signal that India is thinking more strategically about global integration. That kind of signal matters for companies deciding where to place manufacturing, clinical, regulatory and supply-chain investments

Anil Matai
Director General,
OPPI



In today's pharmaceutical industry, market access is increasingly determined by ease of doing business rather than import duties alone, and that is where recent FTAs create the most value

Neeraj Bansal
Partner and Head,
India Global,
KPMG in India

on exports, competitiveness and the future of one of India's largest overseas markets. As explored in this month's cover story, the development is yet another reminder that in today's world, trade policy can alter industry sentiment almost overnight.

This feature, however, begins where that conversation leaves

conviction. Since 2021, India has concluded nine FTAs across 38 countries, signalling a shift in its trade strategy. For pharma, one of the country's largest export sectors, the expectation is clear. The outcome, however, is far less certain.

Indian pharma built its global standing long before the current FTA momentum gathered pace.

More than a tariff story

Much of the public discourse around FTAs tends to revolve around tariff concessions. Yet, for pharma, tariffs have rarely been the defining factor in determining export success. In many developed markets, pharma products already attract relatively low or zero import duties

investments that often take years to translate into commercial returns, predictability carries considerable weight. Vivek Valsaraj, CFO, Piramal Pharma, believes the significance of FTAs extends well beyond their impact on duties. "India's expanding FTA network should be viewed as more than a trade facilitation mechanism. At their core, FTAs

commercial gains increasingly lie in easing the movement of business rather than merely lowering import costs. According to him, agreements such as the India-UAE CEPA, India-Australia ECTA and the India-UK CETA are designed to strengthen regulatory cooperation, improve customs efficiency and enhance policy certainty, making it easier

INDIA'S FREE TRADE AGREEMENTS (2025-26)

Sl. No.	Name of the Agreement	Date of Signing of the Agreement	Date of Implementation of the Agreement
1.	India – United States of America (USA) framework for an interim Agreement	Announced on Feb 2, 2026	
2.	India – The European Union (EU) FTA	Announced on Jan 27, 2026	
3.	India -New Zealand FTA	Announced on Dec 22, 2025	
4.	India – Oman Comprehensive Economic Partnership Agreement (CEPA)	18th December 2025	To be implemented after completion of ratification process by India and the Oman.
5.	India - UK Comprehensive Economic and Trade Agreement (CETA)	24th July 2025	To be implemented after completion of ratification process by India and the UK.

Source: Ministry of Commerce and Industry

for companies to operate across borders. As India's pharma exports crossed USD 31 billion in FY26, reducing such business friction is becoming increasingly important as companies expand across regulated and high-growth markets.

For an industry whose global reputation was built on manufacturing scale, cost competitiveness and quality rather than preferential trade access, this distinction is significant. As Dr Vellaian Karupiah, COO, Shilpa Medicare, points out, "India's export strength was built on manufacturing scale, cost competitiveness, quality systems and one of the largest bases of regulator-approved facilities outside the US — not on tariff preferences." In his view, the significance of the latest agreements lies less in tariff reductions and more in the regulatory cooperation, customs facilitation and greater predictability that accompany them, enabling companies to move from opportunistic, price-led exports towards deeper, long-term supply relationships.

Do FTAs really create a competitive advantage?

Paradoxically, the biggest value proposition of modern FTAs may have very little to do with tariffs. For the pharma industry, preferential market access has never been the sole determinant of export success. Instead, the debate is increasingly shifting towards what happens beyond the tariff schedule — regulatory cooperation, customs facilitation, institutional cooperation and

the ability to reduce the non-tariff frictions that often determine how quickly and efficiently medicines reach global markets.

It is this distinction that many industry leaders believe is often overlooked. As Bansal highlights, "FTAs should be viewed as enablers rather than standalone growth drivers." He argues that market access today is increasingly shaped by ease of doing business rather than import duties alone, with provisions that improve regulatory cooperation, customs efficiency and business certainty often delivering greater commercial value than tariff concessions themselves.

The same sentiment resonates from the manufacturing floor. Dr Karupiah, believes "Tariff concessions are essentially a one-time reset; the durable advantage sits with the other three," referring to regulatory compliance, manufacturing excellence and supply-chain resilience. While lower tariffs may create an initial commercial advantage, sustaining that advantage depends on consistently meeting stringent quality standards, navigating regulatory inspections and ensuring uninterrupted supply.

The commercial implications extend beyond exports to investment decisions themselves. Valsaraj notes, "Tariff benefits are certainly helpful, but in our view, they are only one part of a much larger equation." In an environment marked by geopolitical shifts and supply-chain realignments, he believes the certainty

created by FTAs encourages businesses to make long-term manufacturing investments and forge deeper commercial partnerships.

That perspective extends to the research-based pharma industry as well. According to Anil Matai, Director General, OPPI, investment decisions are influenced as much by confidence in intellectual property protection, regulatory stability and the ability to commercialise innovation as they are by market access itself. In that sense, FTAs are becoming less about lowering barriers to trade and more about signalling a stable, predictable environment for long-term investment.

Taken together, the message is clear. FTAs may widen the doorway to international markets, but walking through it still demands capabilities that no trade agreement can confer. For Indian pharma, competitiveness will continue to be earned through quality, regulatory credibility, innovation and execution rather than tariff concessions alone.

Beyond volume, towards value

If the last three decades established India as the world's pharmacy, the next may well determine what kind of pharmacy it becomes. The industry's global leadership has largely been built on affordable generics, vaccines and cost-efficient manufacturing. Increasingly, however, export growth is expected to come from products where scientific

capability, technical complexity and regulatory expertise command a premium over manufacturing scale alone.

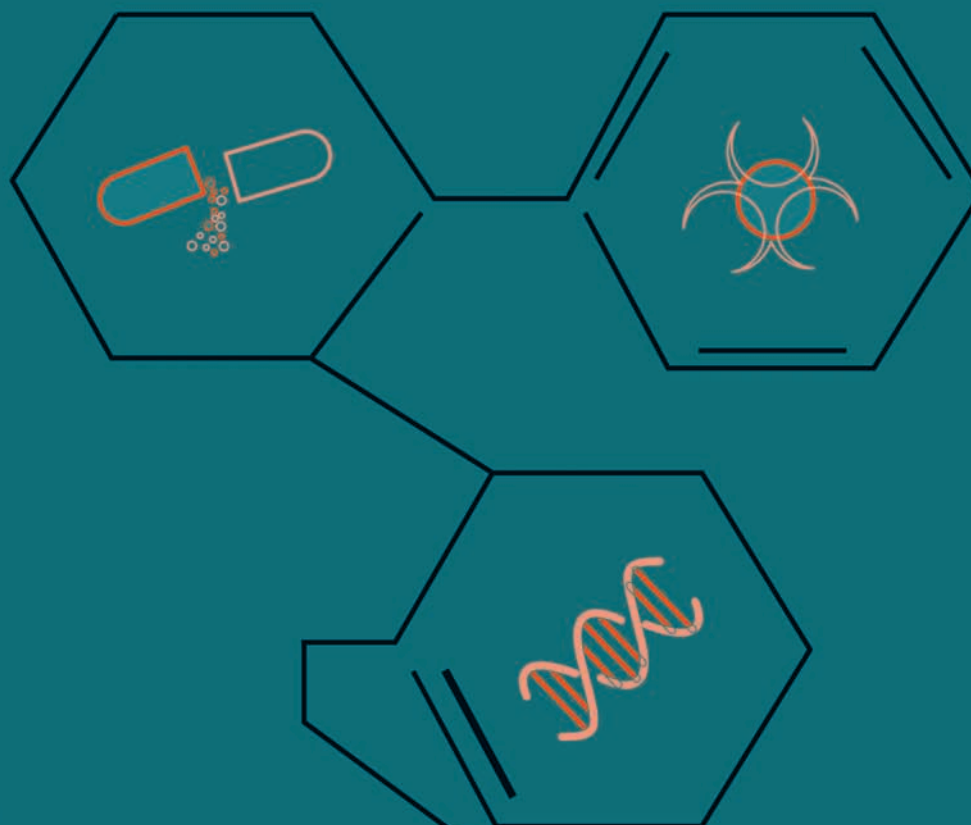
For integrated manufacturers and CDMOs, this shift presents a significant opportunity. Valsaraj, believes "the greatest opportunities are likely to arise in high-value segments where integrated players capable of supporting the full product lifecycle—from development through commercial manufacturing—can differentiate themselves through technical capabilities, quality excellence and execution reliability, rather than cost alone." He points to growing global demand for sterile injectables, complex formulations, antibody-drug conjugates (ADCs), peptide technologies and integrated CDMO services, particularly across North America, Europe, the UK and Japan.

Dr Karupiah, sees a similar shift unfolding within pharma manufacturing. "In plain generics, price competition is intense and a tariff concession is quickly competed away. In complex formulations, injectables, biologics, biosimilars and other specialty segments, the barriers to entry — regulatory, technical and logistical — are far higher, so reduced friction and regulatory cooperation disproportionately help companies that already have depth in these areas." In other words, FTAs may not fundamentally change the economics of conventional generics, but they could improve market access for companies already positioned in differentiated, higher-

value segments.

The opportunity, however, extends beyond expanding exports. It also presents a chance for India to deepen its role within global pharma value chains. According to Matai, "The next opportunity lies in moving up the value chain—from being recognised primarily for scale and affordability to becoming a global centre for innovation-led manufacturing." He believes this transition will depend on strengthening capabilities in biologics, advanced therapies, specialty medicines, novel drug delivery systems and other technology-intensive areas, supported by continued investments in research infrastructure, scientific talent and advanced manufacturing.

Yet, higher-value exports demand higher-value capabilities. As pharma supply chains become increasingly specialised, manufacturers will need to strengthen automation, digital manufacturing, integrated development capabilities and supply-chain resilience. Dr Karupiah emphasises the importance of backward integration, API and key starting material diversification, digitised and traceable manufacturing, scalable capacity and stronger ESG credentials. Similarly, Valsaraj believes competitive advantage will increasingly depend on advanced manufacturing technologies, integrated development and manufacturing solutions, innovation-led capabilities and the ability to serve as reliable long-term partners rather than simply efficient



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manufacturers.

On the other hand, Bansal, argues that the companies most likely to benefit from FTAs will be those that view them as part of a broader growth strategy rather than a standalone trade advantage. He believes firms investing in innovation, complex generics, biosimilars and specialty medicines, while combining strong regulatory track records with reliable manufacturing operations and diversified supply chains, will be better positioned to convert preferential market access into sustained business growth.

Collectively, the experts suggest that the next phase of India's pharma exports will not be defined by greater volumes alone. Rather, it will depend on

whether Indian companies can leverage expanding market access to build deeper capabilities, strengthen innovation and move decisively towards higher-value manufacturing.

What still needs fixing?

While FTAs can create favourable conditions for trade, they cannot, on their own, transform India's pharma export trajectory. Their success will ultimately depend on how effectively they are complemented by domestic reforms that strengthen the industry's competitiveness, resilience and innovation ecosystem.

A recurring theme across industry voices is the need to reduce structural vulnerabilities within the supply chain. Dr

Karuppiiah, believes that reducing dependence on imported APIs and key starting materials remains critical to strengthening supply security. In his view, market access created through FTAs will generate lasting value only if it is supported by continued investment in innovation, quality infrastructure and regulatory credibility at home.

Adding to it, Matai emphasises that intellectual property protection and stronger incentives for R&D, clinical development, advanced manufacturing and talent development will be essential to support long-term investment.

