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APRIL 2026, ₹40

Regulations
Safeguarding the pharma excipients

Strategy
Leading people in the age of AI

PATENT EXPIRIES AHEAD
IS INDIA PHARMA INC READY?

Beyond the semaglutide momentum, a larger wave of patent expiries is set to unfold between 2026 and 2032. For Indian pharma, the opportunity is significant, but so are the risks. Experts weigh in on what it will take to succeed

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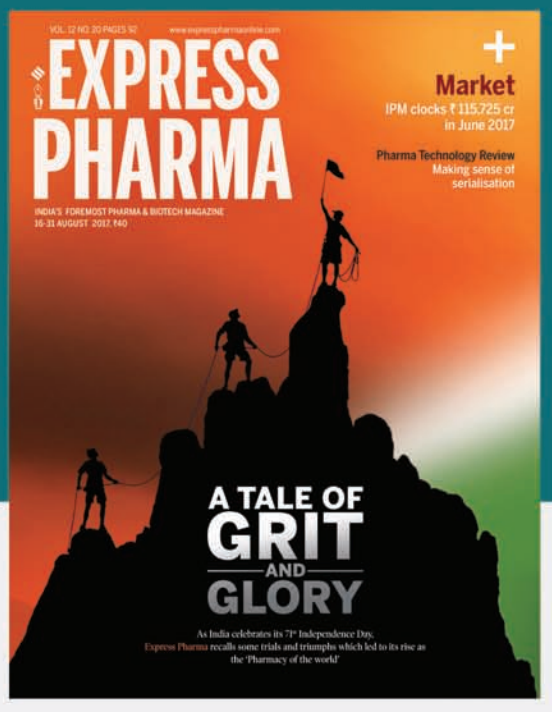

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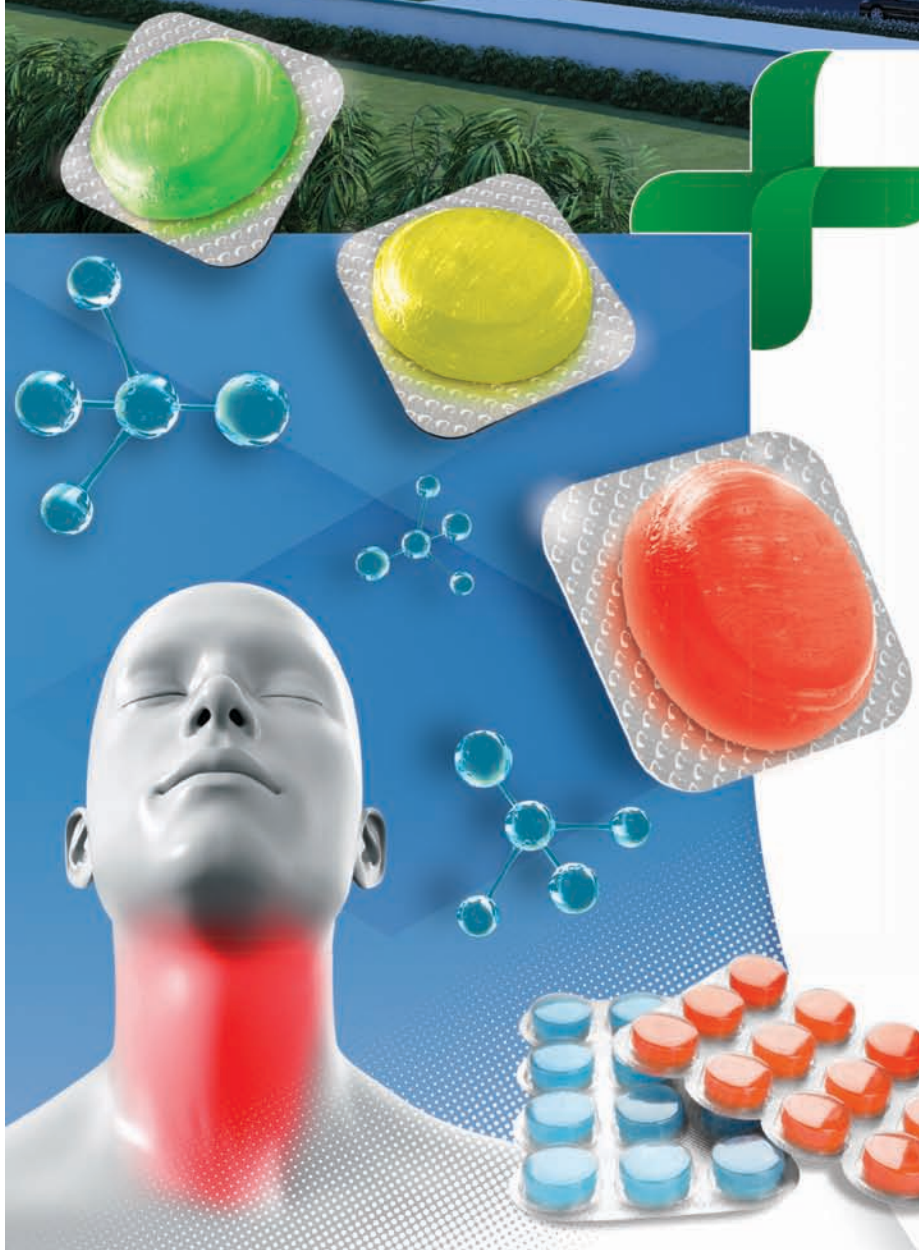

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Midst global headwinds, CDSCO cracks down on GLP-1 gold rush

Amid the geopolitical turmoil of the US-Israel-Iran tussle, the loss of patent exclusivity of semaglutide on March 20 marked the start of another conflict: a price war as companies scrambled to claim a fatter slice of the GLP-1 market.

The flood of generic GLP-1s launched post March 20 will probably be part of many business school case studies, analysing launch strategies and branding gambits. Most of the big names launched within a few days but it is estimated that there could be as many as 40-50 generic semaglutide brands within a few months.

But not all brands will survive the GLP-1 gold rush. Firstly, the regulatory scrutiny has increased many fold, even before the launch of generic GLP-1s. On March 10, the regulator CDSCO issued a strict advisory to all manufacturers, explicitly prohibiting surrogate advertisements and any form of indirect promotion that could mislead consumers or encourage off-label usage. Significantly, the Advertising Standards Council of India (ASCI) was also copied on this advisory, perhaps hinting that consumers could route their complaints through this channel as well.

Clearly, the regulator would like to drive home the message that these are not "weight loss shots", as they have been dubbed on social media reels, but medicines, and like all medicines, come with side effects.

Central and state regulators have also scaled up enforcement activities. Within four days of patent loss, 49 entities were audited and inspected, including online pharmacy warehouses, drug wholesalers, retailers, wellness and slimming clinics. The fact that these inspections were followed by notices served to defaulting entities proves that the Drugs Controller of India /CDSCO will remain vigilant.

A PIB press note dated March 24 release stressed the consequences of the misuse of weight loss drugs without clinical oversight, advising citizens to use such medications only under the guidance of qualified medical practitioners. The release also reiterates that these drugs have been approved in India under specific conditions, and can only be prescribed by endocrinologists and internal medicine specialists and for some indications by cardiologists. Regulatory surveillance will intensify in the coming weeks and the release warns that "non-compliances will be dealt with strictly with actions including cancellation of licenses, penalties, and prosecution under applicable laws."

Secondly, while the regulatory spotlight will hopefully discourage smaller companies hoping to make a quick buck off the semaglutide wave, the real battle will be to make patients overcome needle phobia, and stick to the routine. Even though prices have reduced, a regimen of generic semaglutide is still an expensive prospect.

Savvy pharma companies are already looking beyond semaglutide, to other molecules set to slide off the patent cliff from 2026-2032. Our cover story in the April edition of *Express Pharma*, titled, 'Patent expiries ahead: Is India Pharma Inc ready?', gets experts to break down the opportunity, the risks and the challenges as companies strategise for the next opportunity.

As pharma companies deal with price wars, increasing regulatory heat and a volatile geopolitical situation, navigating this perfect storm perhaps calls for regulator-industry cooperation seen during COVID times

Another story in the April edition, titled, 'Safeguarding the pharma excipients supply chain', analyses a seemingly small but significant policy amendment. From March 1, Quick Response (QR) Codes or barcodes on the labels of the top 300 medicine brands in India will have to include "qualitative details" of excipients used during the making of these products.

Adding excipient data to dynamic QR codes will not entail additional costs for pharma companies already complying with the QR Code Rule. The challenges lie at the excipient supplier's end, as it triggers a move to more transparent systems and standardised excipient nomenclature. These systems need a level of digital readiness which might not be possible for smaller excipient makers. While the industry is ready to comply, they feel a phased roll out would result in better adoption.

Including details of excipients in QR codes has been on the cards for a few years, especially after repeated incidents of deaths linked to cough syrups containing non-medical grade diethylene glycol (DEG) and ethylene glycol (EG). The QR code amendment. if implemented in letter and spirit, is one step towards helping India Pharma Inc rebuild lost trust.

Pharma companies are also tracking another harsh reality check: the US-Israel-Iran situation. Namit Joshi, Chairman of Pharmexcil estimates that a complete disruption of March's exports to the GCC markets could result in a potential loss of approximately Rs 2,500 to Rs 5,000 crores for the Indian pharma industry. He also flags the escalation of costs throughout the pharma supply chain, driven by crude oil price fluctuations, rising logistics costs for APIs and finished formulations and shipping delays that will affect inventory cycles.

There are already reports that certain medicines like vitamins and antibiotics could get more expensive to manufacture as input prices increase.However since these are price controlled, cost increases will have to be absorbed by manufacturers. Once again, smaller companies will feel the pinch more and faster than their larger counterparts.

As pharma companies deal with price wars, increasing regulatory heat and a volatile geopolitical situation, navigating this perfect storm needs patience and resilience. And perhaps the same regulator-industry cooperation seen during COVID times.

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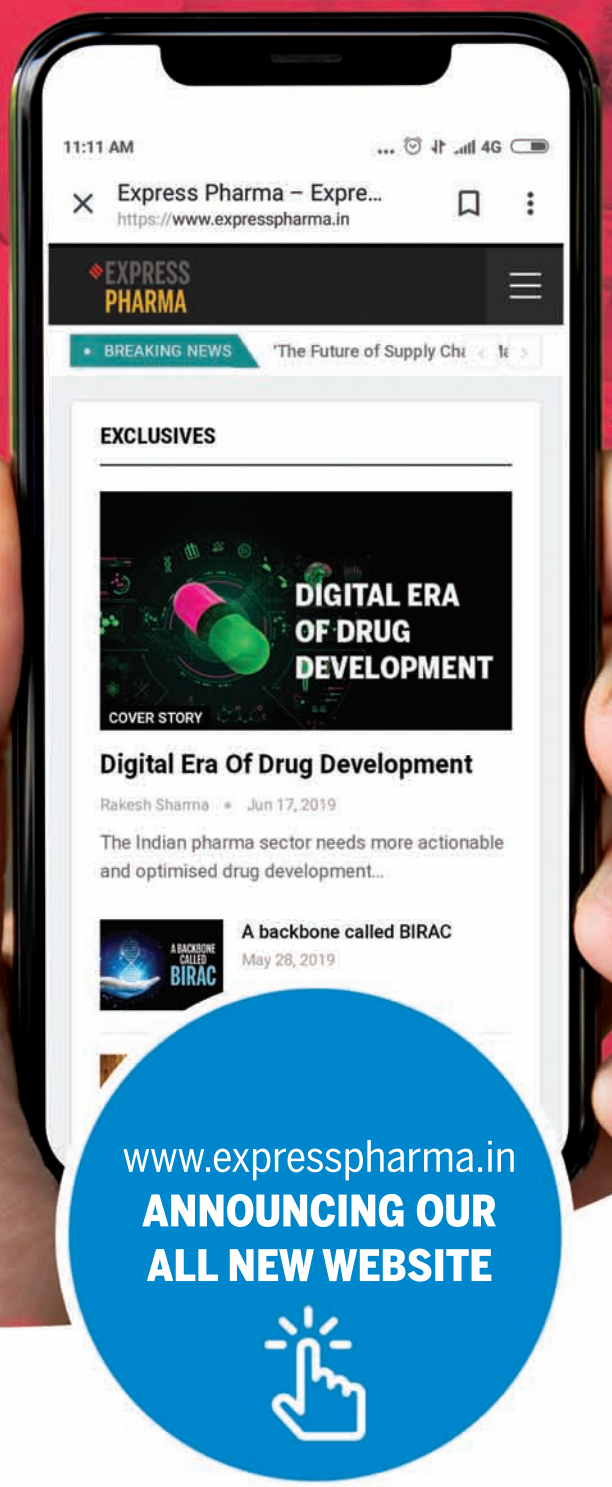

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India brings together a rare and powerful combination of capabilities

Dr Kshitij Panse, Chief Operation Officer, GATINN by Servier, in an interaction with **Kalyani Sharma,** discusses the strategic rationale behind establishing the GATINN platform in India, the growing importance of Single Pill Combinations (SPCs) in improving patient adherence, and how emerging markets are shaping the future of pharma innovation and global supply chains

Servier has announced the establishment of the GATINN platform in India to focus on SPCs. What strategic considerations led to choosing India as the base for this global initiative?
The main reason to establish GATINN in India was to be fast in developing top quality Single Pill combinations and providing it to the patients as the unmet need is very high.