Among this discussion, Bansal, offers a note of caution. While FTAs undoubtedly create new opportunities, they also ex-

pose Indian companies to stronger global competition and increasingly demanding regulatory expectations around quality, sustainability, data integrity and supply-chain traceability. Companies that assume lower trade barriers will automatically translate into higher exports risk overlooking the execution required to compete in these markets. Instead, he believes the greatest gains will accrue to businesses that combine market access with innovation, operational excellence and a deep understanding of evolving customer and regulatory requirements.

Conclusion

Ultimately, trade agreements, much like tariffs, are ultimately

instruments of policy. Their significance lies not merely in what they promise on paper, but in how effectively industry translates those promises into commercial outcomes. As global supply chains continue to evolve and geopolitical considerations increasingly shape pharma trade, India's expanding FTA network offers an important opportunity. Whether that opportunity becomes a lasting competitive advantage, however, will depend less on the agreements themselves and more on the capabilities, innovation and regulatory credibility that Indian pharma brings to the table.

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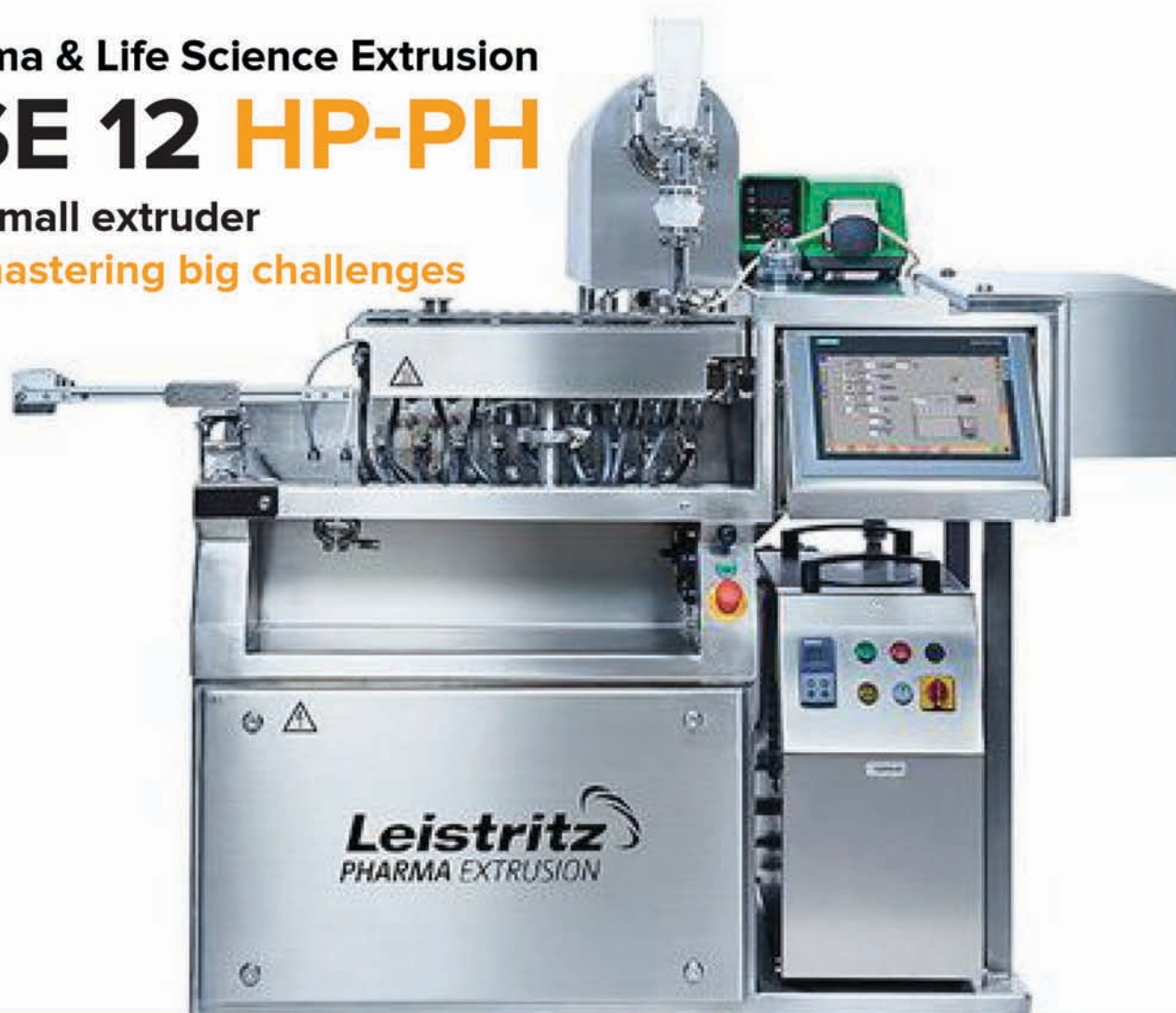
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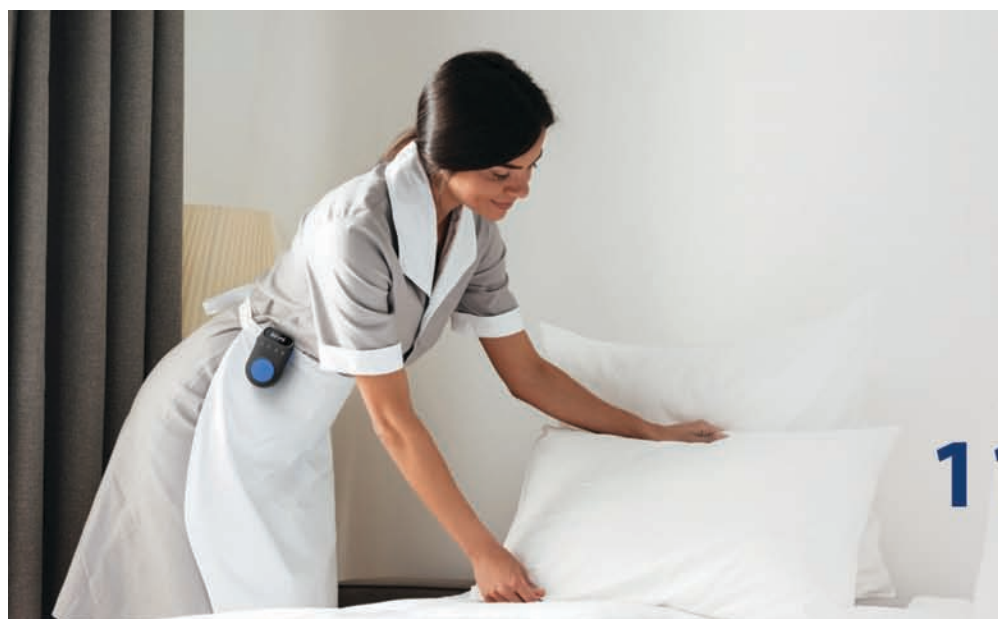
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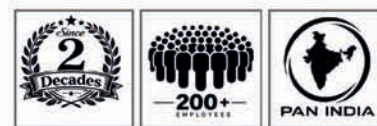
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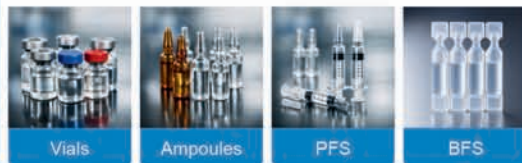
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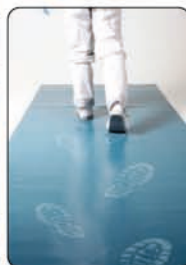
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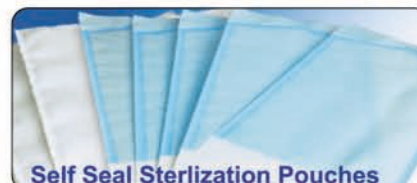
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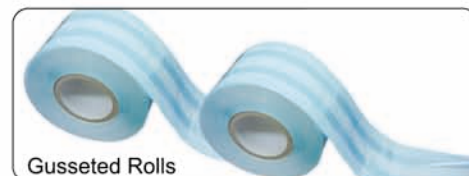
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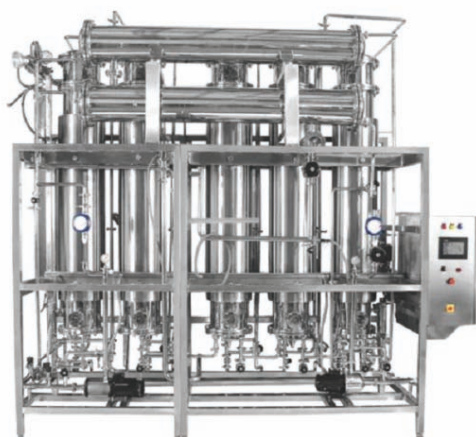


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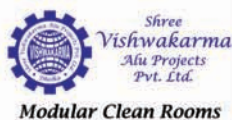


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IDEAL CURES advanced barrier coating technology: From moisture menace to manufacturing confidence

Moisture barrier coating is a protective film applied to tablets, capsules, or other oral solid dosage forms to safeguard critical quality attributes from atmospheric moisture exposure. It is one of the most effective approaches to protect the active pharmaceutical ingredients (API) from hydrolytic degradation during the manufacturing, storage and to provide a secured shelf life.

The formulation research and development include designing a coating formulation with non-hygroscopic/ low water activity excipients and formulating the film forming polymers with the least amount of inherent moisture. The main target is to achieve the moisture barrier function.

Why moisture protection is essential

Approximately 50 per cent of drug substances exhibit hygroscopicity, making them highly sensitive to environmental conditions.

● **Stability:** Limiting Factor-Pharmaceutical stability is profoundly influenced by environmental factors like humidity, temperature, light and oxygen which result to be the driving factor for degradation.

● **Packaging:** Limitations of Conventional Approaches-Variety of packaging solutions are available, keeping in mind the stability, transportation, aesthetics and protection. Various packaging solutions like blisters, desiccants, silica, absorbent cotton may not fully prevent moisture ingress.

● **Formulation modification:** Optimisation of excipi-

Advanced Moisture Barrier Coating Systems by IDEAL CURES PVT. LTD.		
Brand Name	Polymer	Reconstitution
INSTAMOISTSHIELD®	HPMC and EC	9% (Hydroalcoholic)/5% (Organic)
INSTANUTE MB®	HPMC and Stearic acid	10% (Aqueous)
INSTANUTE MB II®	PVA and Stearic acid	22% (Aqueous)

ents can aid in reducing the moisture uptake, but effective protection requires additional strategies.

Today, there is a complete industrial shift from reactive i.e. packaging based to proactive which is formulation integrated stability.

1. INSTAMOISTSHIELD®

INSTAMOISTSHIELD® is a ready-to-use moisture barrier organic/ hydroalcoholic film coating system, which aid the pharmaceutical formulations requiring enhanced protection against atmospheric moisture. This polymeric system combines Hydroxypropyl methyl cellulose (HPMC) and Ethyl cellulose (EC) to create a robust protective film around the tablet surface.

Key features:

- Strong moisture barrier performance
- Flexible and durable film formation
- Suitable for taste/odor masking applications
- Plasticised systems using DEP/DBS/TEC.

2. INSTANUTE MB®

INSTANUTE MB® is a ready-to-use aqueous moisture barrier coating system consisting of HPMC and Stearic

acid; with HPMC being as the primary film-forming polymer and Stearic acid contributing to formation of hydrophobic protective film.

Key Features:

- Effective moisture barrier for hygroscopic formulations
- Aqueous coating system with ease of processing
- Stearic acid provides hydrophobic moisture protection
- Excellent film adhesion and tablet appearance
- Improved surface gloss and finish
- Suitable for pharmaceutical and nutraceutical products
- TiO₂-free formulation utilising calcium carbonate are also available.

3. INSTANUTE MB II®

Instanute MB II® is a synergistic combination of PVA-based moisture barrier film coating system integrating hydrophobic stearic acid technology.

This combination of a dense PVA film matrix and stearic acid-mediated water repellence provides enhanced protection against moisture ingress while maintaining an aqueous, scalable coating process.

and productivity

- Aqueous coating compatibility

Performance evaluation: Water Vapour Transmission Rate Analysis (WVTR)

Water Vapor Transmission Rate (WVTR) is a critical parameter to assess the effectiveness of moisture barrier coatings. The WVTR measures the amount of moisture that passes through a material.

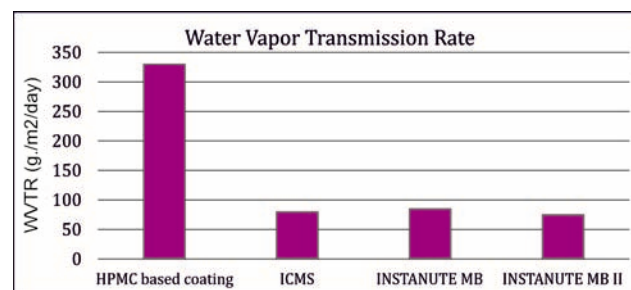
Under controlled conditions (180–200 µm film thickness, 22°C, 60 per cent RH), moisture barrier coatings demonstrated significantly lower WVTR values compared to conventional coatings.

Key features:

- High solid content (up to 22 per cent w/w) for faster coating
- Excellent film formation with low viscosity
- Improved surface finish

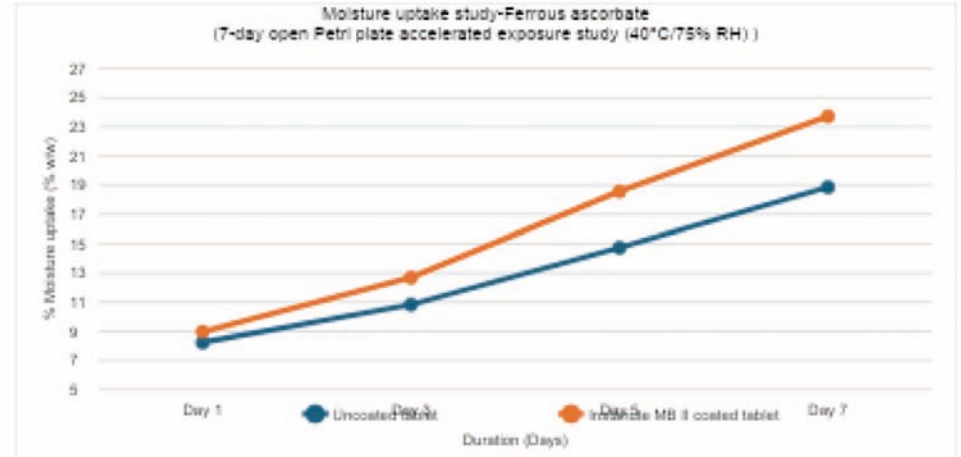


WVTR analysis was carried out for HPMC film coating, and Ideal Cure's moisture barrier coating systems. The results are as below:



	Day 0	Day 1	Day 3	Day 5	Day 7
Uncoated tablet					
Instanute MB II coated tablet					

Uncoated tablets showed visible degradation with time, whereas INSTANUTE MB II coated tablets remained intact with no visible deterioration over 7 days



Moisture uptake study-Ferrous ascorbate tablets

	Day 0	Day 1	Day 3	Day 5	Day 7
Uncoated tablet					
Instanute MB II coated tablet					

Uncoated tablets showed visible degradation with time, whereas INSTANUTE MB II coated tablets remained intact with no visible deterioration over 7 days

- Standard HPMC coating: g/m²/day
-330 g/m²/day
● Advanced systems: -65-100
- This represents a 2-3 times
reduction in moisture
- permeability, confirming
superior protective performance.

Case Study: Application of INSTANUTE® MB II for moisture protection in Ferrous Ascorbate and L-Arginine tablets

Ferrous Ascorbate and L-Arginine were selected to evaluate the moisture-protective performance of INSTANUTE® MB II, representing chemically moisture-sensitive and highly hygroscopic formulations, respectively. Ferrous Ascorbate is highly susceptible to moisture-induced oxidation a physical instability; consequently, many marketed formulations employ dual-coating systems to enhance moisture protection. Similarly, L-Arginine is highly hygroscopic and readily absorbs atmospheric moisture, leading to tablet tackiness, softening, and processing challenges. As a result, conventional formulations often rely on dual-step organic solvent-based coating systems to achieve adequate moisture protection. INSTANUTE® MB II is an immediate-release aqueous film coating system designed to provide a protective barrier against environmental moisture without affecting tablet appearance or release characteristics. The moisture-protective performance of INSTANUTE® MB II was evaluated through a 7-day open Petri plate study under accelerated conditions (40 ± 2°C/75 ± 5 per cent RH) to assess its ability to preserve tablet integrity during exposure to elevated temperature and humidity. Comparative studies between coated and uncoated tablets were conducted to evaluate the moisture-protective efficacy of INSTANUTE® MB II through moisture uptake analysis and assessment of physical changes.

Results and discussion

The open Petri plate exposure study demonstrated a marked difference in the moisture resistance of coated and uncoated tablets. Uncoated Ferrous Ascorbate tablets exhibited progressive surface deterioration and structural degradation over the 7-day exposure period, whereas

INSTANUTE® MB II coated tablets retained their physical appearance and integrity throughout the study. Moisture uptake increased with exposure time for both the tablets; however, coated tablets consistently exhibited lower moisture uptake than uncoated tablets, indicating the effectiveness of the coating in reducing moisture ingress.

In this particular case, customer's initial approach of organic dual coating system was converted to to stable aqueous single step coating system. Similarly, uncoated L-Arginine tablets showed rapid moisture-induced softening and progressive loss of structural integrity, culminating in complete amorphisation by Day 7.

Owing to the extensive physical deterioration of the uncoated tablets, quantitative moisture uptake measurements were not feasible. In contrast, tablets coated with INSTANUTE® MB II remained physically intact with no visible signs of moisture-induced deterioration throughout the study, demonstrating the coating's suitability for hygroscopic formulations.

Conclusion

Moisture-protective film coatings are critical for improving the stability of moisture-sensitive oral solid dosage forms. Application studies demonstrated that INSTANUTE® MB II effectively limited moisture uptake, maintaining the physical stability of Ferrous Ascorbate tablets under open exposure conditions and providing a suitable coating solution for hygroscopic formulations such as L-Arginine tablets. Together, these coating systems provide an effective strategy to improve formulation stability, product robustness, and shelf-life when used with optimised processing and appropriate packaging.

By- Tanvi Sawant & Priya Patwa
(For more information: info@idealcures.com)

Romaco India showcases blister packaging and tableting expertise

Romaco India's Hyderabad Open House highlighted advanced blister packaging and tableting technologies while strengthening collaboration with pharma manufacturers through local expertise and technical support

During an open house event, the experts from Romaco India transformed the Experience Centre in Hyderabad into a venue for professional exchange over the course of three days. From 9 to 11 July 2026, the Romaco team discussed specific production requirements with its guests, presented the S 710 Prime tablet press and, through more than 30 demonstrations featuring the NBL 400 blister line, showcased its capabilities in the field of blister packaging and cartoning.

The event location in Hyderabad provided the perfect setting for the in-depth face-to-face interactions. The Experience Centre houses, amongst other things, a spare parts warehouse, an equipment showroom and a process technology laboratory that combines Romaco's expertise in granulation, tableting and coating of solid pharmaceutical products. Even beyond the Open House, the centre serves as a point of contact for Indian pharmaceutical companies that seek high-performance technologies and technical know-how.

The Indian pharmaceutical industry faces the challenge of establishing and continuously expanding its international competitiveness. However, access to global markets requires more than just production capacity – expertise, operational capabilities and equipment that meet international standards, and are available locally, are crucial.

This is precisely where Romaco India, as a Sales & Service Centre of the Romaco Group – a leading international supplier of pharma



The Romaco India Open House was the perfect venue to showcase Romaco's expertise in blister packaging



Presentation of the S 710 Prime tablet press

machinery specialising in processing and packaging – comes in, bringing together international technologies and resources with local expertise in Mumbai and Hyderabad.

Personal exchanges with experts

This promising connection became particularly tangible from 9 to 11 July: Romaco India hosted a three-day Open House at the Romaco Experience Centre in Hyderabad, that features services ranging from customer training on various technologies to support in the development of new products as well as the ramp-up of new, locally manufactured format parts. The local format part production for blister packaging machines and cartoners was just launched last autumn.

The response was consistently encouraging throughout the event. 86 senior leaders and operational specialists from 24 pharmaceutical companies took part, representing functions such as operations, production, engineering, project management, quality assurance, supply chain, procurement and commercial management.

The mix of decision-makers and technical professionals gave the discussions real depth and additionally many visitors arrived with concrete production, packaging and project requirements, which allowed the Romaco team to address specific challenges and identify suitable solutions on site.

Hands-on technology

The Open House also put technology into action. Romaco India presented the

Kilian S 710 Prime tablet press as an example of high-performance production. With up to 85 press stations, it achieves a maximum output of 1,020,000 tablets per hour. Detailed live demonstrations on the Noack NBL 400 blister packaging line were also conducted. In total, more than 30 demonstrations took place over the three days, in which the blister line showed its versatility in practice.

Customers experienced machine operation, product flow, format changeover, line integration and key performance features first-hand.

With an output of up to 400 blisters and 200 cartons per minute, the NBL 400 blister line operates in lengthwise mode across up to five tracks – ideal for medium batch sizes. Consisting of a blister machine with rotary sealing and a continuous motion cartoner, the line can pack tablets and capsules of a wide variety of specifications either with dedicated feeding or using a brush-box feeder.

Also, the robust machine is very easy to operate, meaning no special technical know-how is needed to carry out product or format changes. In short, this long-lasting technology scores with premium quality and flexibility at low unit packaging costs and with a very low initial investment.



The Open House took place at Romaco India's Experience Centre in Hyderabad

Shaping the future, acting locally

"The Romaco India Open House was very successful with a good customer participation and positive feedback. Customers appreciated the detailed demonstrations, the technical knowledge of our team, the hospitality and the overall arrangements", summarised Sanjeev Nimkar, Managing Director Romaco India. "For us, however, the event was above all an opportunity to address the actual needs of the Indian pharmaceutical industry: we combine

access to state-of-the-art, high-performance technology – for example, in blister packaging – with local support, training and service. This not only makes Indian pharmaceutical companies competitive, but also enables a rapid return on investment."

Romaco Group

Romaco is a leading supplier of machinery specialising in processing and packaging. With its technologies, the international group serves the global pharmaceutical, nutraceuticals, food, cosmetics,

and chemical industries. The one stop solutions provider's portfolio covers the entire process chain from powder processing to the finished pallet. From granulation, tabletting, and coating of solid products through primary packaging in blisters, strips, and rigid tubes as well as sterile and non-sterile filling of liquids and powders to secondary and tertiary packaging, Romaco offers the right solution for every application. Whether standalone or as an integrated line – the supplier configures all technologies



Sanjeev Nimkar, Managing Director, Romaco India, carefully listening to our customers' needs at the Romaco Open House in Hyderabad

flexibly according to each customer's requirements. With its products and solutions, Romaco is committed to sustainable production and to systematically reducing carbon emissions. Through targeted energy, material, and space savings Romaco not only improves the technologies' carbon footprint but also cuts customers' manufacturing costs.