India brings together a rare and powerful combination of capabilities:

- Advanced formulation and development expertise,
- Globally accredited manufacturing ecosystem
- Scale and speed required for multi-market supply

India has a strong base in formulation science, bioequivalence, and clinical development, all essential for SPCs

For Servier, quality is non-negotiable and India does have several partners accreditated by international regulatory authorities that are capable to developing and manufacturing top quality SPCs. India offers the ecosystem where we can combine scientific rigour, execution speed, and scalability—which are essential to build a global SPC platform.

So, this is not about geography alone. It reflects our belief in building capabilities where they create the greatest patient value.

> Regulatory scrutiny has been a positive and necessary evolution for the industry. It reinforces the rational as why, how and which combination therapies should be developed. It also reinforces the importance of quality in development and manufacturing

With plans to invest around €15 million and develop multiple SPC products by 2030, how will the GATINN platform strengthen Servier's global pipeline and expand access to cardiometabolic therapies across international markets?
GATINN is designed as a long-term execution platform, not a one-time initiative.

From a pipeline perspective:

- It allows us to systematically develop a portfolio of clinically relevant SPCs
- We aim to have ~5 products in development by end-2026, with continuous additions thereafter
- First international launches are expected from Q2 2027

From an access perspective:

- The platform enables faster, scalable deployment across multiple markets, especially in regions with high unmet need
- It supports export-led impact across Asia, Latin America, Africa, and the Middle East

Importantly, this is about optimising existing therapeutic options into patient-centric solutions, improving adherence and long-term outcomes at scale.

SPCs are increasingly being discussed as a way to simplify treatment regimens. How do SPCs influence clinical outcomes and healthcare system efficiency in managing chronic diseases?
This is a critical point because in chronic diseases, the challenge is often not treatment availability—but sustained adherence over time particularly because multiple comorbidities often coexist in the same patient and the patient has to take multiple pills

SPCs influence outcomes at multiple levels:

1. Patient-level impact

- They reduce pill burden, making treatment easier to follow
- This directly improves adherence, which is one of the strongest predictors of long-term outcomes
- Better adherence leads to improved disease control and reduced complications

2. Clinical impact

- SPCs combine complementary mechanisms of action, often aligned with treatment guidelines
- They help physicians implement evidence-based therapy more consistently

3. Healthcare system efficiency

- Improved adherence translates into fewer hospitalisations and complications
- Treatment pathways become simpler and more standardised, reducing system complexity

Hence more and more scientific guidelines are recommending single pill combinations.

At Servier, we see adherence as a design principle, not an afterthought.SPCs are therefore not just about convenience—they are about delivering better outcomes at scale.

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Emerging markets like India are becoming important hubs for pharmaceutical development and manufacturing. What factors are driving this shift, particularly in the context of global supply chains and innovation?

This shift is being driven by a combination of structural, economic, and strategic factors.

From a global supply chain perspective:

- Companies are moving toward more diversified and resilient manufacturing networks.
- India has always been cost-effective but over the years what has been improving is the quality in development and manufacturing
- Pharmaceutical exports from India exceed $25 billion annually, reflecting its global integration

From an innovation and capability standpoint:

- India has over 1,000 pharma companies with R&D capabilities and a strong base in formulation science
- It contributes significantly to global clinical research participation, supporting development programs

From an ecosystem perspective:

- Availability of high-quality CDMOs, CROs, and regulatory expertise
- Strong track record in scaling production while maintaining quality standards

For Servier, this aligns with our broader philosophy of building capabilities across geographies where they deliver the greatest scientific, operational, and patient value. Hence GATINN was established in India to develop, manufacture and export top quality SPCs from India to the countries that need the most.

Fixed-dose combinations have existed for decades in therapeutic areas such as hypertension and diabetes. In your view, how do today's Single Pill Combinations differ in terms of clinical rationale, formulation, or positioning?

Fixed-dose combinations are indeed not new. What has changed is the intent and scientific rigour in line with the evolving scientific guidelines.

Key differences include:

1. Stronger clinical rationale

- Today's SPCs are more and more built on clear scientific evidence and guideline alignment
- Components are selected based on complementary mechanisms of action

2. Patient-centric design

- The focus is on simplifying long-term therapy, not just combining molecules
- Adherence is embedded into product design itself

3. Advanced formulation science

- Improved technologies enable precise dosing, stability, and bioequivalence
- This ensures that combining molecules does not compromise efficacy or safety

In essence, SPCs have evolved from formulation-led combinations to evidence-driven therapeutic solutions.

As a consequence of all this, SPCs are increasingly viewed as integral components of standard treatment pathways

Regulatory agencies have previously cracked down on irrational combinations in several markets, including India. How has this shaped the way pharmaceutical companies approach the development and validation of combination therapies today?

Regulatory scrutiny has been a positive and necessary evolution for the industry.

It reinforces the rational as why, how and which combination therapies should be developed. It also reinforces the importance of quality in development and manufacturing

- Companies are increasing starting with a clear scientific and clinical rationale, rather than formulation convenience

There has to bea stronger emphasis on:

- Pharmacokinetic compatibility
- Demonstrated clinical benefit over monotherapy
- Robust safety and efficacy data

Development has to be increasingly aligned with:

- Global treatment guidelines
- Regulatory expectations across multiple markets

This leads to a more disciplined, evidence-based approach, ensuring that combinations are developed only when they deliver meaningful patient benefit.

At Servier, this aligns naturally with our philosophy of scientific rigour and long-term therapeutic value.

From a clinical and regulatory standpoint, what factors determine whether a combination therapy is considered rational and beneficial for patients rather than simply a convenient formulation?

A combination therapy is considered rational and beneficial when it meets four key criteria:

1. Complementary mechanisms of action

Each component addresses a different aspect of the disease, creating a synergistic therapeutic effect

2. Demonstrated clinical benefit

There must be clear evidence that the combination provides better outcomes than individual therapies

3. Safety and dosing optimisation

The combination should maintain or improve efficacy without increasing safety risks or complexity

4. Real-world patient relevance

It should simplify treatment and improve adherence, making it easier for patients to stay on therapy long term

Ultimately, regulators and clinicians expect combination therapies to be:

- Scientifically justified
- Clinically meaningful
- And relevant to real-world patient needs

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Leading people in the age of AI

As AI reshapes pharma, HR leadership is being drawn into a deeper question that goes beyond technology to the future of people and work, finds **Lakshmipriya Nair**

AI is no longer changing just one part of pharma. It is reshaping everything, all at once.

R&D teams are identifying drug candidates in weeks instead of years. Manufacturing floors are catching quality issues before they happen. Regulatory submissions are being drafted in minutes, not days. Field teams are being evaluated and optimised by algorithms.

According to a report titled, '*Scaling gen AI in the life sciences industry*', researchers from McKinsey Global Institute, estimated that generative AI alone could unlock $60–110 billion annually for the pharma and medical-products sector by accelerating discovery, speeding development and improving commercialisation.

Individually, these changes look like upgrades. Together, they signal something much bigger. A fundamental shift in how pharma organisations think, decide and operate.

And right at the centre of this shift is a function being redefined in real time: HR.

A transforming playbook

The questions HR leaders are being asked today look very different from before. It used to be about headcount, appraisals, attrition and hiring metrics. Now it is this: How do we lead people through a technological revolution that is rewriting the rules of one of the world's most regulated industries?

For the people inside pharma organisations, the nature of their work is changing, the skills required to do it well are changing, and the judgment they are expected to exercise is changing too.

This is not a talent question. It is not just about change management. It is a question about power, architecture and ownership. About who shapes the system before the system shapes the organisation.

Puneet Rajput, CHRO of Piramal Pharma, puts it clearly, "HR leaders are now seen as enterprise shapers, rather than functional stewards. Capability building that supports organisational growth and promotes innovation takes precedence over traditional HR functions such as hiring and developing policy frameworks."

That shift is already visible on the ground. Animesh Dhari Singh, GM – Human Resources, Naprod Life Sciences, describes what it looks like across India's pharma sector, "In India's pharma industry, people leadership has evolved from a support function into a core driver of business performance and long-term growth. Talent strategies are now closely aligned with scientific pipelines, regulatory demands, and market realities. Across organisations, culture is being shaped deliberately to support innovation in research, discipline and quality

HR leaders are now seen as enterprise shapers, rather than functional stewards. Capability building that supports organisational growth and promotes innovation takes precedence over traditional HR functions such as hiring and developing policy frameworks

Puneet Rajput
CHRO, Piramal Pharma

People leadership has evolved from a support function into a core driver of business performance and long-term growth. Talent strategies are now closely aligned with scientific pipelines, regulatory demands, and market realities

Animesh Dhari Singh
GM – Human Resources,
Naprod Life Sciences

The CHRO operates at the intersection of business and people strategy—ensuring that capability gaps do not become execution gaps. The role is not just to enable transformation, but to actively de-risk it

Alind Sharma
President and CHRO,
Glenmark Pharmaceuticals

In highly regulated sectors like pharma, trust is not just cultural, it is operationally critical. CHROs must move beyond viewing verification as a backend HR process and embed it into the organisation's core governance framework

Ajay Trehan
CEO and Founder,
AuthBridge

in manufacturing, and ethical, sustainable growth in commercial functions. The focus has shifted from managing headcount to building future-ready capabilities that can support complex therapies, global compliance expectations, and rapid industry change."

This is the new reality of HR in pharma, and the boardroom has taken notice. As Rajput outlines, "In the VUCA world, pharma companies have a unique position at the intersection of science, regulation, technology and patient impact. The strong alignment of people strategy with business strategy, focus on innovation, adaptability will lead to an overall multiplier effect on organisations that will strive and thrive in this fast-changing world. This is changing expectations of CEOs and Board of Directors from HR leadership."

Today, the mandate for pharma HR leaders is clear. It is to design how humans and machines work together across a complex value chain.

HR LEADERS' PRIORITIES IN THE AI AGE

- Move from AI adoption to AI design
- Build future-ready skills at scale
- Use predictive people insights
- De-risk before scaling
- Make culture operational
- Strengthen leadership depth
- Own AI governance
- Close the trust gap

The gap that cannot be ignored

Yet as the expectations placed on HR leaders grow, a critical gap is emerging.

The workforce disruption driven by AI is real. The World Economic Forum's Future of Jobs Report 2025, drawing on data from over 1,000 companies, found that 63 per cent of employers identify skill gaps as the single biggest barrier to business transformation. An estimated 59 out of every 100 workers will require reskilling or upskilling by 2030. In high-complexity sectors like pharma, the pressure is acute.

Which makes one thing clear. This is not just about adopting AI. It is about deciding how work itself will be defined.

And that is the risk now. Despite being deeply involved in implementing AI, be it deploying tools, enabling adoption, or managing the human side of change, fewer HR leaders are part of the decisions that actually shape how these systems work.

Yet, boards are asking more of HR leadership than ever before. As Rajput describes it, "To foster an environment where decision-making, ownership and problem-solving will be widely distributed, boards of directors are now relying on HR to develop deep levels of leadership throughout the organisation. In an industry characterised by a simultaneous focus on quality, speed and regulatory requirements, leadership cannot continue to be limited to the top echelon of an organisation."

She informs,"There is also a strong push to future proof the workforce. This includes building digital fluency, data literacy, and advanced scientific capabilities, while ensuring employees are equipped to work in increasingly technology enabled and cross-functional environments. At the same time, culture has become a board level priority. HR is expected to embed purpose, ethics, inclusion, and patient and customer centricity into everyday behaviours, making culture a driver of performance and trust."

"Another emerging expectation is improved workforce intelligence and HR leaders are increasingly expected to give forward-thinking insights into skills, succession, and organisational readiness so that leadership teams may make proactive decisions. Finally, CEOs and boards regard HR as a custodian of agility and resilience, tasked with creating an organisation that can adapt to change and disruptions while delivering both economic success and societal benefit," she adds.