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The growing importance of GLP-1 products and biosimilars for the Indian pharmaceutical market

Nawed Sidiqi, Technical Sales Manager, OPTIMA pharma GmbH, explains how the rise of GLP-1 therapies and biosimilars is reshaping fill-finish manufacturing requirements for the Indian pharmaceutical industry

The focus of the Indian pharmaceutical market is increasingly shifting to biologics, including peptides, biosimilars, and GLP-1-based therapies. This trend is driven by two factors: the growing global demand for treatments for diabetes and obesity, and the increasing ability of Indian manufacturers to establish high-quality sterile production environments.

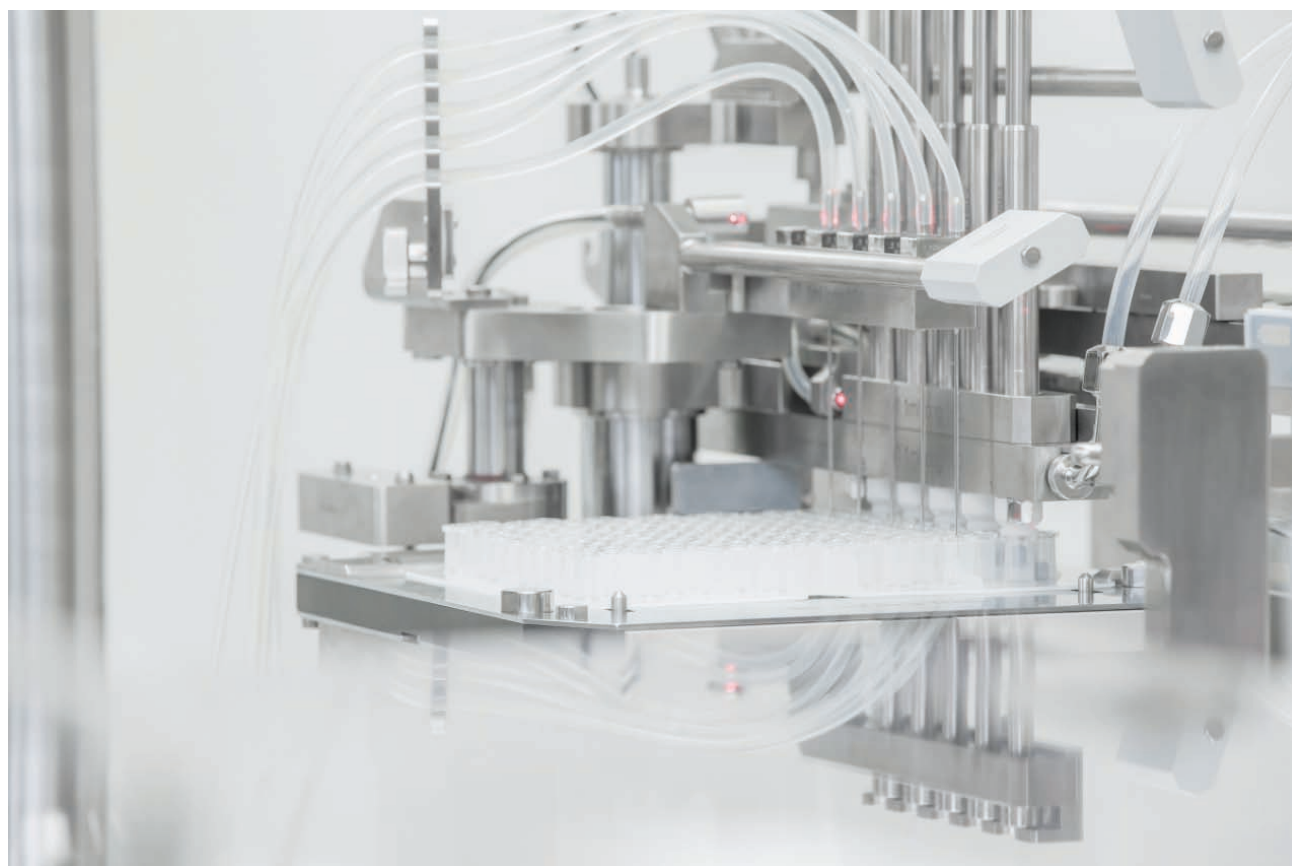
GLP-1 formulations are transforming the production landscape

GLP-1 agonists are considered one of the key growth drivers in the injectables sector. They are highly sensitive, sometimes viscous, and are primarily filled into pre-filled syringes and cartridges. As a result, the demands on filling accuracy, material handling, and process stability are increasing significantly. Systems must not only enable high throughput but also ensure consistent quality. This is a crucial factor for both originator drugs and biosimilars, which are expected to account for a significant share of India's export business in the future.

Technological requirements are increasing, and with them, complexity

Conventional filling technology is no longer sufficient to produce GLP 1 products. The following are required:

- Precise, sensor-based filling technologies capable of handling different viscosities
- Integrated containment and isolator solutions to reduce manual intervention
- Plant designs that combine high volumes with stable process control
- Modular systems capable of



handling both small clinical batches and large commercial batches

At the same time, regulatory requirements are becoming more stringent worldwide. Manufacturers therefore need validated processes, short qualification times, and robust systems that facilitate audits.

India as a driving force in global competition

India's pharmaceutical transformation is creating ideal conditions for modern, highly automated fill-finish processes. Companies are investing in advanced production technologies, particularly for injectable

therapeutics, including GLP-1 products. The combination of strong market growth, technological advancements, and local expertise is enhancing India's significance on the global stage.

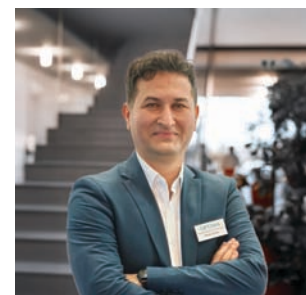
Conclusion – GLP 1 demands new standards in precision, flexibility, and speed

The industrial processing of GLP-1 products places high demands on facilities, processes, and quality assurance measures. This creates a clear need for manufacturers to find solutions that combine speed, reproducibility, and safety.

Optima addresses these requirements with fill-finish systems specifically developed for GLP 1, such as the H6-10 (up to 38,000 containers per hour) and SV125 (up to 20,000 containers per hour) platforms. Both systems are designed for sensitive, viscous formulations, support all common RTU container types, and enable high process stability through sensor-based filling technologies. This is complemented by turnkey solutions that significantly shorten validation times and reduce risks in complex projects.

Optima provides comprehensive technological solutions

for Indian manufacturers seeking to produce GLP 1 products or biosimilars safely and at scale.



Expert:
Nawed Sidiqi,
Technical Sales Manager,
OPTIMA pharma GmbH

Dehumidification: The silent guardian of pharma integrity

Bry-Air highlights how advanced dehumidification is supporting product integrity, manufacturing efficiency, and compliance across pharmaceutical operations

India's pharmaceutical industry has firmly established itself as a global powerhouse, supplying high-quality medicines and vaccines across the world. According to Mordor Intelligence, the Indian pharmaceutical market stood at USD 57.61 billion in 2025 and is estimated to reach USD 60.32 billion in 2026, further projected to grow to USD 79.74 billion by 2031. As this growth trajectory accelerates, maintaining product integrity has become more critical than ever.

While advanced machinery and stringent quality protocols dominate conversations around pharma

Even the slightest presence of excess humidity within a manufacturing facility can trigger biochemical reactions, promote microbial growth, and negatively impact product accuracy

manufacturing, one often-underestimated challenge continues to silently compromise product quality — moisture. Even the slightest presence of excess humidity within a manufacturing facility can trigger biochemical reactions, promote microbial growth, and negatively impact product accuracy. Consequences such as tablet disintegration,

uneven coating, caking, and decomposition of formulations are frequently attributed to uncontrolled moisture levels — ultimately risking product recalls and damaging both a company's reputation and patient safety.

To effectively counter this threat, maintaining consistent dry conditions throughout every production stage —

from processing and storage to research, testing, and packaging — is absolutely essential. Advanced dehumidification solutions have proven highly effective in controlling relative humidity (RH) as low as one per cent during critical manufacturing processes, ensuring product quality and stability throughout its shelf life.

Companies like Bry-Air have pioneered energy-efficient, desiccant-based dehumidification technologies that comply with international quality standards, including those mandated by the Food & Drug Administration (FDA). These solutions not only ensure superior hygiene and cleanliness within facilities but also contribute to cost-effective and sustainable pharma production.

As India continues to strengthen its position as the "pharmacy of the world," adopting cutting-edge dehumidification solutions will be pivotal in delivering safe, reliable, and effective medicines to patients globally.

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Veggie and vegan capsules: A greener future for oral drug delivery

Growing demand for ethical and sustainable healthcare is driving the shift towards plant-based capsule technologies, reshaping formulation strategies and the future of oral drug delivery

The capsule market is shifting due to the growing importance of ethics and sustainability in driving consumer behavior. The ethical spending market has shown year-on-year growth since 1999, and spending on ethical products grew by over 20 per cent in 2022 alone. This is already shaping the field of capsule formulation. In the pharmaceutical sector, oral dosage is the preferred mode of administration for the majority of patients, with 77–92 per cent of patients expressing a preference for an oral form over an injection. Oral dosage forms make up 83 per cent of the top 200 prescribed drugs in the US. Although gelatin-based capsules are still the most common, the market share of vegetarian-based capsules is growing (reaching 40 per cent in 2025).

What is driving growth in the vegetarian and vegan market?

Modern consumers are increasingly likely to consider factors like environmental concerns, social responsibility, and their own health and well-being when making brand and product choices. The numbers of consumers with ethical or religious beliefs that require special dietary preferences, such as vegetarianism or veganism, now represent a significant segment of the market. The healthcare industry will need to consider the best formulations to meet the needs and preferences of the consumer when developing new products. The impact of this change will likely be most apparent in over-the-counter medications, where the consumer has more freedom of choice over prescription drugs.



This empowered ethically minded consumer is driving the market trend away from animal-derived products, most notably gelatin, to plant-based alternatives, such as hydroxypropyl methylcellulose (HPMC).

The future of hard capsules is being shaped by the growing demand for vegetarian and vegan products. By embracing this trend and investing in innovation, manufacturers can meet the evolving needs of consumers and position themselves for long-term success in the hard-capsule market.

HPMC capsule market

size is estimated to be over 540 million USD in 2025 and is predicted to grow to 1.29 billion USD over the next 10 years (representing more than 9 per cent compound annual growth rate). HPMC capsules without gelling aids are expected to be the dominant segment, compared to those with gelling agents, maintaining close to 80 per cent market share due to dietary and clean-label preferences.

What are the advantages of vegetarian capsules for formulators?

The plant-based nature of HPMC offers several distinct

advantages over gelatin beyond those related to consumer preference. They eliminate the risk of cross-linking reactions, which delay drug release, and their low moisture content makes them better suited to hygroscopic substances and low-humidity conditions.

Within the HPMC category, capsules can be divided into those that do and do not use gelling agents. Originally, HPMC capsules were manufactured in a similar process to gelatin capsules, by dipping cold pins into a hot solution. Gelling agents such as carrageenan or gellan gum

were used to overcome the lower solubility of HPMC in hot water, but this had some notable drawbacks. Most significantly, the addition of gelling agents impacted the dissolution properties of the HPMC capsules, resulting in variable dissolution profiles depending on the dissolution media. Lastly, capsules produced with a gelling agent are dull in luster rather than crystal clear.

To overcome these potential drawbacks, second-generation HPMC capsules, Capsugel® Vcaps® Plus capsules, took advantage of the high solubility of HPMC in cold water. The unique and patented thermo-gelation process reverses traditional capsule manufacturing by dipping hot pins into a cold solution, producing a capsule without the need for gelling agents, with a high-gloss finish. Capsugel® Vcaps® Plus capsules offer the usual HPMC advantages with respect to gelatin and have been shown to provide an equivalent pharmacokinetic profile. They are compatible with solid or liquid fill and high-speed filling.

Conclusion

Capsugel® Vcaps® Plus capsules provide a solution for formulators looking to meet the needs of an increasingly ethically and sustainability-conscious market: plant-based, high-gloss, with an equivalent pharmacokinetic profile to gelatin capsules, no risk of cross-linking, suitable for hygroscopic drugs and high-speed filling. Capsugel® Vcaps® Plus capsules offer dependability and versatility to meet the needs of formulators and preferences of consumers.

From vision to execution: How Piyush Das is driving the next phase of growth at Haier Biomedical India

As India's healthcare and life sciences sectors evolve, Haier Biomedical India is helping build smarter, more connected ecosystems. Under Mr. Piyush Das's leadership, the company is driving this transformation through innovation, technology, and customer-first thinking

Leadership is often measured by numbers—market growth, business expansion, and financial performance. However, enduring leadership is defined by something greater: the ability to create a vision, inspire people to believe in it, and execute it with consistency and purpose. As Mr. Piyush Das completes two years as Country Head & General Manager of Haier Biomedical India & South Asia, his journey reflects a leadership philosophy built on integrity, innovation, customer trust, operational excellence, and sustainable growth.

At a time when India's healthcare and life science sectors are witnessing unprecedented transformation, Mr. Das has positioned Haier Biomedical India as more than an equipment manufacturer. Under his leadership in India & South Asia, the organization has evolved into a strategic technology partner supporting CDMOs, hospitals, blood centres, research laboratories, pharmaceutical companies, biotechnology organizations, Institutes & universities, IVF centres, and public healthcare institutions in their pursuit of better patient outcomes and scientific advancement.

"Success in Life Sciences will not be defined by products alone, but by intelligent ecosystems that connect technology, data, sustainability, and people," believes Piyush Das. This philosophy has shaped every aspect of Haier Biomedical India's growth strategy & execution over the past two years.

One of his defining achievements has been strengthening Haier Biomedical India's position across the country's healthcare, Biotechnology and life science landscape. The

company's portfolio today extends far beyond conventional cold chain solutions. It encompasses complete cleanroom solutions – LAF, Biosafety Cabinets, Isolators, a comprehensive centrifuge range – Benchtop centrifuges, biopharma batch centrifuges, blood component centrifuges along with CO2 Incubators, Shaker Incubators, Growth chambers, Lyophilizers & many other intelligent IoT-enabled monitoring platforms.

For Piyush, however, technology is only valuable when it solves real-world challenges.

His leadership, therefore, has consistently focused on understanding customer requirements before introducing solutions. Whether supporting a blood bank in improving inventory management, enabling pharmaceutical companies to maintain temperature integrity, or helping research laboratories safeguard & transport critical biological samples, the objective has remained the same—"to create measurable value through innovation"

This customer-first mindset has strengthened Haier Biomedical India's relationships with leading healthcare institutions, Biopharmaceutical companies, scientific organizations, and channel partners across the country. It has also reinforced the company's reputation as a trusted partner capable of delivering integrated solutions rather than stand-alone products.

Digital transformation has been another cornerstone of his leadership.

Recognizing that healthcare & life sciences is becoming increasingly connected and data-driven, Mr. Das has championed intelligent technologies that enable remote monitoring,



Piyush Das



predictive management, equipment connectivity, and real-time visibility across laboratory and healthcare operations. By integrating IoT-enabled systems with biomedical equipment, Haier Biomedical India is helping institutions improve compliance, reduce operational risks, enhance efficiency, and ensure the highest standards of quality.

Yet, what distinguishes his leadership is the equal importance he places on sustainability.

Healthcare infrastructure is expanding rapidly, but growth must be responsible. Under Piyush's leadership, Haier Biomedical India has aligned its business strategy with environmentally conscious innovation by promoting energy-efficient refrigeration technologies, environmentally responsible refrigerants, intelligent energy management systems, and

products designed to reduce environmental impact without compromising performance.

For him, sustainability is not a corporate initiative—it is a business imperative.

"True innovation is measured not only by technological advancement but by the positive impact it creates for people, healthcare systems, and the planet," he often emphasizes.

Internally, Piyush Das has focused on building a culture that encourages ownership, collaboration, and continuous learning. He believes that sustainable business success begins with empowered people. By nurturing talent, promoting accountability, and encouraging cross-functional collaboration, he has cultivated a high-performance culture where teams are motivated to innovate, execute with agility, and deliver exceptional customer experiences.

His approachable leadership style has also strengthened organizational alignment. Employees across functions share a common purpose—to improve healthcare delivery through intelligent technologies while maintaining the highest standards of quality, integrity, and customer service.

Beyond business growth, Piyush has actively represented Haier Biomedical India across major healthcare, diagnostics, blood banking, biotechnology, and life science platforms. His engagement with industry leaders, clinicians, researchers, and policymakers reflects a broader vision of contributing to India's healthcare transformation by facilitating technology adoption, knowledge exchange, and collaborative innovation.

Looking ahead, Piyush Das

sees immense opportunities for India & South Asia.

As the country accelerates investments in biotechnology, genomic research, precision medicine, vaccine manufacturing, pharmaceutical innovation, and advanced diagnostics, the need for intelligent laboratory infrastructure and dependable cold chain ecosystems will continue to grow. Haier Biomedical India is strategically positioned to support this transformation through innovation-led solutions that combine digital intelligence, operational efficiency, and environmental responsibility.

Completing two years at the helm is not simply a milestone—it marks the beginning of an even more ambitious journey.

With a clear strategic vision, deep market understanding, and an unwavering commitment to customer success, Mr. Piyush Das continues to lead Haier Biomedical India with confidence and purpose. His leadership demonstrates that business excellence is achieved not merely through expansion, but by creating lasting value for customers, empowering people, embracing sustainability, and continuously innovating to meet the evolving needs of society.

As Haier Biomedical India enters its next chapter, one message remains clear: vision creates possibilities, but disciplined execution creates impact. Under the leadership of Piyush Das, that impact is being felt across Biopharma companies, hospitals, laboratories, blood centres, research institutions, and healthcare ecosystems throughout India—helping shape a future where technology serves humanity, innovation drives progress, and sustainability remains at the heart of growth.

Sustainability in single-use bioprocessing: Myth, reality and the path forward

Dr Priyabrata Pattnaik, CEO, Ami Polymer explains why sustainability in single-use bioprocessing must be assessed through lifecycle evidence rather than waste alone

Over the past two decades, single-use systems (SUS) have transformed biopharmaceutical manufacturing. Disposable bags, tubing, connectors, filters and integrated fluid-management assemblies have enabled faster facility deployment, reduced cleaning requirements, improved operational flexibility and supported rapid scale-up of biologics, vaccines and advanced therapies. Yet their growing adoption has also intensified an important debate: can a manufacturing model built around disposable polymer components genuinely be sustainable?

The question is legitimate, but the answer is more complex than the visible accumulation of plastic waste after a production campaign. Sustainability in bioprocessing cannot be judged by one material stream in isolation. It must be assessed across the complete lifecycle of a manufacturing system—from raw material production and component manufacturing to transportation, facility operation, resource consumption and end-of-life treatment.

Viewed through this broader lens, the apparent contradiction between “single-use” and “sustainable” becomes far less straightforward.

The sustainability paradox

Stainless-steel systems are reusable for many years, while single-use components are intentionally discarded after one manufacturing cycle. This comparison naturally creates the perception that reusable systems must be environmentally superior. However, stainless-steel bioprocessing re-

quires repeated cleaning-in-place (CIP) and sterilisation-in-place (SIP), consuming substantial quantities of purified water, Water for Injection, steam, electricity and cleaning chemicals throughout the operating life of a facility.

Single-use systems eliminate or substantially reduce many of these recurring requirements. Their environmental burden is therefore concentrated more heavily in material production and end-of-life management, whereas conventional facilities carry significant operational burdens over decades of use.

This is why Life-Cycle Assessment (LCA) is essential. LCA evaluates environmental impacts across the complete product or process lifecycle rather than focusing on a single, highly visible metric. Studies comparing single-use and stainless-steel bioprocessing systems have frequently shown that SUS can reduce overall water consumption, cumulative energy demand, greenhouse gas emissions and chemical use, depending on process scale, facility configuration and local infrastructure.

The important lesson is that sustainability decisions must be based on lifecycle evidence—not intuition.

Water and energy: The less visible environmental gains

Water conservation is arguably one of the strongest sustainability advantages of single-use bioprocessing. Conventional facilities require large quantities of high-quality water for equipment cleaning, rinsing, sterilisation, validation and utility operations. The environmental footprint

extends beyond the water itself to the energy, infrastructure and chemicals required for its generation, storage, distribution and treatment.

By removing many cleaning and sterilisation steps, single-use systems can substantially reduce water demand. Depending on process and facility design, lifecycle studies have reported reductions ranging from approximately 40 per cent to 90 per cent. The benefits extend further: lower water consumption means less wastewater, reduced chemical use, smaller utility systems and lower energy requirements.

This becomes particularly significant in water-stressed regions, where water availability is increasingly a strategic manufacturing risk rather than merely an environmental concern.

A similar systems perspective applies to energy. Polymer manufacturing consumes energy, but conventional facilities also require continuous steam generation, hot-water circulation, CIP and SIP cycles, extensive utility networks and supporting HVAC infrastructure. Over the operating life of a facility, these recurring energy demands can outweigh the embodied energy associated with disposable components.

For companies pursuing net-zero commitments, the relevant question is therefore not simply, “How much plastic are we using?” but, “What is the total resource and carbon intensity of the manufacturing system?”

Waste is the challenge—But not the whole story

The strongest criticism of single-use technology remains waste generation. After each

production campaign, bags, tubing, filters, connectors and assemblies must be removed and treated. Unlike energy or water consumption, this waste is immediately visible.

The concern is valid. However, waste volume alone does not define environmental impact. Material composition, contamination status, transportation and end-of-life treatment all influence the final outcome. Where appropriate infrastructure exists, decontaminated polymer waste may be directed toward energy recovery or emerging material-recovery pathways rather than landfill.

The more difficult issue is recyclability. Many single-use products are sophisticated multilayer structures engineered to provide sterility assurance, barrier performance, mechanical strength, chemical compatibility and low extractables and leachables. These properties often require combinations of polymers that are difficult to separate using conventional mechanical recycling.

Pharmaceutical requirements add further complexity. Biological contamination concerns, traceability expectations and limited specialised recycling infrastructure restrict available options. Consequently, controlled incineration, including waste-to-energy where appropriate, remains an important end-of-life pathway.

The solution is not to deny this limitation, but to innovate around it. The industry is increasingly exploring mono-material constructions, design-for-recycling principles, chemical recycling, improved waste segregation and collaborative recovery models. The next generation of single-use

technology must be designed not only for process performance, but increasingly for end-of-life performance.

Sustainable polymers: The next frontier

Material innovation will be central to this transition. Historically, polymers for bioprocessing have been selected primarily for biocompatibility, chemical resistance, mechanical integrity, sterility assurance and extractables and leachables performance. These requirements remain non-negotiable.

Sustainability, however, is becoming an additional design criterion.