This, then, is a moment of choice for HR leaders. They can remain enablers of AI, or step into a more strategic role, shaping the principles, decisions and systems that will define how organisations actually function.

John Kotter, a Harvard Business School professor and

author of Leading Change, argues that the central failure of most change efforts is not a lack of effort but a lack of urgency at the right level. "Whenever smart and well-intentioned people avoid confronting obstacles," he writes, "they disempower employees and undermine change."

For HR leaders, that urgency is not just about driving initiatives, it is about being present where key decisions are made and shaped.

Because the companies that get this right will not just be faster. They will be better designed. And HR leaders will be central to that design: moving from technology adopter to business strategist.

De-risking change

Alind Sharma, President and CHRO, Glenmark Pharmaceuticals, frames the people strategy imperative well and states, "In today's fast-evolving pharma landscape, a strong people strategy is built on three strategic pillars: leadership, engagement and talent. Of these, leadership acts as a force multiplier across the two. Transforming on the people front begins with leadership clarity. It shapes engagement through opportunity, growth, and culture, and defines how talent is identified, attracted, and developed across the organisation."

At the centre of this sits the CHRO. As Sharma puts it, "The CHRO operates at the intersection of business and people strategy ensuring that capability gaps do not become execution gaps. The role is not just to enable transformation, but to actively de-risk it. At Glenmark, this translates into building future-ready capabilities, fostering a purpose-driven, performance-led culture, and enabling our teams to apply science with purpose, expand access at scale, and deliver with disciplined execution."

> Fear of obsolescence is real. Pharma professionals across functions worry about AI replacing them and wonder whether their roles will become redundant. The real leadership challenge in Indian pharma is about helping scientists, medical representatives, quality professionals and medical affairs teams feel relevant, valued and capable in a landscape that is shifting beneath their feet

In an AI-driven organisation, the risks are not only operational. They are ethical and cultural, embedded in the design of systems that will determine how people are hired, how they are evaluated, how their career trajectories unfold, and how the organisation responds when things go wrong.

And, de-risking begins before an employee walks through the door. Ajay Trehan, CEO and Founder of AuthBridge, insists that trust must be operationalised, not assumed, "In highly regulated sectors like pharma, trust is not just cultural, it is operationally critical. CHROs must move beyond viewing verification as a backend HR process and embed it into the organisation's core governance framework."

That means rethinking where verification sits in the hiring journey. As Trehan explains, "A key strategy is to establish verification-led hiring, where identity checks, credential validation, and employment history screening are integrated early in the hiring journey rather than treated as a post-offer formality. This ensures discrepancies are identified before onboarding, reducing downstream risks."

And AI is making proactive risk management possible in ways that were not previously feasible. As Trehan notes, "Advanced systems can analyse large datasets, cross-reference multiple databases, and detect anomalies such as identity inconsistencies, falsified credentials, or undisclosed histories with far greater accuracy." The implication is significant, HR leaders who harness this capability move from reacting to risk to anticipating it, earning a seat at the strategic table that reactive processes could never have secured.

Building culture as infrastructure

In *Hit Refresh*, Satya Nadella borrows from poet Rainer Maria Rilke and says, "The future enters into us, in order to transform itself in us, long before it happens." It posits that change does not begin with a strategy deck, but with a shift in how people inside an organisation see themselves and their work.

In a sector as complex as pharma, culture needs to be infrastructure. It determines whether AI tools are adopted with curiosity or faces resistance, whether the organisation learns from failure or conceals it.

Singh describes what building that infrastructure looks like, "Within research and development, emphasis is placed on creating environments that encourage scientific thinking, collaboration, and continuous learning. Career paths increasingly recognise research contribution and domain expertise, while workforce planning is aligned to emerging areas such as biologics and advanced therapies. In manufacturing, strong attention is given to quality-first mindsets, frontline leadership, and accountability, recognising that people behaviour directly impacts compliance and patient safety. In commercial teams, performance is being balanced with ethics, digital readiness, and responsible engagement with healthcare stakeholders, ensuring growth is sustainable and reputation-led."

Thus, culture needs to be an operational strategy deliberately designed, function by

function, to hold the organisation together as technology pulls it in new directions. And, HR leaders are uniquely positioned to build it by shaping the everyday conditions such as how decisions are made, how dissent is heard, how capability is rewarded, and how an organisation behaves under pressure.

And when that internal transformation is done right, as Nadella writes, "when people and cultures re-create and refresh, a renaissance can be the result."

Enabling effective and ethical governance

Culture, however, can only carry an organisation so far. As AI moves into core business processes, the questions of governance such as who sets the rules, who monitors the outcomes, who is accountable when systems fail, become urgent. And HR cannot afford to leave these questions to technologists alone.

Trehan notes that at scale, the challenge is not merely screening people once, it is building systems that remain vigilant continuously. He says, "At scale, workforce integrity is sustained not just by pre-hiring checks, but by building a continuous trust framework where verification, compliance, and risk management operate as interconnected systems rather than isolated processes."

Governance, in this context, is not a compliance exercise. It is about ensuring that as AI takes on more reponsibilities of the organisation, its values and standards remain intact. Leaders who will engage in the design of AI systems, not merely their rollout, will help determine whether their organisations earn or erode the trust of the people they employ and the patients they serve.

Tackling the trust deficit: A key challenge

Transformation fails when people do not trust it. And trust is fragile in pharma, an industry built on evidence, scrutiny and the understanding that what you do affects patient lives.

Fear of obsolescence is real. Pharma professionals across functions, be it R&D, manufacturing, quality or commercialisation, worry about AI replacing them and wonder whether their roles will become redundant.

The real leadership challenge in Indian pharma today is not about deploying AI faster. It is about helping scientists, medical representatives, quality professionals and medical affairs teams feel relevant, valued and capable in a landscape that is shifting beneath their feet.

This is where HR's expertise becomes irreplaceable. No algorithm can navigate tough conversations with senior scientists whose roles are changing as AI takes over parts of their work. And, chatbots cannot guide a sales manager through the human side of leading a team when AI starts setting targets. These are fundamentally human skills and in pharma, where the stakes are higher, they are more valuable now than ever.

As Singh captures it, "Across functions, greater effort is being made to align diverse work cultures under a shared purpose centred on patient outcomes and public health impact. Performance frameworks now combine results with behaviours, leadership accountability, and values-based decision-making. At the same time, organisations are investing in reskilling, digital adoption, and employee experience to support transformation. Together, these shifts reflect a more strategic approach to people and culture, one that directly influences innovation, operational excellence, and long-term competitiveness in India's pharma sector."

Because in the end, the organisations that get this right won't just be the ones that used AI well. They'll be the ones that stayed human in how they led their people through it.

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The GLP-1 revolution

A new class of drugs is reshaping global health, but India's generics wave could change who benefits. **Dr Rajpushpa Labh,** Consultant Physician, health-tech entrepreneur, and AI researcher explains

The pill that changed everything

In December 2025, the US Food and Drug Administration approved the first oral GLP-1 pill for weight loss — the Wegovy pill. Within ten weeks, an estimated 400,000 Americans had added it to their daily routine, making it one of the fastest drug launches in recorded history. The injectable versions — *Ozempic, Wegovy, Mounjaro, Zepbound* — had already reshaped how the world thinks about obesity and diabetes. But the pill changed the calculus entirely.

Then, on March 21, 2026, something perhaps even more consequential happened 8,000 miles away: Novo Nordisk's patent on semaglutide — the active ingredient behind both Ozempic and Wegovy — expired in India. Within hours, more than 40 Indian pharma companies began launching over 50 generic brands, with prices plummeting by as much as 90 percent. The world's most populous nation, home to over 77 million diagnosed diabetics and a projected 440 million overweight or obese people by 2050, suddenly had access to a drug class that had been the preserve of the affluent.

This is the story of GLP-1 receptor agonists: how they work, what they promise, what risks they carry, and why India's generic revolution could reshape global health economics for a generation.

Understanding the science

GLP-1 stands for glucagon-like peptide-1, a hormone naturally produced by the small intestine after eating. When blood sugar rises, GLP-1 signals the pancreas to produce more insulin. These drugs mimic that natural hormone, but their effects extend far beyond blood sugar regulation. They slow gastric emptying — keeping food in the stomach longer — which creates a prolonged sense of fullness. They also target hunger receptors in the brain, fundamentally altering the appetite signals that drive overeating.

The result is a class of medications that addresses obesity and diabetes simultaneously, through mechanisms the body already uses but cannot sustain on its own at the levels needed for therapeutic effect.

The key players

■ **Semaglutide (Novo Nordisk):** The active ingredient in both Ozempic (approved for type 2 diabetes) and Wegovy (approved for weight loss). Available as a weekly injection and, since January 2026, as a daily pill. Clinical trials show average weight loss of 13–16% of body weight. The landmark SELECT trial demonstrated a 20% reduction in major cardiovascular events.

■ **Tirzepatide (Eli Lilly):** Sold as Mounjaro (diabetes) and Zepbound (weight loss). Unlike semaglutide, tirzepatide is a dual-action drug — it mimics both GLP-1 and a second hormone called GIP (glucose-dependent insulinotropic polypeptide). In the SURMOUNT-5 head-to-head trial, tirzepatide achieved 20.2% average weight loss versus 13.7% for semaglutide over 72 weeks.

■ **Retatrutide — 'Triple G' (Eli Lilly, in trials):** The next generation. Retatrutide mimics three hormones — GLP-1, GIP, and glucagon. In clinical trials, it has produced average weight loss of up to 29% of body weight after 68 weeks, significantly exceeding all current options. Eli Lilly is completing seven additional trials expected to wrap up in 2026 and could file for FDA approval as early as this year.

■ **Orforglipron (Eli Lilly, pending approval):** A non-peptide oral GLP-1 pill that can be taken without food or water restrictions — a practical advantage over the Wegovy pill, which has specific dosing requirements

SERIOUS BUT RARE SIDE EFFECTS

Side Effect	Details	Incidence
Pancreatitis	Inflammation of the pancreas. Presents as sudden, severe abdominal pain. Meta-analyses have not confirmed a definitive causal link, but monitoring is advised.	Rare; < 1%
Gallbladder Disease	Semaglutide increases gallstone risk by 2.6x versus placebo. Notably, tirzepatide showed no significant biliary risk in pooled analyses.	Uncommon
Thyroid Tumors	FDA black box warning based on rodent studies. Across 10 human studies (14,550 participants), thyroid cancer incidence was less than 1%, suggesting no significant risk in humans.	Very rare
Vision Loss (NAION)	Non-arteritic anterior ischemic optic neuropathy. Possibly linked to rapid blood sugar drops reducing blood flow to the optic nerve. MHRA has revised labelling.	~1 in 10,000
Kidney Injury	Primarily through dehydration from persistent vomiting or diarrhea. Tirzepatide may have protective renal effects.	Rare
Gastroparesis	Delayed gastric emptying can increase aspiration risk during anaesthesia. Surgeons increasingly ask patients to pause GLP-1s before procedures.	Uncommon

around meals. FDA approval is anticipated before the end of June 2026.

Beyond weight loss: A broader therapeutic horizon

What has made GLP-1 drugs genuinely remarkable is the expanding list of conditions they appear to influence. A comprehensive study by Washington University in St Louis, analysing de-identified medical records from the US Department of Veterans Affairs, mapped GLP-1 associations across all organ systems and found a sweeping range of effects.

The drugs were linked to reduced risks of seizures, substance addiction (alcohol, cannabis, opioids), suicidal ideation, self-harm, and neurocognitive disorders including Alzheimer's and dementia. Researchers believe this may be because the drugs act on brain receptors involved in impulse control, reward, and addiction pathways.

> "South Asians experience heart attacks nearly six years earlier than many other populations. Waist circumference and waist-to-hip ratio provide a more accurate risk picture than BMI alone."
> — Indian Cardiologist Consensus Panel, Mumbai, October 2025

The cardiovascular benefits are now firmly established. The SELECT trial confirmed significant reductions in heart attacks, strokes, and cardiovascular death. Newer research suggests benefits for heart failure with preserved ejection fraction (HFpEF), kidney disease, liver disease (MASH/NAFLD), and even osteoarthritis — a March 2026 study published in *Cell Metabolism* showed semaglutide increased cartilage thickness by approximately 17 per cent over 24 weeks.

However, the magnitude of most non-weight-related benefits is modest — roughly a 10–20 per cent reduction in risk for most conditions — suggesting these drugs work best alongside lifestyle changes and other treatments, rather than as standalone miracle cures.

The side effect profile

■ **Common side effects:** Gastrointestinal issues dominate the side effect landscape. In clinical trials, approximately 74 per cent of semaglutide participants and 78–82 per cent of tirzepatide participants reported at least one adverse event, with nausea, diarrhea, vomiting, and constipation being the most frequent. These are mostly mild-to-moderate, transient, and concentrated during the dose-escalation period. About four to eight per cent of participants discontinued treatment due to GI side effects.

Encouragingly, these effects diminish over time. In a 12-month real-world study, the proportion of participants reporting no side effects increased from approximately 42 to 60 per cent for tirzepatide and from 54 to 68 per cent for semaglutide. The body appears to adapt.

■ **The weight regain problem:** Perhaps the most important long-term concern is not a side effect per se, but a consequence of discontinuation. Studies consistently show that stopping semaglutide or tirzepatide results in significant weight regain and regression of metabolic improvements. In the STEP 4 study, participants who

switched to placebo after 20 weeks regained an average of 6.8 per cent of body weight. This raises a fundamental question about whether GLP-1 therapy is a lifelong commitment — with corresponding lifelong costs.

India's generic tsunami

On March 21, 2026, Novo Nordisk's patent on semaglutide expired in India. The timing is significant: by end of 2026, core patents will have expired in 10 countries representing 48 per cent of the global obesity burden, including Brazil, China, South Africa, Turkey, and Canada. In the US, UK, and most of Europe, patent protection extends until 2031 and beyond. India is the first major test case for what a post-patent semaglutide world looks like.

■ **The numbers:** More than 40 Indian pharma companies have launched or are preparing over 50 branded generic versions. The major players include Sun Pharma (Noveltreat, Sematrinity), Dr. Reddy's (Obeda), Zydus Lifesciences (Semaglyn, Mashema, Alterme), Natco Pharma with Eris Lifesciences (Semanat, Semafull, Sundae), Glenmark (Glipiq), and Mankind Pharma (Samakind).

Importantly, tirzepatide (Mounjaro) is a different molecule and is not affected by the semaglutide patent expiry. Eli Lilly's patent remains intact, but the availability of generic semaglutide at a fraction of the cost will exert enormous downward pressure on tirzepatide's pricing in India.

■ **Market opportunity**: India's obesity drug market is projected to grow from approximately ₹15 billion today to ₹50–80 billion ($530–856 million) by 2030, according to estimates from CareEdge Ratings and Pharmarack. The GLP-1 segment reached approximately ₹1,446 crore in the twelve months leading up to February 2026, with Eli Lilly's Mounjaro commanding over 60 per cent market share.

The South Asian data gap

One of the most consequential issues underlying India's GLP-1 adoption is the relative scarcity of population-specific clinical data. The landmark trials that established these drugs' efficacy and safety were conducted predominantly in Western populations.

The SELECT cardiovascular outcomes trial enrolled participants who were 84 per cent white and only eight per cent Asian. Crucially, it did not study people below BMI 27 — precisely where cardiometabolic risk concentrates for South Asians, who develop heart disease, diabetes, and metabolic syndrome at significantly lower BMI levels than Western populations.

Several India-specific studies have begun to fill this gap, though they remain limited in scale:

■ **PIONEER 6 Trial:** Included 206 participants from India within the global cardiovascular safety trial for oral semaglutide, establishing CV safety but not providing India-specific efficacy data.

■ **PIONEER REAL India:** A 34–44-week, multicenter, non-interventional study of oral semaglutide in Indian adults with type 2 diabetes. Researchers noted that Indians' greater predisposition to central abdominal fat accumulation at lower BMI and heightened insulin insensitivity could influence treatment effects.

■ **SOLID Study:** A prospective study across eight Indian centres evaluating 152 patients over 12 months found significant improvements in glycaemic parameters and weight reduction.

■ **Max Hospital Delhi (Real-World):** A retrospective study found oral semaglutide effective for HbA1c and weight reduction, but GI side effects were notably frequent — 52.4 per cent of patients experienced them, and 9.7 per cent discontinued treatment.

A narrative review published in *Cureus* in July 2025 specifically examining safety in Asian populations found a dose-dependent increase in gastrointestinal adverse events among Asians compared to non-Asians, suggesting that lower starting doses might be preferable. This has direct implications for how generics are prescribed in India.

Product	Monthly Cost	Reduction
Branded Ozempic (Novo Nordisk)	₹8,800 – ₹11,175	Baseline
Branded Wegovy (Novo Nordisk)	Up to ₹16,400	Baseline
Generic — Pen Device	₹4,000 – ₹4,500	~50–60%
Generic — Multi-Dose Vial	₹1,290 – ₹1,750	~85–90%

The bigger question is whether India can build the clinical infrastructure and regulatory oversight to ensure this massive wave of adoption happens safely

The adoption outlook: India's GLP-1 future

The trajectory of GLP-1 adoption in India will be shaped by forces fundamentally different from those in Western markets. Understanding these dynamics is essential for anyone — from pharma executives to public health policymakers — trying to forecast what comes next.

■ **The urban-first funnel:** Even at ₹1,290 per month for generic vials, annual treatment costs of approximately ₹15,000 remain meaningful in a country where median household income hovers around ₹2.5–3 lakh. Initial adoption will be concentrated among urban, upper-middle-class populations in metros and tier-1 cities: Delhi, Mumbai, Bangalore, Hyderabad, Pune, and Chennai. These are the same demographics that already invest in gym memberships, wellness apps, and private healthcare.

■ **The cosmetic use risk**: India already has a massive, largely unregulated weight-loss industry. With 50+ generic brands flooding the market and enforcement historically uneven, semaglutide risks becoming the new "lifestyle drug" in urban India — prescribed liberally for people who don't meet clinical thresholds. Aggressive marketing through Instagram, telehealth platforms like Tata 1mg and Practo, and wellness clinics repositioning themselves as "metabolic health" centres will accelerate this trend. The fact that many generic brands are incorporating "sema-" into their names signals direct consumer marketing is a core strategy.

■ **The doctor bottleneck:** India's prescription drug market is physician-driven, and most endocrinologists and diabetologists are concentrated in urban areas. For the first 12–18 months, adoption will be gated by physician familiarity and confidence with individual brands. This functions as both a bottleneck and a natural quality filter — doctors will gravitate toward generics from trusted manufacturers, and weaker players with poor-quality products will struggle. Industry analysts expect the market to consolidate around 10–15 serious players within two to three years.

■ **Diabetes first, obesity second**: Unlike the US, where the GLP-1 narrative has been primarily about weight loss, Indian adoption will follow the diabetes pathway first. The country has over 77 million diagnosed diabetics, an established treatment culture around injectable insulin and oral medications, and existing insurance frameworks (where they exist) that cover diabetes treatment more readily than obesity. Semaglutide will be positioned as a superior diabetes drug that also helps with weight — rather than a weight-loss drug that also helps with diabetes. The obesity indication will expand over time as awareness grows and prices continue to decline.

■ **The infrastructure gap:** Effective GLP-1 therapy requires more than just the drug. Proper use demands regular monitoring — blood sugar tracking, kidney function tests, thyroid monitoring, and dietary guidance. In urban India, this ecosystem exists through private hospital networks and diagnostic chains like Thyrocare and Metropolis. In tier-2 and tier-3 cities and beyond, it remains thin. Without adequate monitoring infrastructure, higher rates of adverse events are likely — particularly given Asian populations' documented higher GI sensitivity — which could generate negative word-of-mouth and slow broader adoption.

■ **The competitive dynamic:** Mounjaro (tirzepatide) currently holds over 60 per cent of India's GLP-1 market share, and its patent is intact. The sudden availability of generic semaglutide at a fraction of the cost creates a direct competitive threat. Eli Lilly will likely respond with aggressive price cuts or expanded patient support programmes. The resulting competition is excellent for patients but creates a confusing treatment landscape that requires strong physician guidance to navigate.

A projected adoption timeline

■ **Near term: 2026 — The rush and the reckoning:** Expect an initial market rush followed by rapid consolidation. Over 50 brands will overwhelm prescribers with aggressive marketing campaigns. Early uptake will be concentrated in metros, driven by telehealth platforms and social media awareness. There will likely be adverse event reports in media — in-

evitable with poorly supervised mass uptake — which will temporarily dampen enthusiasm and force regulatory attention. Doctors will begin defaulting to five to eight trusted brands.

■ **Medium term: 2027–2028 — Structured growth:** Medical guidelines specific to Indian BMI thresholds and South Asian metabolic profiles will be formalised. Telehealth and e-pharmacy platforms will become major distribution channels. Corporate wellness programmes may begin covering GLP-1s for employees. The market consolidates to 10–15 serious players. Large-scale, India-specific clinical studies begin reporting results, enabling more nuanced prescribing.

■ **Longer term: 2029–2030 — Mass market penetration:** Prices drop further as competition intensifies, potentially reaching ₹500–800 per month for vials. Tier-2 cities see significant adoption. If the mid-2026 U.S. Medicare/Medicaid GLP-1 pilot proves successful, it could influence Indian government health schemes (Ayushman Bharat) to consider coverage. India-specific clinical data matures. The market reaches ₹50–80 billion.

The global play: India as GLP-1 generic hub

Perhaps the most consequential long-term implication extends beyond India's domestic market. By end of 2026, semaglutide patents expire in countries representing 48 per cent of the world's population and an estimated 33 per cent of global adult obesity. Indian pharmaceutical companies are uniquely positioned to serve these markets — mirroring the role they played in the HIV antiretroviral revolution that transformed global access to AIDS treatment.

Dr. Reddy's has already announced plans to launch its generic semaglutide in Canada by May 2026. Lupin signed an exclusive licensing agreement with China's Gan & Lee Pharmaceuticals for a novel GLP-1 receptor agonist. Biocon has been building a biosimilar pipeline in this class. Zydus has partnered with both Lupin and Torrent Pharmaceuticals for domestic and international distribution.

The domestic adoption story is significant, but the export opportunity could be transformative for Indian pharmaceutical revenues on a scale not seen since the generic HIV drug era.

Conclusion: A cautious revolution

The GLP-1 drug class represents one of the most significant pharmaceutical developments of the 21st century — a genuine advance in treating obesity and diabetes as the chronic, interconnected diseases they are. India's patent expiry and generic revolution accelerate the story dramatically, bringing a drug class once confined to the affluent within reach of millions.

But the narrative of unbridled optimism requires tempering. The clinical data on South Asian populations remains limited. The infrastructure for safe, monitored prescribing is unevenly distributed. The risk of cosmetic misuse in an unregulated market is real. And the fundamental question of whether these are lifelong medications — with corresponding lifelong costs — remains unanswered.

What is clear is that India's experience over the next two to three years will serve as a template for the rest of the developing world. How the country navigates the tension between access and safety, between market opportunity and public health responsibility, will determine whether the GLP-1 revolution delivers on its extraordinary promise — or becomes a cautionary tale about the gap between pharma innovation and healthcare infrastructure.

DISCLAIMER: This article is for informational purposes only and does not constitute medical advice. GLP-1 receptor agonists are prescription medications with significant side effects and should only be used under medical supervision. Consult a qualified healthcare professional before making any treatment decisions. The market projections and adoption timelines discussed are analytical estimates and should not be construed as investment advice.

India's biogenerics moment: Shaping the future of affordable biologic care

India's biogenerics sector is emerging as a key driver of affordable biologic therapies, supported by strong regulatory frameworks and growing manufacturing capabilities. **Dr Syed S Abbas**, Director, IGMPI highlights how India is positioning itself as a global leader in accessible, high-quality biologic care

The rise of generic medicines has changed the economics of healthcare worldwide. By offering identical versions of chemical drugs at lower prices, generics succeeded in making essential treatments affordable for millions of patients. But this cost-effective model could not be replicated easily in biologic medicines, even though they are essential for complex therapies such as cancers, autoimmune conditions, and other serious diseases.

Biologic drugs are large molecules having intricate structures and sensitive manufacturing processes. Producing the exact molecule is scientifically impossible, as even a small variation can influence the final product. Out of this challenge emerged the biosimilar, answering the demand for a biogeneric solution. They are stated as "similar" because exact copies are not feasible, but equivalence in benefit is achievable.

With the development of biosimilars, some of the most expensive treatments in modern medicine are becoming more affordable and accessible. This move has modified how advanced treatments reach patients across healthcare systems.