Bio-based polymers, mass-balance resins, lower-carbon materials and more recyclable polymer architectures offer promising pathways to reduce dependence on fossil-derived feedstocks and improve lifecycle performance. Yet adoption in biopharmaceutical manufacturing must remain scientifically rigorous. A material cannot be considered sustainable if it introduces unacceptable risks to product quality, process reliability or patient safety.

The objective is therefore not simply to develop “greener” polymers. It is to develop materials that combine measurable environmental improvement with uncompromising pharmaceutical-grade performance.

From waste management to the 5R framework

A practical sustainability strategy for single-use manufacturing can be built around five principles: Refuse, Reduce, Reuse, Recycle and Recover. Refuse means eliminating unnecessary materials, excessive packaging and

non-value-adding complexity. Reduce focuses on improving material efficiency through optimised designs, lighter components and more efficient manufacturing. Reuse has limited application for product-contact components but remains relevant for transport systems, packaging and non-product-contact assets. Recycle requires designing products and material streams with future recovery technologies in mind. Recover recognises that some waste will remain unavoidable and seeks to extract value through energy or material recovery.

Together, these principles shift sustainability from a disposal problem to a lifecycle design philosophy.

Sustainability is becoming a business requirement

Environmental performance is no longer confined to corporate responsibility reports. Pharmaceutical companies increasingly request data on carbon emissions, energy consumption, water use, waste generation and responsible sourcing during supplier qualification and strategic procurement.

This shift is driven partly by corporate net-zero commitments and the growing importance of Scope 3 emissions. For many pharmaceutical companies, a substantial proportion of their environmental footprint lies within the supply chain. Suppliers must therefore provide credible data if customers are to measure and reduce their own indirect impacts.

As a result, sustainability is emerging as a fourth dimension of supplier competitiveness alongside quality, cost and delivery.

Organisations capable of demonstrating robust ESG performance, transparent reporting and measurable environmental improvement are increasingly viewed as more resilient strategic partners. Sustainability is also becoming an innovation driver: efforts to reduce materials, energy, water and waste frequently improve operational efficiency and lower costs.

Sustainability is a supply-chain challenge

No single company can make single-use bioprocessing sustainable in isolation. The envi-

ronmental footprint of an assembly reflects the combined activities of resin manufacturers, film producers, component manufacturers, assembly facilities, logistics providers, biopharmaceutical companies and waste-management organisations.

Progress therefore requires collaboration.

Shared lifecycle data, harmonised sustainability metrics, responsible sourcing, joint material-development programs and circular-economy partnerships can achieve improvements that individual organisations cannot deliver alone. Alignment with recognised frameworks—including the UN Sustainable Development Goals, Science Based Targets initiative, Global Reporting Initiative, CDP and emerging international sustainability disclosure standards—can further strengthen transparency and comparability.

The future of sustainable bioprocessing will depend on ecosystems, not isolated initiatives.

The path forward

The sustainability debate

around single-use bioprocessing should move beyond the simplistic question of plastic versus stainless steel. Single-use systems generate waste, and the challenges of recyclability and material circularity are real. But conventional manufacturing also carries substantial environmental burdens through water consumption, energy demand, cleaning chemicals and utility infrastructure.

The scientifically credible approach is to evaluate the complete lifecycle.

The path forward is not a choice between sustainability and single-use technology. It is the continued evolution of single-use systems through better materials, smarter design, rigorous lifecycle assessment, improved waste recovery, transparent ESG reporting and deeper collaboration across the supply chain.

Sustainability should not be viewed as a constraint on bioprocessing innovation. Properly integrated, it can become a catalyst for more efficient facilities, more resilient supply chains and better manufacturing technologies.

The organisations that

lead the next era of bioprocessing will not be defined solely by the quality of the products they manufacture. They will be distinguished by their ability to combine scientific excellence, patient safety, operational performance and environmental responsibility. The real opportunity is not simply to make single-use bioprocessing less unsustainable, but to redesign its entire lifecycle so that quality, innovation and sustainability advance together.



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NEW testo 174 Mini Dataloggers: Revolutionising indoor climate monitoring

Testo India highlights how the new testo 174 mini dataloggers simplify indoor climate monitoring with Bluetooth connectivity, digital documentation and regulatory compliance

Testo, a leader in measurement technology, introduces the new testo 174 BT (BT is Bluetooth enabled) series mini data loggers, designed to optimise indoor climate monitoring and ensure precise temperature and humidity control. The range offers smart, intuitive features that save time, reduce costs and provide hassle-free digital documentation for a wide range of industries, including food production, pharmaceuticals, and industrial sectors.

Innovative features for enhanced efficiency

The new testo 174 mini data loggers come in multiple models: testo 174 H BT, testo 174 T BT, testo 174 H, and testo 174 T. These loggers support Bluetooth and USB-C connectivity, providing seamless integration with mobile devices or PC software for easy data access and management. These loggers are designed to meet stringent quality assurance requirements and simplify compliance with regulatory standards.

Bluetooth-enabled data loggers: convenient and efficient

The testo 174 H BT (for temperature and humidity) and testo 174 T BT (temperature only) are equipped with Bluetooth, allowing for convenient wireless monitoring. Users can easily configure, record and evaluate measurement data using the free Testo Smart App. The app connects directly to the loggers from up to 30 meters away, enabling real-time data retrieval without the need to remove the device from its monitoring location. This wireless functionality ensures more efficient operations and significant time savings.

With automatic data backup,



even if the battery is replaced, all previously recorded data remains intact. The Testo Smart App allows for seamless excel exports, as well as the generation of professional PDF reports with signature and comment functionality. These features eliminate the need for manual record-keeping, reducing the risk of human error and ensuring paperless documentation.

Both Bluetooth models are HACCP certified, ensuring they meet food safety standards, and the testo 174 T BT also holds NSF certification and complies with EN 12830, making them ideal for industries that require stringent monitoring, such as food production and pharmaceuticals.

USB-C data loggers: Simplified data acquisition

For users who prefer traditional PC-based data management, the testo 174 H (temperature and humidity) and testo 174 T (temperature only) models with USB-C offer an intuitive solution. These loggers feature a

large measurement range, from -30 °C to +70 °C for the Testo 174 T and -20 °C to +70 °C for the Testo 174 H, ensuring precise readings for a wide variety of applications.

With a data storage capacity of up to 16,000 readings, these devices can operate for extended periods, ensuring continuous monitoring. The data can be easily accessed and analysed using the ComSoft Basic software, included with the devices, for fast configuration and readout. ComSoft Professional offers advanced features for batch programming, data analysis, and report generation, making it easier to handle complex quality assurance tasks.

Like the Bluetooth models, these USB-C loggers also meet HACCP standards and EN 12830 requirements and the testo 174 T is NSF certified, ensuring reliable product safety in sensitive industries.

Why choose testo 174 Mini Data Loggers?

Time & cost efficiency: Digital documentation and easy data

retrieval reduce manual labour and the risk of human error, saving time and costs.

Wireless connectivity: Bluetooth-enabled models offer convenient data readout via the Testo Smart App, streamlining processes.

Large data storage: With up to 16,000 readings, these loggers support extended measurement periods without the need for constant monitoring.

HACCP and NSF certification: Compliance with international standards ensures reliable product safety in food, pharmaceutical and industrial environments.

User-friendly software: The free Testo Smart App and ComSoft software make data management simple and efficient.

Whether you're ensuring the quality of temperature-sensitive goods or maintaining optimal indoor climates, the testo 174 series mini data loggers provide a reliable, efficient, and intuitive solution for all your measurement needs.

Service & calibration:

Located at our Head Office in Pune, Testo India has a high quality NABL accredited service & calibration lab. Instruments of any brand/make can be calibrated and serviced locally maintaining international standards. All calibrations are traceable to highly accurate international standards of the PTB Germany.

We undertake calibration jobs for temperature: contact as well as non-contact, humidity, pressure, air velocity, RPM, sound, flue gas & dew point instruments of any brand/make.

Testo India

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PRUV® -The original Sodium Stearyl Fumarate

JRS Pharma's PRUV® is the original sodium stearyl fumarate (SSF) introduced in the market over 20 years ago

Pharma lubricants are the inactive agents i.e. excipients added into tablet and capsule formulations in a very small quantity (usually 0.25-5.0 % w/w) to improve the processing properties of formulations. They decrease the friction at the interface between tablet's surface and the die wall during the compression and ejection phase of the tableting so that the wear on punches and dies are reduced. They prevent sticking of tablets to punch faces as well as sticking of capsules to dosators and tamping pins. In terms of powder flow, lubricants can improve the flowability of blends and aid unit operations^[1].

A good balance between hydrophobic and hydrophilic moieties in PRUV® (Sodium Stearyl Fumarate) makes it an ideal lubricant^[2].

Common lubricants used in drug development

Most of the lubricants used in the pharma processes are boundary lubricants. Certainly, metallic salts of fatty acids such as magnesium stearate; stearic acid and sodium salt of fatty acid such as sodium stearyl fumarate are the most common ones.

A. Fatty acid esters: Fatty acid esters, including glyceride esters (glyceryl monostearate, glyceryl tribehenate, and glyceryl dibehenate), sugar esters (sorbitan monostearate and sucrose monopalmitate) and alcohol ester of stearic alcohol with fumaric acid, including sodium stearyl fumarate are often used as lubricants. In particular, sodium stearyl fumarate and glyceryl dibehenate are effective lubricants to replace magnesium stearate when the latter hampers dissolution and has chemical incompatibility issues. Relative to magnesium stearate, sodium stearyl fumarate has similar lubrication efficiency with a higher optimal concentration (around 2%,

w/w). In addition, the use of sodium stearyl fumarate does not affect compressibility^[1].

B. Metallic salts of fatty acids: Use of the metallic salts of fatty acids as lubricants has a long history in the pharma industry and they are still the most dominant class of lubricants. Magnesium stearate, calcium stearate and zinc stearate are the three common metallic salts of fatty acids used^[1].

C. Fatty acids: Fatty acids are also common lubricants used in the pharma industry with stearic acid as the most popular one. Chemically, stearic acid is a straight-chain saturated monobasic acid found in animal fats and in varying degrees in cotton seed, corn and coco. The commercial material of stearic acid has other minor fatty acid constituents such as myristic acid and palmitic acid^[1].

D. Inorganic materials and polymers: Inorganic materials and polymers are also used as lubricants when magnesium stearate cannot be used. In terms of inorganic materials, talc (a hydrated magnesium silicate ($\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$), is often used as a lubricant or as a glidant in formulations. Talc provides some essential lubricity for pharma operations because of its hydrophobicity and weakly bonded sheet structure^{[1][6]}.

Mechanism of lubrication:

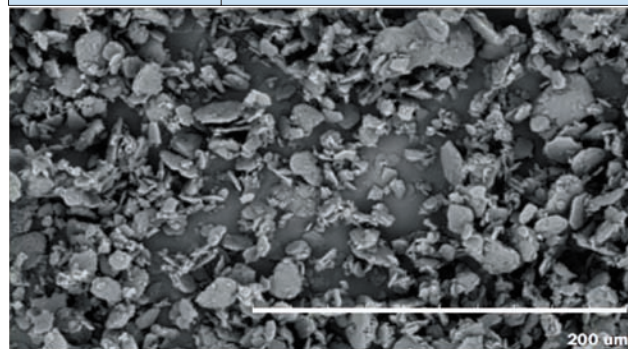
There are four lubrication mechanisms:^[1]

1. Hydrodynamic lubrication,

2. Elasto-hydrodynamic lubrication,
3. Mixed lubrication, and
4. Boundary lubrication.

As their names imply, the first three mechanisms are related to the usage of liquid lubricants to some extent. In the pharma industry, boundary lubrication is the most common mechanism functioning in unit operations.