The biosimilars required a sophisticated regulatory vision, as the conventional drug laws designed for small-molecule generics could not address the complexity of biologic medicines. India recognised this early and introduced one of the world's first dedicated frameworks for biosimilars in 2012. The guidelines were jointly issued by the Central Drugs Standard Control Organisation and the Department of Biotechnology to define how similarity in quality, safety, and efficacy should be scientifically demonstrated.

2016 onwards, revisions in the policy and law have strengthened this framework and aligned with the World Health Organization along with other major regulators. Over time, India put practical rules in place for comparability testing, clinical assessment, and post-marketing safety monitoring. National efforts such as the Pharmacovigilance Programme of India, together with routine compliance with Good Manufacturing Practices, support the quality and safety of biosimilars. This has helped India gain recognition not just for producing affordable medicines, but also for developing more mature and credible regulations for biologics.

Putting regulations in place was only an initial step. What really matters is showing, in practice, that similarity with a reference biologic also leads to comparable safety and clinical benefit. Because of this, biosimilars are first examined through detailed analytical studies and then assessed in clinical settings to ensure that treatment outcomes do not differ in any meaningful way. As experience has grown, national guidelines have been revised to spell out expectations for quality testing, manufacturing controls, and safety follow-up. Ongoing post-marketing surveillance under the Pharmacovigilance Programme of India plays an important role in identifying safety signals that may appear only after wider use. This continuing evidence base has helped biosimilars

gain acceptance beyond regulatory approval and into regular clinical practice.

Biosimilars increased access to advanced therapies and manufacturing capabilities. This link between access and technology is most visible in India's biopharmaceutical ecosystem. The Production Linked Incentive scheme supports domestic manufacturing of complex biological products, including therapeutic proteins and monoclonal antibodies. This fulfils the basic requirements for biosimilar production. Initiatives such as Make in India and the BioPharma Mission, led by the Department of Biotechnology, are expanding research and manufacturing capacity for biologics through focused clusters in Hyderabad, Bengaluru, and Pune.

According to official communications, more than Rs 1,00,000 crore has been allotted to the biopharma and life sciences ecosystem to emphasise research infrastructure, skilled labour, manufacturing scale, and regulatory science. Since biosimilars rely on the same depth, consistency, and quality systems, their effects naturally extend to biopharmaceuticals, even though these measures are intended to strengthen the larger biopharmaceutical ecosystem.

These targeted efforts have helped Indian manufacturers to build one of the world's largest biosimilar portfolios. Affordable biologic therapies produced in India now has a international reach, expanding its image of "Pharmacy of the World" in biological care also.

Scientific progress must be followed by acceptance of the products in the real world among medical practitioners. The last mile success of biosimilars depends on enhanced familiarity with the science behind these therapies and reduced safety concerns among physicians and patients.

To deal with this gap, awareness building became part of the wider pharma approach rather than a separate activity. The Pharmacovigilance Programme of India was expanded to cover biologics and biosimilars as well, allowing safety information from this sensitive area to be reported as it emerges in real-world use. At the same time, prescribing practices are being shaped through medical education initiatives, many of which are supported by the Department of Biotechnology and professional associations. Together, these efforts are gradually moving practice away from cautious hesitation toward informed and evidence-based use, helping align scientific oversight with public confidence.

Biosimilars are hard to regulate because they are not simple copies. Unlike chemical drugs, biologics depend heavily on how they are made. Even small changes in cell sources or manufacturing steps can change the final product, which is why extensive testing cannot be avoided. For manufacturers, the real challenge is handling this complexity without driving up costs.

Global standardisation and regulatory harmonisation of biogenerics is a continuous process. Evolving approval pathways and data requirements limits acceptance. The cost of therapy must balance affordability for patients and sustainability for producers to achieve consistent clinical assurance and scientific progress. Addressing these challenges will determine how fully biosimilars can deliver on their promise of equitable, high-quality healthcare.

The evolution of biogenerics is a turning point in modern medicine, as it introduced affordability via innovation, as the global health community recognises biosimilars as essential to sustainable healthcare systems.

Having established one of the earliest and most structured frameworks for biosimilars, India has shown that the nation can lead not only in manufacturing but also in regulatory and scientific maturity. Its experience offers lessons in positioning evidence-based regulation with industrial capacity and access-driven health priorities.

As biologic therapies become life-saving and critical in disease management, the role of biogenerics becomes important. India's journey made the world understand that the future of healthcare equity lies not only in discovering new cures but also in ensuring that proven therapies reach those who need them the most.

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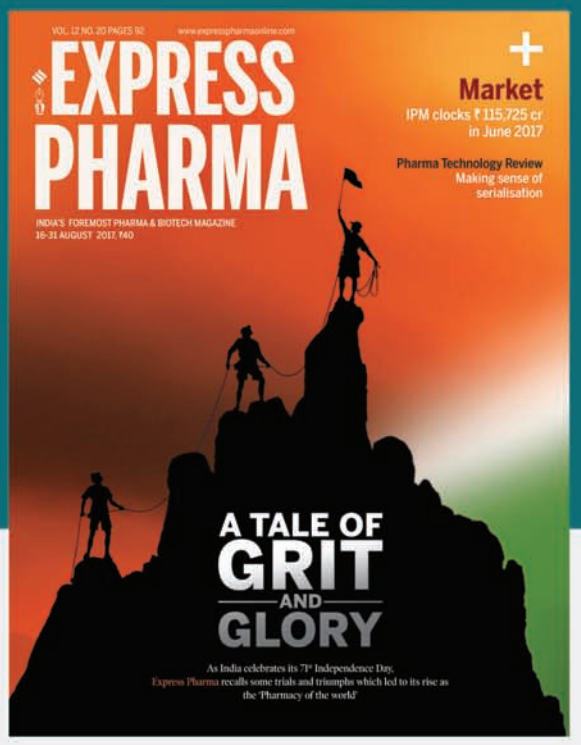

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PATENT EXPIRIES AHEAD

IS INDIA PHARMA INC READY?

Beyond the semaglutide momentum, a larger wave of patent expiries is set to unfold between 2026 and 2032. For Indian pharma, the opportunity is significant, but so are the risks. Experts weigh in on what it will take to succeed

Patent cliff to drive next phase of growth for Indian pharma industry

The global pharmaceutical industry is entering a decisive phase, with an estimated $200+ billion worth of blockbuster drugs expected to lose exclusivity between 2026 and 2032. While semaglutide has drawn immediate attention, it is only one part of a much larger structural shift that spans oncology, cardiovascular disease, immunology, and specialty biologics.

For Indian pharmaceutical companies, this is not a cyclical opportunity. It is a strategic inflection point. India's strength has traditionally been anchored in its ability to deliver high-quality, affordable generics at scale. Over the past two decades, this capability has evolved significantly. Today, Indian companies are not only volume-driven manufacturers but increasingly complex product developers with growing expertise in injectables, biosimilars, and regulated market compliance.

The upcoming patent expiries of molecules such as pembrolizumab, apixaban, nivolumab, and daratumumab signal a clear shift towards high-value, specialty-led opportunities. Unlike traditional small-molecule generics, these segments demand deeper scientific capability, robust clinical understanding, and strong regulatory execution. Companies that can invest ahead of the curve in these areas will be best positioned to capture disproportionate value.

Equally important is the export opportunity. As healthcare systems globally face cost pressures, the role of Indian pharma in expanding access to affordable therapies will become even more critical. India already supplies a significant share of the world's generics, and the next phase of growth will be defined by its ability to move up the value chain into complex and specialty products.

At the same time, the domestic market presents a parallel opportunity. As seen with semaglutide, patent expiry can unlock access in therapy areas where affordability has historically limited adoption. This is particularly relevant in chronic diseases such as diabetes, cardiovascular disorders, and cancer, where treatment gaps remain substantial.

However, realising this opportunity will require a balanced approach. Scale must be matched with quality. Speed must be aligned with compliance. And commercial ambition must remain grounded in patient-centricity.

As highlighted earlier, affordability, accessibility, and availability remain the three defining levers of impact in India's healthcare journey . The patent cliff will test how effectively the industry can operationalise these principles across both domestic and global markets.

The opportunity is significant, but it will favour those who are prepared.

US patent cliff (2026–2032) likely to disrupt pharma market

The value at risk is substantial. According to GlobalData's Pharma Intelligence Center, the cumulative sales risk from blockbuster drugs losing patent protection between 2026 and 2032 is estimated to exceed US$200 billion in the US. A total of 33 blockbuster biologics and 28 blockbuster small molecule drugs are expected to lose patent protection during this period. The opportunities arising from the expiration of blockbuster biologic drugs are projected to exceed US$137 billion, while those from small molecule blockbuster drugs are expected to surpass US$63 billion.

Some of the leading biologics set to expire include Dupixent, Keytruda, Wegovy, and Opdivo. Similarly, notable small molecule drugs include Kisqali, Jakafi, Erleada, and Eliquis. Indian firms, such as Biocon Biologics, are developing biosimilars for Opdivo, Keytruda, Herceptin, and others. Zydus Lifesciences has secured rights for a Keytruda biosimilar with the aim of commercialising it in the US and Canada.

Major US payers and formulary systems are becoming increasingly receptive to biosimilars and generics, particularly for expensive biologics and oncology drugs, especially as drug prices and healthcare costs come under scrutiny.

The US patent cliff between 2026 and 2032 is likely to significantly disrupt the pharmaceutical market. For Indian pharmaceutical companies, this represents a generational opportunity to make substantial inroads—from generics and complex generics to biosimilars, particularly in oncology and immunology—if they can meet the necessary quality, regulatory, and commercial benchmarks. While the groundwork is being established, the speed, scale, and strategic focus will determine how much of this opportunity India can capture.

Historically, Indian companies have dominated the generics market in the US due to their strong capabilities in small molecule chemistry, process development, and cost-efficient manufacturing.

However, their presence in the biosimilars market is relatively limited, with Biocon being a major player from India in the US. The limited presence in the biosimilars space can be attributed to the need for advanced manufacturing capabilities, clinical comparability trials, and significant capital investment for the development and manufacturing of biosimilars.

Given the sales risk associated with blockbuster biologics and small molecules between 2026 and 2032, biosimilars present a greater opportunity compared to generics. Therefore, it is crucial for Indian companies to enhance their market position within the biosimilars market as well.

The upcoming patent cliff is not merely a volume opportunity it represents a strategic inflection point

The wave of patent expiries expected between 2026 and 2032 represents one of the most significant opportunities for the global generics industry. While much of the current focus is on semaglutide and the rapidly expanding GLP-1 market, a broader set of blockbuster molecules across oncology, immunology and diabetes are expected to lose exclusivity over the next few years.

Drugs such as pembrolizumab, apixaban and palbociclib are among several high value therapies approaching patent expiry. Collectively, these therapies represent billions of dollars in annual global sales, creating a large opportunity for companies that possess scientific, manufacturing and regulatory capabilities.

Indian pharmaceutical companies have built a strong reputation over the past two decades as reliable suppliers of high-quality generics to regulated markets. However, the opportunity today is more complex than in earlier patent cycles. Pricing pressure in mature markets such as the United States remains intense, with several molecules experiencing rapid price erosion following multiple generic launches. In many segments of the generics market, annual price erosion in the range of 5–10 percent (many times even significantly higher than this range) has become common due to heightened competition and buyer consolidation.

As a result, companies are increasingly shifting toward complex generics and specialty formulations, where entry barriers are higher and competition is relatively limited. These include areas such as respiratory inhalers, long-acting injectables, drug-device combinations and ophthalmic products.

Biosimilars are another important growth area, particularly in therapeutic segments such as oncology, immunology and diabetes. Biosimilars of widely used biologics such as trastuzumab, bevacizumab, insulin glargine and adalimumab are expanding access to advanced therapies while also creating new growth avenues for manufacturers with strong biologics capabilities.

Strategic partnerships are also becoming an important part of the industry's evolution. Increasingly, companies are collaborating with global biotechnology firms and research organisations to co-develop complex therapies, accelerate regulatory approvals and expand commercial reach across markets.

At the same time, companies are diversifying geographically beyond traditional markets into Europe, Japan, Latin America, Southeast Asia and the Middle East, where demand for affordable specialty medicines and biosimilars are growing.

Ultimately, the upcoming patent cliff is not merely a volume opportunity it represents a strategic inflection point. Companies that combine scientific capability, regulatory strength and disciplined portfolio choices will be best positioned to capture value and strengthen India's role as a global leader in affordable and complex medicines.

This is only the beginning of a much larger global patent-cliff cycle

As the patent expiry of semaglutide is almost there in India, several Indian pharma firms are preparing to introduce generic versions, highlighting the sector's agility in responding to high-value loss-of-exclusivity opportunities. However, this is only the beginning of a much larger global patent-cliff cycle expected in next 5-6 years, when numerous blockbuster drugs across the therapies are set to lose exclusivity. Indian pharmaceutical companies are strongly positioned to capture a meaningful share of this opportunity due to their globally recognised generics manufacturing base, cost-efficient chemistry capabilities, and large number of USFDA-approved production facilities. Over the past decade, the industry has also steadily strengthened its R&D capabilities and regulatory expertise, enabling faster filings and quicker entry into regulated markets when patents expire.

Importantly, the next phase of the patent cliff will increasingly favour companies that can develop complex generics and specialty formulations rather than simple dosage forms. Many upcoming opportunities lie in areas such as sterile injectables, peptides, inhalation products and biosimilars, which require advanced manufacturing capabilities and strong regulatory compliance. Indian pharma companies have already begun investing heavily in these segments, building expertise in complex dosage forms and strengthening global supply chains to serve both regulated and emerging markets. As a result, the industry is transitioning from a volume-driven generics model to a more innovation-led, technology-intensive generics strategy, positioning it well to benefit from the upcoming wave of global patent expiries.

India pharma poised to tap patent cliff with generics and complex drug capabilities

India's pharmaceutical industry is well positioned to capitalise on the upcoming patent cliff through its strong generics expertise, cost-efficient manufacturing, and expanding capabilities in the manufacturing of complex formulations of small molecules and biologics. As several blockbuster therapies lose exclusivity between 2026 and 2032, Indian generics companies have a significant opportunity to play a larger role in enabling faster, more affordable global access to critical medicines.

Over the past two decades, India has built one of the world's most sophisticated generics ecosystems, supported by a large base of US FDA-approved manufacturing facilities, deep regulatory experience, and strong chemistry and process development expertise. This foundation allows Indian pharmaceutical companies to rapidly develop high-quality generic versions of small-molecule drugs once patents expire, helping healthcare systems manage costs while expanding patient access.

STUART NEEDLEMAN

Chief Commercial Officer & Chief Patient Centricity Officer, Piramal Pharma Solutions

At the same time, the nature of drugs approaching the patent cliff is evolving. Many upcoming opportunities involve complex formulations, highly potent APIs, peptide-based therapies, and biologics rather than traditional small molecules. Indian pharmaceutical companies have increasingly invested in advanced manufacturing technologies, high-potency containment, and specialised development capabilities to support these more sophisticated therapies. These investments are positioning the industry to move beyond traditional generics and participate in higher-value segments of the market.

Contract development and manufacturing organisations (CDMOs) will also play a critical role in this landscape. As innovator and emerging biotech companies seek to bring follow-on products and alternative formulations to market quickly and efficiently, experienced partners with global regulatory track records become essential.

By combining manufacturing scale with growing innovation and technical expertise, well-established Indian CDMOs such as Piramal Pharma Solutions can support partners across the development and commercialisation lifecycle. From complex API development and advanced drug product manufacturing to specialised capabilities such as antibody-drug conjugates and high-potency compounds, these partnerships can help accelerate the delivery of high-quality, affordable medicines to patients worldwide.

Future opportunities in biologics and biosimilars will demand significant investment

Semaglutide's patent expiry in India in March 2026 has become the immediate trigger for the next wave of pharmaceutical development activity, but the larger opportunity goes well beyond semaglutide itself. Semaglutide is the molecule behind Ozempic and Wegovy, and its loss of exclusivity in markets like India is only the beginning of a broader patent-cliff cycle that will unfold across small molecules, peptides, complex injectables, device-led products and, later, biologics.

India is well positioned to benefit from this cycle because of its strong manufacturing base, cost competitiveness and long experience with regulatory filings in the US, EU and ROW markets. However, the opportunity today is very different from the traditional generics cycle. Many of the upcoming products involve complex delivery systems, peptides, advanced injectables or biologics, which require deeper scientific capabilities and significantly higher investment in development and analytical infrastructure.

SAURABH AGARWAL

Director at HAB Pharma

In conventional small molecules, companies with strong formulation capability, filing experience and cost discipline can move quickly. For example, molecules such as Eliquis (apixaban) and Entresto represent important future opportunities, although timelines and market entry strategies can vary due to litigation, exclusivity provisions and regulatory pathways.

The next layer of opportunity lies in more complex therapies. Products such as semaglutide require peptide chemistry expertise, formulation stability work, device strategy and strong regulatory planning. Similarly, future opportunities in biologics and biosimilars will demand significant investment in analytical characterisation, process development and manufacturing infrastructure.

At HAB Pharmaceuticals, we see this patent-cliff cycle as a long-term capability-building opportunity rather than a short-term launch cycle. We are currently setting up a new R&D centre in Vasai specifically focused on developing future off-patent molecules for India, ROW and regulated markets including Europe. Our development programs will focus on oral solids, complex injectables, peptides and device-led combination products, while we are also building early capabilities in monoclonal antibody development for the future.

At the same time, some caution is necessary. Every high-value molecule that goes off patent tends to attract a large number of entrants very quickly, which can lead to intense competition and margin compression. Therefore, the companies that ultimately succeed in this next phase will be those that combine cost competitiveness with the ability to develop complex products and maintain high regulatory standards over the long term.

Safeguarding the pharma excipients supply chain

Adding excipient details to QR codes of the top 300 drugs may not be a tough task. But as CDSCO plans to expand QR codes to cover other critical drug categories in phases, all segments of the pharma value chain need to tighten their systems, analyses Viveka Roychowdhury

From March 1 this year, the Quick Response (QR) Codes or barcodes on the labels of the top 300 medicine brands in India have to include "qualitative details" of excipients used during the making of these products. This amendment to the Sub-Rule 7 of Rule 96 of the Drugs Rules, 1945, sometimes referred to the QR code amendment, is part of the larger regulatory reform rolled out by the Central Drugs Standard Control Organization (CDSCO) in December 2023, which resulted in the revised Good Manufacturing Practice norms under Schedule M.

Though the QR code amendment might seem routine, it is anything but.

In a recent blog post, titled, Advanced excipients: India's gate to high-value drug formulation, Saransh Chaudhary, President – Global Critical Care,Venus Remedies and CEO,Venus Medicine Research Centre (VMRC) explains the significance thus, "For the first time, excipients are moving from the background to the foreground of regulatory scrutiny. Ingredients once treated as passive "fillers" are now central to how India will be judged on transparency, safety and quality. In that sense, excipients are no longer peripheral. They are becoming one of the levers that can shape India's future competitiveness in complex formulations." *(https://www.expresspharma.in/advanced-excipients-indias-gate-to-high-value-drug-formulation/)*

Looking at "regulation as a catalyst, not a constraint", Chaudhary's article points out how the revised Schedule M guidelines, together with the broader quality framework under ICH Q8, Q9, Q10 and Q12, are reshaping how Indian manufacturers think about quality by design. "The new excipient labelling mandate under Rule 96 adds another layer of discipline. Requiring the qualitative disclosure of excipients on the innermost container for relevant products is more than a labelling change. It improves traceability, strengthens pharmacovigilance and makes it easier for regulators, prescribers and patients to understand what goes into a medicine. Over time, this can help build trust in Indian brands in both domestic and export markets."

There are plans to expand QR code requirements beyond the top 300 brands. Future phases are expected to cover critical categories such as narcotic and psychotropic substances (NDPS), vaccines, anti-cancer drugs and anti-tubercular medicines. Implementation will likely occur in a phased manner through further amendments or administrative orders

Dr Santosh Indraksha
Deputy Drugs Controller (India), CDSCO, DGHS, Ministry of Health and Family Welfare, Government of India

For the first time, excipients are moving from the background to the foreground of regulatory scrutiny. Ingredients once treated as passive "fillers" are now central to how India will be judged on transparency, safety and quality. In that sense, excipients are no longer peripheral. They are becoming one of the levers that can shape India's future competitiveness in complex formulations

Saransh Chaudhary
President – Global Critical Care, Venus Remedies and CEO, Venus Medicine Research Centre (VMRC)

At present, there is no specific CDSCO or Drugs Rules provision that itemises, in a detailed matter, what precise 'details of excipients' must be provided or encoded for purposes of the QR Code Rule requirement. The amendment simply adds a requirement to capture 'qualitative details of excipients', without further sub-categorisation. Such generalisation of requirements in labeling often results in wide ambiguity as to the actual purpose for which the requirement was intended

Ashishchandra Rao
Partner, Economic Laws Practice

The trigger for change

Excipients have proved untrustworthy in the recent past. Cough syrups containing non-medical grade diethylene glycol (DEG) and ethylene glycol (EG) have been linked to the deaths of more than 140 children in India, Gambia, and Uzbekistan. Last year, DEG was linked to the deaths of 22 children in Madhya Pradesh.

Referencing these instances, Rishi Agrawal, Co-Founder and CEO, TeamLease RegTech opines that repeated violations in India's pharma ecosystem are rooted in predictable blind spots rather than isolated misconduct. He highlights weak raw material governance, particularly in excipient procurement, pointing out that DEG/EG contamination episodes have consistently traced back to inadequate supplier qualification and insufficient incoming material testing.

Clearly, the QR code amendment aims to weed out the use of unsafe excipients from underqualified

suppliers. The resulting reputational loss, threat to India's image as the "pharmacy of the world", and negative impact on pharma exports, has also triggered questions in Parliament, putting pressure on regulators to crack down and institute reform.

As Ashishchandra Rao, Partner, Economic Laws Practice recalls, "The government in answering questions in Rajya Sabha Unstarred Question No. 293 (02 December 2025) and Lok Sabha Unstarred Question No. 293 (13 February 2026) mentioned that the QR Code Rule is a regulatory and enforcement measure after the deaths caused due to cough syrup counterfeits."

Emphasizing the rationale, Rao says, "The main aim for including details of excipients within QR codes/barcodes is patient safety. Adverse reactions can arise from excipients such as parabens, dyes, or lactose, rather than the active drug. Hence, the 2025 amendment requires QR Codes on Schedule H2 drugs to include qualitative excipient details, enabling users to access this information as full lists cannot fit on small packages."

Other obvious goals are increased transparency and pharmacovigilance. Rao points out, "The QR Code reduces information gaps about drug formulations. It is also easier for regulators to find batches if there is a safety issue when they record excipient details at the pack level. This lets them do more focused investigations or recalls. The requirement also builds on India's existing QR-based track and trace system for the top 300 brands, which is meant to make the supply chain more visible and curb the counterfeit drugs menace."

Repeated violations in India's pharmaceutical ecosystem are rooted in predictable blind spots rather than isolated misconduct. The first is weak raw material governance, particularly in excipient procurement. DEG/EG contamination episodes have consistently traced back to inadequate supplier qualification and insufficient incoming material testing

Rishi Agrawal
Co-Founder and CEO, TeamLease RegTech

From a policy standpoint, enabling QR codes to link to centralised digital repositories and issuing clear guidance on qualitative disclosure will further strengthen this initiative while reducing compliance burden. Overall, this is a progressive move that elevates India's pharmaceutical quality standards globally. As both Secretary of IPEC India and CEO of Nitika Pharma, I believe close collaboration between regulators and industry will be key to ensuring that this initiative delivers real value for patient safety, supply chain transparency and global competitiveness

Dr Ravleen Singh Khurana
Secretary, IPEC India and CEO, Nitika Pharma

Policy in practice

How prepared are pharma companies to implement this new mandate, given that they have had six months to comply?

Dr Ravleen Singh Khurana, Secretary, IPEC India and CEO, Nitika Pharma applauds the policy saying, "The amendment to Rule 96(7), effective March 1, 2026, is a significant and timely step toward strengthening transparency and patient safety in India's pharmaceutical sector. While the mandate is directed at finished dosage manufacturers, excipient manufacturers are central to making this initiative meaningful and implementable. We are already seeing our customers — pharma companies, CDMOs and bulk drug manufacturers — seeking greater traceability, standardised excipient identification and more structured technical documentation. At Nitika Pharma, we have proactively begun aligning our systems to support this shift, as we believe excipients are not just inactive ingredients but critical contributors to drug quality and performance."

He however cautions that implementation will require careful calibration. "Challenges such as non-standardised excipient nomenclature, complex multi-excipient formulations, and digital readiness — particularly among smaller manufacturers — need practical regulatory guidance. A phased rollout and harmonised naming framework would significantly ease adoption across the industry," is his recommendation. Looking ahead, Dr Khurana says, "From a policy standpoint, enabling QR codes to link to centralised digital repositories and issuing clear guidance on qualitative disclosure will further strengthen this initiative while reducing compliance burden. Overall, this is a progressive move that elevates India's pharmaceutical quality standards globally. As both Secretary of IPEC India and CEO of Nitika Pharma, I believe close collaboration between regulators and industry will be key to ensuring that this initiative delivers real value for patient safety, supply chain transparency and global competitiveness."