Typical properties of PRUV®: ^[5]	
pH	About 8.5 (10% aqueous solution at 90°C)
Saponification value	142.2-146.0
Moisture	<5.0%
Solubility	0.5mg/100 ml at 25°C/
	10 g/100 ml at 80°C
	20 g/100 ml at 90°C
Melting point	224-245°C



SEM Picture of PRUV®

For boundary lubrication, a lubricant typically forms layers/film between surfaces or at interfaces to reduce friction, where the penetration of the lubricant into surface asperities

occurs. Structurally, the lubricants commonly used for boundary lubrication are long chain molecules with active end-groups. The typical end-groups include:

1. -OH (long chain alcohol);
2. -NH₂ (long chain amine);
3. -COOH (long chain fatty acids); and
4. Metal ions such as Mg²⁺.

Considerations for selecting a lubricant

There are many factors to be considered for selecting an appropriate lubricant for preparing solid dosage forms, including low shear strength, being able to form a durable layer covering the surface/particles, non-toxic, chemically compatible with APIs and other components in the formulation, low batch-to-batch variability, and

consideration when selecting a lubricant because both of these two parameters greatly affect the performance of pharma products and processes.^{[1][6]}

After understanding what are lubricants, commonly used lubricants in pharma formulation, mechanism of lubricants and considerations for selecting the best lubricant, let's focus on more detail regarding PRUV® (Sodium Stearyl Fumarate) lubricant from JRS Pharma.

PRUV® (Sodium Stearyl Fumarate) characteristics:

- ◆ Highly efficient lubricant and anti-adherent
- ◆ More water-soluble than Magnesium stearate
- ◆ Well-defined particle size and specific surface area
- ◆ High melting point (230°C)
- ◆ Lamellar structure
- ◆ High purity and batch-to-batch consistency

How PRUV® works?

- ◆ PRUV® reduces inter-particle friction during tablet manufacturing while acting as a boundary lubricant in the formulation.
- ◆ PRUV® facilitates lubrication during blending through shearing.
- ◆ PRUV® is more hydrophilic, dissolution is not compromised wherever facing dissolution issue with magnesium stearate.
- ◆ PRUV® goes beyond lubrication and it also accelerates dissolution.

Applications of PRUV®

PRUV® can be used in dry granulation as well as wet granulation technology to avoid sticking of intra-granular blend to roller or RMG wall. PRUV® can also be used in capsule dosage by reducing friction between the particles. PRUV® is a perfect lubricant for high-speed tableting/continuous manufacturing because it is less sensitive to heat. PRUV® can also be used in hot melt

extrusion due to its higher melting point (224-245°C).

Following are the case studies of PRUV® to evaluate the effect on physio-chemical properties on tablet dosage form^[4].

In this study, the effect of different lubricants on Acetaminophen formulation was studied. Acetaminophen API blended with PROSOLV SMCC HD 90 for 15 min and afterwards blended with sieved lubricants for three minutes. Different lubricants like PRUV,

Magnesium stearate, stearic acid and sodium stearate are used. Tablets were compressed to 800 mg weight. tablet.

Magnesium stearate is the most widely used lubricant in the pharma industry. Hence, PRUV® is compared with Magnesium stearate in the following section:

PRUV® helps to avoid API incompatibilities and enhances API stability. With a few exceptions, PRUV® can be applied to any formulation for lubrication,

particularly those in which API stability or tablet taste is compromised due to magnesium stearate. Magnesium cation (Mg²⁺) is electrophilic, it interacts with the free electrons of an API and forms insoluble salts. This is one of the many causes of API incompatibility with magnesium stearate.^[4]

Electrostatic Properties: Magnesium stearate shows higher voltage and retention time than PRUV®. Low electric charge and retention improve lubricant dispersion during blending. As a result, PRUV® due to its low voltage and retention can be considered a superior lubricant with improved lubricant uniformity.

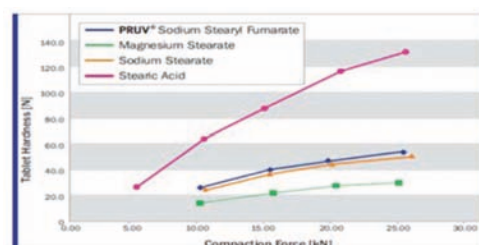
PRUV® was carefully designed to consistently deliver the following functional characteristics:

Ingredients	Quantity (%)	Quantity (mg/unit)
Acetaminophen	62.5%	500 mg
PROSOLV® SMCC HD 90	35.5%	248 mg
Lubricant	2.0%	16 mg
Total	100.0%	800 mg

LUBRICANTS: PRUV® (SODIUM STEARYL FUMARATE), MAGNESIUM STEARATE, STEARIC ACID, SODIUM STEARATE)

Tablet Hardness/Compactability

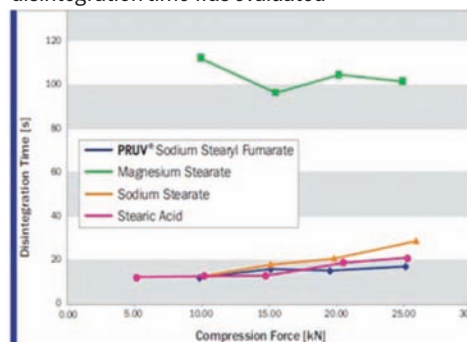
In this study, the effect of different lubricant on tablet hardness was evaluated



Observation: The kind of lubricant used had a significant influence on the hardness of the tablets. While tablet lubricated with stearic acid resulted in the highest tablet hardness, those made from magnesium stearate exhibited the lowest hardness. Tablets made from PRUV show intermediate hardness.

Disintegration time

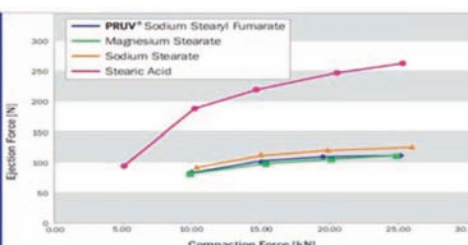
In this study, the effect of different lubricant on disintegration time was evaluated



Observation: Tablets lubricated with magnesium stearate needed by far the longest time for disintegration. All other tablets were found to have disintegration times in the same range

Lubrication efficiency

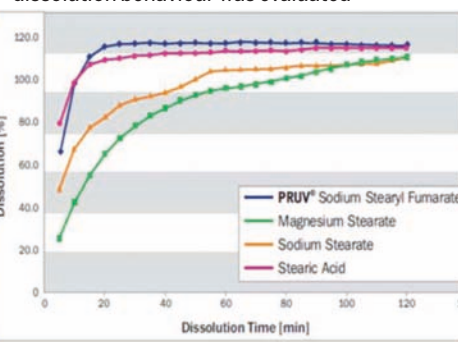
In this study, the effect of lubrication efficiency of different lubricants was evaluated



Observation: As for compactability, a similar trend observed in the ejection forces. The tablets lubricated with stearic acid showed the highest ejection forces, while magnesium stearate was found on the lower end of the ejection force spectrum. Tablets made with PRUV exhibited the same low ejection forces as compared to magnesium stearate.

Dissolution behaviour

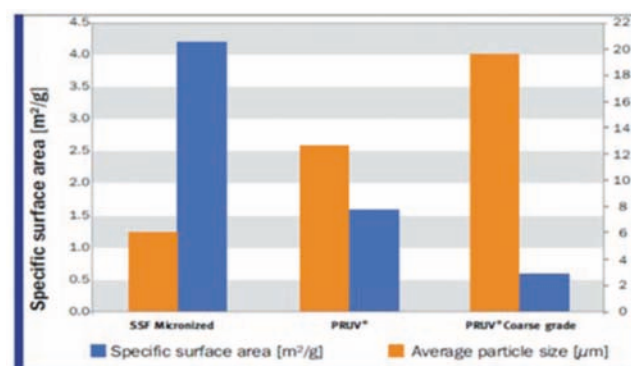
In this study, the effect of different lubricants on dissolution behaviour was evaluated



Observation: Tablets containing magnesium stearate showed by far the slowest dissolution rates. Sodium stearate and stearic acid-lubricated tablets released the API much faster. The faster drug release was observed for tablets lubricated with PRUV®

Grade	D(50)	BET
SSF Micronized	7.6	4.2 m ² /g
PRUV®	13.6	1.6 m ² /g
PRUV® CG (Coarse Grade)	20.4	0.6 m ² /g

PARTICLE SIZE AND SPECIFIC SURFACE AREA FOR DIFFERENT GRADES OF SSF^[4]



- ◆ Tight particle size distribution
- ◆ Well-defined specific surface area
- ◆ Reproducible particle morphology

The outstanding performance of PRUV® is based on its well-controlled particle size and shape. Following studies show the effect of deviating from the ideal values.

Conclusion:

Beyond tablet lubrication properties of PRUV®:

It shows:

- ◆ Improved API stability
- ◆ Superior blending properties
- ◆ Faster disintegration
- ◆ Faster dissolution times

The choice of lubricant can influence the quality of the tablets as well as the dissolution rates. Since APIs tend to be less water-soluble and difficult to compress, choosing the right lubricants continues to become an even more important task.

Most commonly available lubricants are very hydrophobic and thus increase dissolution times significantly. In such cases, a less hydrophobic lubricant can help to decrease the dissolution times as well as increase the API release.

PRUV® Sodium Stearyl Fumarate complies with Ph.Eur., NF and JPE. It has the ideal particle size and specific surface area to offer a perfect balance between all functionality

aspects. It is the preferred choice over magnesium stearate in terms of improving disintegration time and dissolution.

Furthermore, different particle sizes are available, which help to fine tune tablet formulation resulting in the desired dissolution profiles.

Regulatory status of PRUV®:

- ◆ Ph.Eur., NF, JPE, GRAS status
- ◆ C-DMF is available for PRUV®
- ◆ Non-animal origin
- ◆ BSE/TSE-free
- ◆ GMO-free
- ◆ OVI-free (USP<467>) and conforms to the residual solvents requirement of Ph.Eur.(5.4) and USP <467>
- ◆ QBD dossier available
- ◆ Elemental impurity statement available

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Lieberman, Joseph L. Kanig. *The theory and Practice of Industrial Pharmacy*, Varghese publication house, 3rd edition, 1990, 123-144.

QR Code:

Scan the QR code for more details regarding PRUV® from JRS Pharma.



Mr Prashant Bhangdiya

Technical Manager, Pharma Business unit, Rettenmaier India

Prashant Bhangdiya, Technical Manager, Pharma Business Unit, Rettenmaier India, is responsible for the JRS Pharma's Excipients Business in South India, East India and Bangladesh, including but not limited to, supporting the business development team, customer service and logistics team.

He completed M Pharmacy from Poona College of Pharmacy, Pune (Bharati vidyapeeth). He has also completed Diploma in Intellectual Property (IP) rights from Symbiosis International, Pune.

He has over 10 years of experience in the field of formulation development and pharma excipients.



Clean room high-speed doors for controlled manufacturing environments

Gandhi Automations highlights how self-repairing clean room high-speed doors help maintain controlled environments, minimise air leakage and support manufacturing efficiency

High Speed Doors designed and manufactured by Gandhi Automations are sturdy, dependable, and the ideal solution for medium and large entrances. The doors are manufactured with European collaboration, technology, and innovative and creative engineering.

Better quality or yield is the primary reason for investing in a cleanroom space. It goes straight to your bottom line. Numerous manufacturing facilities now require a controlled environment in which you limit the amount of dust and dirt in the area of the manufacturing. Medical instrument manufacturing and packaging, electronics and computer manufacturing, food preparation, and some military applications are but a few of the instances that have strict requirements for maintaining a clean environment. You need to know the requirements for your specific product or process. Clean rooms have become an integral part of pharma manufacturing facilities.