An industry expert from Merck points out, "The March 1, 2026 Gazette Notification under Rule 96(7) of the Drugs & Cosmetics Rules, 1945 requires manufacturers of specified Schedule H2 finished drug formulations (as listed by CDSCO) to include qualitative details of excipients in the QR code or barcode on the product label (primary packaging, or secondary packaging where space is limited). In practice, implementation of this labelling requirement sits with the manufacturers of the relevant finished formulations; excipient suppliers are not required to add QR or barcode information under this mandate. Excipient suppliers can support pharmaceutical manufacturers by ensuring excipient quality through rigorous testing, consistent manufacturing processes, and adherence to international pharmacopeial standards, and by providing documentation that supports transparency and traceability across the supply chain."

One segment of India's pharma brands might find it easier to comply. As Rao analyses, "The top 300 Indian drug brands under Schedule H2 (top 300 brands) of the Drugs Rules, 1945, (Drugs Rules) were already required to print bar codes and QR codes on their labels carrying eight core data points such as product and manufacturer identifiers, batch number and expiry date, under Rule 96 (7) of the Drugs Rules since 2023 (QR Code Rule). A new coding obligation is not created under the Drugs (Second Amendment) Rules, 2025, rather it extends this existing framework by requiring manufacturers of Schedule H2 formulations to also encode the qualitative details of excipients used in each product. Hence the further obligation is with respect to the data and not the hardware."

To comply with these rules, Rao says most pharma companies have preferred to print a dynamic QR code i.e., a link to a webpage on the packaging as opposed to a

static QR code. This does not add any additional costs for pharma companies already complying with the QR Code Rule as the details of the excipients can be updated on the webpage link and the printed QR code need not be changed. According to him, with regards to printing the QR Code itself, bigger domestic and multinational manufacturers are better able to comply with the QR Code Rule.

A widening regulatory divide?

Given that regulatory oversight is set to increase, will such amendments widen the divide between larger pharma companies which already comply with the previous mandate for the top 300 brands, while pharma MSMEs struggle to comply?

For instance, Rao draws attention to a further Notification G.S.R. 173(E) dated March 9, 2026, Draft Rules published by the Ministry of Health and Family Welfare (Department of Health and Family Welfare) for the proposed amendment of the Drugs and Cosmetics Rules, 1945 whereby in Rule 74 of the Drug Rules, sub rule g(i) to g(vii) are to be inserted. As per the proposed amendment, manufacturers are to now notify the licensing authority in writing of any changes in the manufacturing process, 'excipients', packaging, shelf life, specifications, testing or documentation.

He explains that this is an additional safeguard proposed to be added as dynamic / webpage-based QR Codes can be updated unilaterally and very easily, leaving changes only at the level of the webpage and would effectively move excipient control 'off-label' and outside the regulated approval/variation system.

TeamLease RegTech's Agrawal opines that India's pharma regulation is moving towards enforcement-led control owing to the risk to life, triggered by repeated incidents of contamination with DEG/EG which hampered India's credibility as a global supplier.

He also points out that quality failures escalate because regulatory information and operational response are disconnected. He advocates the use of digital compliance infrastructure to bridge that gap by converting regulatory change into executable workflows. He suggests that a structured compliance platform integrated with notifications from the CDSCO and state regulators can trigger automated alerts for banned formulations, labelling changes, or revised Schedule M requirements. At the manufacturing level, digital tracking of excipient sourcing, vendor qualification and batch-level testing can create real-time exception reporting, reducing dependency on post-facto audits.

Industry feedback

As per ELP's Rao, "Industry representatives have mostly agreed that starting with the top 300 brands was a good initiative. The popular opinion is that even if QR printing is a big 'change control' in manufacturing processes, it is a way to build the ecosystem before expanding to other areas of industry."

Calling the excipient amendment "a data governance exercise" for manufacturers that have already invested in serialisation, QR printing, and integrated packaging/IT systems to meet both export requirements and the existing Schedule H2 mandate, Rao states that despite official statistics not being available at the moment, a reasonable inference can be drawn from how these companies have handled earlier QR Code Rule compliance.

Rao opines that companies that depend on contract manufacturing are less prepared for the QR Code Rule, recalling that when the top 300 brands rule was introduced, industry commentary noted that small and mid-sized firms would face financial and operational challenges to implement the QR Code Rule. The cost of 2D printers, vision systems, and integrating code-generation software with basic ERPs can be significant and may also slow production lines.

Overall, Rao believes that the sector had a head start on infrastructure but not full compliance. Since 2023, it appears that the top 300 brands have complied with the QR Code requirements. The excipient requirement only adds to the information in those codes starting on August 18, 2025, and companies had until March 1 this year to comply.

However, Rao points out, "CDSCO hasn't made clear adoption data available, which makes it hard to figure out how well everyone is following the rules. Often times, bigger manufacturers are equipped for the implementation, but smaller companies

POLICY IN EVOLUTION

Dr Santosh Indraksha, Deputy Drugs Controller (India), CDSCO, DGHS, Ministry of Health and Family Welfare, Government of India, traces the origin of the amendment to a patient complaint. A patient reported allergic reactions caused by certain excipients—specifically parabens such as methylparaben and propylparaben, which are commonly used preservatives in pharma formulations. The concern extended beyond parabens to other excipients that may cause hypersensitivity or allergic reactions.

Dr Indraksha elaborates that patient groups advocated for greater transparency in drug composition, including listing excipients on packaging—even at the level of individual strips or blister packs. The goal was to empower patients to make informed choices, consult physicians for alternatives, or request substitute medicines from pharmacists if they are sensitive to certain ingredients.

This concern was formally discussed during the 61st Drug Consultative Committee (DCC) meeting held on June 1, 2023. The DCC, a statutory body under the Drugs and Cosmetics Act, deliberates on issues related to uniform implementation of drug regulations across states.

The committee deliberated that details of excipients should be in the package insert of medicines. However, presently there is no provision which makes it mandatory for the manufacturer to provide package inserts along with the drugs manufactured/marked in the country. The criteria to mandate mentioning the details of excipients on the drugs formulations have to be evaluated at length for its implementation. Considering the overall perspective, the DCC recommended issuing an advisory for mentioning the details of excipients on drug formulations by various means/modalities on a voluntary basis.

Dr Indraksha recalls that in the subsequent 62nd DCC meeting held on September 26, 2023, while reviewing the action taken report of 61st DCC for agenda no. 8, DCC recommended that mentioning all the excipients on the product label is a practical challenge and also there is no mandatory requirement. DCC deliberated and suggested capturing this information through the QR code or by capturing this information in a package insert. DCC recommended that GSR 823 (E) dated 17.11.2022 may be amended for capturing the requisite information in the QR code at least for top 300 brands initially.

The proposal was also subsequently deliberated by the Drugs Technical Advisory Board (DTAB), the apex advisory body for drug regulation, in its 90th meeting held on January 25, 2024. The DTAB opined that it is difficult to include the details of all the excipients on every strip of medicine. Further, the Board also suggested preparing a list of excipients causing hypersensitivity which may be considered for mention on the label. However, DTAB agreed to the proposed amendment with respect to capturing the requisite information in QR code for top 300 brands.

Accordingly, the Ministry of Health and Family Welfare published draft amendments in Sub-Rule 7 of the Rule-96 of the Drugs Rules, 1945 vide GSR 391 (E) dated July 12, 2024 inviting the objections/suggestions from the stakeholders. After due consideration of the objections/suggestions, the Ministry published final notification vide GSR 554 (E) dated August 18, 2025, thereby amending the Schedule H2 and making it mandatory to include the "Qualitative details of excipients" in the QR code on the label of top 300 brands. These Rules were made effective from March 1, 2026.

Dr Indraksha clarified that, at present, the requirement applies only to the top 300 brands already mandated to carry QR codes. Similar amendments were also made vide GSR 20 (E) dated January 18, 2022, effective from January 1, 2023 which requires that labels of Active Pharmaceutical Ingredients (APIs) shall bear QR code with requisite information as per Sub-Rule 5 of Rule 96 of the Drugs Rules, 1945.

and brands have trouble with the same."

Ambiguity in the amendment

The QR code amendment also needs more clarifications. Sounding a cautionary note, Rao points out, "At present, there is no specific CDSCO or Drugs Rules provision that itemizes, in a detailed matter, what precise 'details of excipients' must be provided or encoded for purposes of the QR Code Rule requirement. The amendment simply adds a requirement to capture 'qualitative details of excipients', without further sub-categorization. Such generalisation of requirements in labeling often results in wide ambiguity as to the actual purpose for which the requirement was intended."

From a legal and regulatory perspective, Rao posits that the most reasonable reading is that at a minimum, excipient-related information that is functionally analogous to the data fields already prescribed in Rule 96 (7) for the finished formulation i.e., clear identification of the excipient substances used (names/identifiers), sufficient to allow traceability and pharmacovigilance, but not extending to disclosure of proprietary know-how.

A question mark over QR codes

The irony is that counterfeiters have already found ways to subvert QR code based systems. Rao highlights that QR Code technology may not effectively prevent counterfeit medicines and may even create a false sense of authenticity. He points out that counterfeiters have been able to replicate medicine packaging including the QR Code so precisely that scanning the code on fake products can still return a message confirming the pack as genuine.

Giving an example, Rao cites one documented case involving counterfeit versions of an anti-epileptic drug, where each fake blister pack carried a different active QR Code with a unique serial number, meaning that scans did not reveal duplication and instead validated the counterfeit product as authentic.

As he explains, "This suggests that QR Codes, which are relatively easy to replicate or compromise through digital theft of serial-number banks, can be manipulated by sophisticated counterfeiters. As a result, the system may fail to detect fake medicines while misleading consumers and regulators into believing that a counterfeit product is legitimate, thereby undermining the very objective of the policy."

Giving the CDSCO's perspective on this front, Dr Indraksha acknowledges the importance of establishing a robust "parent-child" traceability system, where each unit can be tracked back to its origin. However, efforts made to implement such systems—led not only by regulators but also by the Directorate General of Foreign Trade (DGFT)—have faced resistance. He points out that industry reluctance, particularly among MSMEs, is attributed to the costs and complexity of adopting advanced traceability technologies. As a result, earlier requirements for such systems were withdrawn in 2025 by DGFT.

Policy recommendations to safeguard the pharma excipients supply chain

While regulatory reform signals intent, will intent translate into monitoring and enforcement? As Agrawal stresses, "Regulatory capacity must expand in proportion to industry scale. Oversight of excipient sourcing, testing and certification cannot rely on limited laboratory infrastructure or inspection bandwidth. India requires a stronger network of accredited testing laboratories, trained inspectors and digital monitoring systems capable of tracking high-risk inputs such as solvents and glycerin derivatives across the supply chain."

Secondly, pointing out that regulatory certainty is critical for manufacturers and suppliers, he recommends that clear and stable standards for excipient quality, supplier qualification and batch-level testing should be uniformly enforced across states. Predictable regulatory guidance reduces ambiguity for manufacturers while ensuring that compliance investments are directed towards well-defined quality benchmarks rather than shifting enforcement priorities.

Thirdly, excipient supply chains require structured traceability and verification mechanisms. Agrawal mentions that mandatory supplier qualification protocols, authenticated certificates of analysis and digital batch traceability should become standard practice for high-risk excipients. Integrating manufacturers, accredited laboratories and regulators through interoperable digital systems can enable real-time reporting of test results and quality deviations, significantly reducing the risk of contaminated inputs entering pharmaceutical production.

Agrawal's final recommendation is that encouraging domestic manufacturing of high-risk excipients, building strategic supplier networks and creating risk-based import monitoring systems can reduce dependence on opaque global supply chains.

Expanding the regulatory net

Dr Indraksha confirms that there are plans to expand QR code requirements beyond the top 300 brands. Proposals have already been discussed and approved in principle by both the DCC and DTAB. Future phases are expected to cover critical categories such as narcotic and psychotropic substances (NDPS), vaccines, anti-cancer drugs and anti-tubercular medicines. "Implementation will likely occur in a phased manner through further amendments or administrative orders," says Dr Indraksha.