One of the most important aspects of cleanrooms is the doors you choose for the cleanroom facility. The time for which the door is open will play a critical role in avoiding dust, outside temperature, humidity, etc. The opening and closing of the door have to be



quick enough to isolate the outside environment and internal facility.

At Gandhi Automations Pvt Ltd, we provide Clean Room High Speed Doors specifically designed for the above purpose. Our clean room high-speed doors are best suited for facilities where you need a controlled environment. The opening and closing of the door are quick enough to separate the outside environment from the internal facility.

Gandhi Automation's High-Speed Clean Room Doors are meticulously engineered, boasting the following features:

- Concept of low air permeability in pressurised rooms with positive and negative air pressure
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- Minimises air leakage
- Can be equipped with transparent PVC horizontal sections or vision windows
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Virosil Pharma: A revolutionary, eco-friendly fumigant

Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations

ABSTRACT

In the past years, the pharma and healthcare industry has witnessed tremendous growth and there have been tie-ups with a number of multinationals for production and R&D facilities to be nurtured in India. Organisations are applying for ISO standards and upgrading themselves to the latest norms related to health and hygiene.

Microbial contamination and pollution play a significant role in the pharmaceutical industries. Control of microbes has always been the biggest challenge to these industries. A load of microbes are present in areas such as production, storage/packaging, R&D, Q.A/Q.C., filling etc. They are present everywhere in the air, surface, water, instruments, linens etc.

Hence the disinfectant used should be so precise that it should not only take care of the microbial contamination but also be user and eco-friendly. Virosil Pharma meets all the required standards for the pharmaceutical industry.

ABOUT US

Sanosil Biotech, a Mumbai-based company, has launched a range of multipurpose disinfectants which are eco-friendly, chlorine-free and completely biodegradable and have applications in the pharma and healthcare industry as well as in the food processing industry. It is manufactured in India in technical collaboration with SANOSIL AG of Switzerland. SANOSIL AG in Switzerland is the patent holder and has joint venture agreements in more than 15 countries such as France, Italy, Spain, Holland, Norway, South Africa, Australia, Saudi Arabia, Oman, the UAE, etc. The product is being used in various countries by reputed institutions and has been thoroughly tested under

strict regulations imposed by European Health bodies.

PRODUCT DESCRIPTION

Virosil Pharma is a multicomponent fumigant and disinfectant. The oxidizing agent used is hydrogen peroxide, which is bonded with stabilizing agents to form a complex solution. A long-lasting effect is ensured by the addition of silver, which acts as a catalyst in trace amounts. The bactericidal effect of silver is based on the fact that the monovalent silver

ion Ag⁺ binds very firmly to bacterial proteins by a covalent or co-ordinate bond, and thus inactivates or precipitates these.

◆ Its effectiveness against bacteria, viruses, amoebae, fungi and algae; i.e. its extremely wide range of application makes it easy to handle for the end user; i.e. only one product is needed, where so far 2, 3 or various products were necessary.

◆ Owing to the good stability of the product, a long storage



ADVANTAGES

- # Eco-friendly - It is totally biodegradable since (H₂O₂) breaks down into water & oxygen
- # Chlorine free
- # Non-toxic (no irritation to skin or eyes)
- # No effect on pH
- # Non carcinogenic and non mutagenic
- # Excellently rinseable with no remains

PROPERTIES

- # Can easily be dosed
- # Does not foam
- # Decomposes into water and oxygen
- # It is excellently rinseable with no remains
- # Treats any other material with consideration

USFDA DRAFT GUIDELINES

Clean Area Classification	Microbial limit Cfu / 10 cu.ft.	Microbial limit Cfu / 10 cu.m.
100	< 1a	< 3a
1000	< 2	< 7
10,000	< 5	< 18
100,000	<25	<88

a = samples from class 100 environments should normally yield no microbiological contaminants

WHO 2002 MICROBIAL LIMITS

Grade	Max. no. of microorganisms permitted / m3
A	Less than 1
B	5
C	100
D	500

EU GMP 2002

Grade	Air sample cfu / cu.m.	Settle plates (90mm) cfu / 4 hours	Contact plate 55mm cfu / plate	Glove print Cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

time can be guaranteed. As the product remains stable at high water/air temperatures, and as its effectiveness is even increased at high temperatures.

◆ Due to its long-term effectiveness and pronounced characteristics to prevent recontamination, this product is perfectly suited for disinfection of drinking water and wells.

◆ Virosil Pharma is ecologically harmless. Its principal constituent - hydrogen peroxide - does not pollute waste wa-

ter, because it breaks down into water and oxygen (H₂O and O₂), i.e. it produces no noxious by-products.

◆ The two basic substances (H₂O₂ and Ag) enhance their advantages (*synergism). The bactericidal effect comes into action quicker and more intensively than if either substance was used on its own.

Fumigation with Virosil Pharma, the perfect Salternative to Formalin

Fumigation is one of the most

important factors associated with pharma industries, it plays a vital role in maintaining the sterility of areas and is directly related to production.

Sanosil Biotech is the first company to pioneer the novel concept of eco-friendly fumigation. The company has great respect for human health and the environment. The CEO, Dev Gupta, an MBA from the Bentley Graduate School of Business, Boston, has been actively marketing the brand nationally. According to Gupta, "Virosil Pharma has simplified the lives of so many people who work in the pharmaceutical industry as they are guaranteed sterility with the minimum risk exposure". As there was a high risk to the staff involved in the use of Formaldehyde/Glutaraldehyde for sterilization and disinfection.

Owing to the stringent integrated micro contamination control and biosafety requirements, it is desirable to have micro-contamination control procedures and methods that could be monitored, evaluated and assessed periodically, which are convenient, cost-effective and safe.

A glimpse at the standards put down by various would monitoring agencies would help an individual or an organization help decide on choosing the most appropriate control procedure/methods. The important microbial limits which have been prescribed by various agencies is as follows:

To meet those requirements aerial disinfection (fumigation) with formaldehyde was the most convenient method. With the regulatory having restricted the use of formaldehyde and also putting into place the monitoring levels of formaldehyde after fumigation makes it a procedure with its own limitations.

Formaldehyde is a known carcinogen (IARC & NTP). Formalin is toxic by inhalation, toxic if swallowed, may be fatal if swallowed, causes eye burns, may cause blindness, strong sensitizer, causes irritation to skin, eyes, and respiratory tract. Repeated or prolonged exposure increases the cancer risk.

COMPARISON	
VIROSIL PHARMA	FORMALIN
Eco-friendly, Non-toxic	Highly toxic
Room gets sterilized within 1 hour after fumigation	Requires overnight fumigation
Requires no de-fumigation	Requires de-fumigation
Person can be present during fumigation	Causes skin, eye irritation even after next day of fumigation
Time Saving	Time consuming
Multiple Applications	Application restricted

Virosil Pharma has been a direct alternative to Formalin Fumigation. Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations. Virosil Pharma can even be successfully used in AHU which are responsible for optimal and steady air exchange in production facility, of which the ducts, air shafts, humidifier, filters, etc. are often contaminated with loads of bacterial and bio-films.

The main aim of Virosil Pharma is to increase productivity by cutting down disinfection time while at the same time providing a totally microbe-free environment.

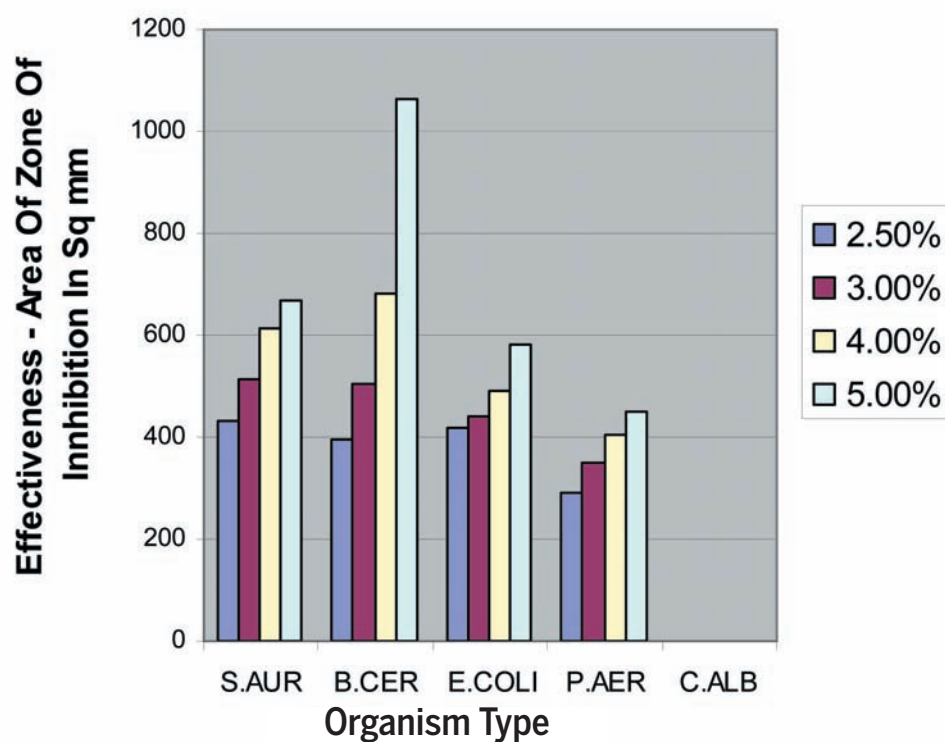
Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to re-wash equipment and surfaces disinfected with Virosil Pharma since it is H₂O₂ based and decomposes into water and oxygen.

Virosil Pharma has been tested by several reputed and renowned institutions in India with respect to its disinfection and fumigation applications in Pharmaceutical Industry

Because of all these factors, Virosil Pharma has attained maximum satisfaction of the customers in controlling the microbial contamination in their respective applications. The introduction of an eco-friendly, non-carcinogenic and totally biodegradable versatile product, like Virosil Pharma,

A GRAPHICAL VIEW ON DISINFECTANT EVALUATION DATA - VIROSIL PHARMA

Disinfectant Effectiveness Evaluation Data
Virosil Pharma



	S.AUR	B.CER	E.COLI	PAER	C.ALB
2.50%	429.83	397.4	418.15	289.38	0
3.00%	514.44	502.4	440.92	349.48	0
4.00%	615.44	683.14	490.625	404.5	0
5.00%	669.32	1063.07	580.77	452.16	0

has not only brought an end to the era of conventional biocides but has completely solved the disinfection requirements which these healthcare industries were prone to.

Targets

Sanosil Biotech is marketing this disinfectant under the 'Virosil Pharma' brand name and is targeting the entire industrial belt of India. The com-

pany has already set up a distribution and infrastructure network having establishments in Maharashtra, M.P., Hyderabad, Chennai and Delhi.



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Superfast Disintegration and Dissolution Improver



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Taste Masking of Bitter Drug

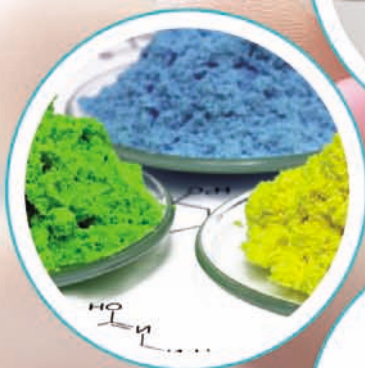
Suspensions | Dry Syrup | Mouth Dissolving Tablet
Dispersible Tablet | Chewable Tablet



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Oral Care | Emulsifier | Suspending Agent



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