Choosing to see a silver lining in the higher regulatory compliance, Venus Remedies' Chaudhary believes, "India stands at a crossroads where excipient innovation can meaningfully reshape its position in the global pharma value chain. Moving from commodity-grade materials to engineered, functional excipients is not just a scientific upgrade; it is a strategic one. It underpins manufacturing modernisation, strengthens regulatory credibility and opens new export avenues."

He points out that over the next decade, as continuous manufacturing becomes more common and biologics gain a larger share of pipelines, excipients will only grow in importance. To realise this opportunity, large companies, smaller manufacturers and early-stage innovators will need to work in the same direction: towards advanced materials, data-informed formulation design and alignment with international quality expectations.

Signing off on a positive note, Chaudhary predicts that if India can combine regulatory reform, scientific capability and purposeful investment, advanced excipients may well become one of its most important advantages in the next phase of pharmaceutical growth.

When the familiar is no longer safe

Perhaps the additional stress on the quality and provenance of pharma excipients will prepare the sector to deal with novel excipients, especially those used in biologics. In a LinkedIn blogpost, titled, Grassroots and GRAS: Rethinking Safety, Consciousness, and Responsibility in the Age of Novel Excipients, regulatory consultant Dr Ajaz Hussain reminds us that in pharmaceutical science, a mundane ingredient can carry the heaviest consequences. *(https://www.linkedin.com/pulse/grassroots-gras-rethinking-safety-consciousness-age-hussain-ph-d--fcoae/)*

Dr Hussain, a former Deputy Director Office of Pharmaceutical Science, CDER, US FDA (January 1995 - October 2005) who now describes himself as an Advisor in Regulatory Drift, Technocratic Tensions & Historical Collapse, reminds us that the acronym GRAS, or Generally Recognized As Safe, grants substances exemption from FDA premarket approval if a consensus of qualified experts deems them safe for their intended use. As he terms it, "GRAS represents a legacy shortcut—a permission slip based on familiarity rather than fresh scrutiny."

He goes on to ask: "What happens when familiarity fades? What if the "generally recognized" consensus is inherited, not earned? This becomes more than a regulatory question when novel excipients—like ionizable lipids used in lipid nanoparticle (LNP) formulations for mRNA vaccines—enter the scene. Unlike traditional food or drug excipients, these synthetic lipids lack the GRAS pedigree."

Perhaps the way forward is Dr Hussain's parting advice, on a philosophical note, "As excipients move from the margins to the center of pharmaceutical innovation, so must our collective consciousness. In time, what we once called "inactive" may be recognised as the functional ingredient, not just in our formulations but also in our frameworks for moving closer to the truth, trust, and transformation. If we aspire to transform our technologies and ourselves, then the path forward is not to dismiss dissent, but to evolve our capacity to hear critically, compassionately, and courageously."

As India's pharma sector gears up for higher regulatory scrutiny, all segments need to move in sync. Each segment is a link, small or large, in the life sciences value chain. A chain is only as strong as its weakest link. Excipient makers, pharma companies and regulators will have to work together to shore up this weak link.

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2026 amendments to NDCT Rules: Foreword to India's biosimilars story or a step too short?

Kosturi Ghosh, Partner, and **Ajeya B G,** Sr Associate, in the Corporate practice at Trilegal, assess India's 2026 NDCT amendments as a timely push for biosimilars, but not enough on their own. The article highlights that stronger policy clarity and ecosystem support will be critical to truly unlock growth

It has almost become impossible to have a conversation on India's development today without simultaneously discussing alarming statistics on chronic health diseases, lifestyle disorders and environmental concerns. The Economic Survey of India 2026 was testament to this fact when it noted the concerns of rising lifestyle diseases, rising burden of cancers, increasing antibiotic resistance, and falling general immunity levels have exacerbated as a consequence of nutritional deficiencies. Non-communicable diseases like cardiovascular diseases, cancers and diabetes account for 57 per cent of deaths in India today.[1]

The Finance Minister launched a 1000 crore Biopharma Shakti plan with the objective of shaping India into a biologics and biosimilars hub and attempting to make India leapfrog from being a mere generics player. While the ambition is both timely and necessary, its realisation will depend on sustained policy support and ecosystem readiness.

The first step is to understand what biologics, generics and biosimilars mean. A 'biologic' is a medicine that contains an active substance from a biological source, such as living cells or organisms (like vaccines, insulin, etc.). Biologics are complex, large-molecule drugs that are used to treat various conditions, including autoimmune diseases, cancers and more. While the pharma industry is notoriously opaque to reveal actual development costs, some estimates put costs of development for a biologic at anywhere between $800 million and $2.6 billion.

Generics are exact, small-molecule chemical copies of brand-name drugs, while biosimilars are large, complex, and highly similar—but not identical—products derived from living organisms. Because biologics are made with substances from a biological source, they are inherently more variable and complex than their small-molecule counterparts. This complexity makes it impossible to produce an exact copy of a biologic, which is where biosimilars come in. A biosimilar is designed to be highly similar to an already approved biologic, known as the reference product, with no significant clinical differences in terms of safety and effectiveness. Thus, clearly, developing a biosimilar is not the same as developing a generic. Biosimilar development is estimated to cost between $100 million and $250 million[2] and to take 8-10 years.

Kosturi Ghosh

> Of the 118 biologics expected to lose patent protection by 2034, only 12 molecules had biosimilars in development as of June 2024. While this may seem like an opportunity to Indian pharma exporters, it also highlights the difficulties in developing and marketing biosimilars

The drug development process is also quite different for a biosimilar as compared to a biologic (or any other drug, for that matter). As a biosimilar relies on similarity with the reference biologic, preliminary analytical studies with access to the reference biologic is the first step in any study.

This is where the 2026 amendments to the New Drugs and Clinical Trials Rules, 2019 (the 2026 amendments) come into the picture. In India, unlike the US and many other jurisdictions, regulatory approval was previously required for manufacturing a new drug, investigational (i.e., not authorised to be marketed in any country) or otherwise, for non-clinical testing purposes as well. The 2026 amendments remove this requirement, and now new drugs may be manufactured for 'analytical and non-clinical testing purposes' with only a prior intimation to the CDSCO. This move certainly benefits biosimilar manufacturers as it removes the first obstacle in the road to developing a feasible and marketable biosimilar. While the Biopharma shakti plan proposes to "build the ecosystem for domestic production of biologics and biosimilars", it is key to note that this relaxation does not extend to, inter alia, cytotoxics and biologics with live microorganisms. Neither term has a definition under law; while they may have widely accepted meanings within the industry. Further clarity around these exceptions could help reduce interpretational ambiguity and enhance ease of implementation. Over time, a calibrated move towards a more trust-based regulatory approach could further streamline innovation, alongside strong enforcement of manufacturing standards

The 2026 amendments are certainly welcome, especially the reduced approval timelines. The window within the authorities have to either approve or respond to an application (including applications for manufacturing new drugs for BA/BE studies, clinical trials, etc.) has been halved from 90 days to 45 days. These changes indicate the government's push towards early-stage research, faster 'lab-to-market' times and enabling Indian pharma companies to compete in global markets for biologics and biosimilars.

That said, there remains an opportunity to further strengthen the framework. For instance, the Biologics Price Competition and Innovation Act in the US (the primary legislation regulating biosimilars) provides for a 'patent dance'. The law facilitates a discussion between the biosimilar manufacturer and original innovator on potential infringement claims that the innovator believes it would be entitled to make and an agreement between them on what claims would be litigated first.[3]

While the Delhi High Court did recently shut down[4] Roche's

fishing expedition against Zydus in a Pertuzumab patent dispute, incorporating a structured mechanism for early-stage patent alignment could help improve predictability and reduce the time and cost associated with dispute resolution. This may prove to be useful even where drugs are hitting their supposed patent 'cliffs'- these should be seen more as gradual slopes, as companies like Merck & Co typically build 'patent' wall of protection around their products, and it may take years before biosimilar manufacturers can get around to process patents that underly the principal product patent. Keytruda (or Pembrolizumab), for example, is Merck & Co's, and quite possibly the world's, best-selling drug which has significantly boosted overall survival rates across different types of cancer[5], and more materially (for this discussion), costs 7994 per cent of India's average monthly income[6]. Keytruda is backed by 129 patent applications, of which only 26 per cent are product patents, and the principal product patents are expiring in 2028 in many jurisdictions, including India[7]. Of the remaining process patents, the expiration date for many run well into the 2030s. And it's not just Keytruda; Perjeta (pertuzumab), Blincyto (blinatumomab), Ocrevus (ocrelizumab), Ozempic (semaglutide) and many other blockbuster drugs are hitting their patent cliffs before 2030.

Surprisingly, however, an IQVIA Institute report from 2025[8] acutely identified a 'biosimilar void'; of the 118 biologics expected to lose patent protection by 2034, only 12 molecules had biosimilars in development as of June 2024. While this may seem like an opportunity to Indian pharma exporters, it also highlights the difficulties in developing and marketing biosimilars. While India's pharma industry is well-placed to offer competition with its technical capabilities and good manufacturing practices, the very complex nature of biosimilars makes this a tough challenge. This is where government policy could have a real impact. For example, post-approval change processes in India can be slower and less predictable than they are in the time-bound EMA models, discouraging cost-saving improvements.

The 2026 amendments do provide a push that India's biosimilar industry was looking for at this time, but they might just be a step too short.

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Unused pharma alcohol: From waste to resource

Milind Sathe, VP IP-Tech and Scientific Affairs, Themis Medicare reviews enactments governing alcohol in pharma and allied industries that may help unlock efficiencies and reduce pressure on India's petroleum import bill

Global oil prices surged by approximately 50 per cent since the US-Iran conflict began on February 28, 2026. This disruption has led to widespread fuel price hikes, with some regions experiencing spikes in petrol and diesel costs of up to 30 per cent to 68 per cent. Petroleum imports consistently account for around 25 per cent–30 per cent of India's total import bill, making it the largest import expenditure. By the end of the financial year 2024-25, India imported roughly 243 million metric tons of crude oil, with the total import bill exceeding $137 billion.

India has seen substantial liquor seizures annually, primarily in dry states like Bihar and Gujarat.

Consolidated nationwide figures of liquor destroyed or unused pharmaceutical alcohol destroyed by state excise authorities are not available. It is estimated that in Maharashtra alone about 5000 to 20000 liters and in Gujarat approximately 10,000–50,000 bulk liters per year of unused pharma/industrial ethanol is destroyed per year. There are 28 states and 8 Union territories in the country housing robust pharmaceutical industry. Therefore, figures of alcohol destroyed pharmaceutical industry and confiscated liquors is mind boggling. There is urgent need of central mechanism to list nationwide figures and review the phenomenon in the light of Iran America war for the benefit of India. Alcohol is treated differently in liquor and pharma industry.

> Recover alcohol from unused alcohol or confiscated liquors. Do not destroy. Use it to dilute petrol. Amend enactments to allow such use in prevailing energy crisis and thereafter forever

Reasons for differential treatment

Liquor destruction enforces excise laws against deterioration, protecting revenue and health. Pharma treats alcohol as an excipient with strict expiry for potency, despite studies showing stability years beyond dates, driven by industry profit from disposals.

Regulatory framework and shelf-life determination

Neither the Indian Pharmacopoeia (IP), Drugs and Cosmetics Act 1940 (D&C Act), nor its Rules or Schedule P (Life Period) specify a fixed shelf life or expiry date for Ethanol IP or Ethanol 95 per cent. Ethanol as excipient follows supplier CoA/re-test period. Receiving pharma units assess usability through internal testing, QC release before use and report to excise if unfit or unused beyond storage limits (often 3-6 months), leading to destruction—not based on producer-labeled dates. FSSAI expiry mandates apply only to consumer alcoholic beverages under specific ABV thresholds, excluding industrial pharma alcohol.

Key rules on expiry

Industrial alcohol for pharma is regulated under the Medicinal and Toilet Preparations (Excise Duties) Act, 1955, and state excise rules. The Drugs and Cosmetics Rules, 1945, does not require expiry dates on alcohol. Unused alcohol in pharma units is considered expired based on its labeled shelf-life or manufacturer's expiry date, as per bond warehouse conditions in state excise rules (e.g., Odisha Excise Rules 2017 or similar state manuals). Units report such stock to the excise officer for supervised destruction or rebonding.

Expired alcohol cannot be stored indefinitely; rules mandate removal or disposal within timelines like three months post-receipt if unused, with chemical testing for fitness.

Disposal process

Pharma units apply for a "destruction permit" under appropriate state forms. Destruction occurs in the presence of an excise inspector, documented in stock registers. Non-compliance leads to penalties, including license suspension under state acts like Karnataka Excise Act 1965.

Destruction process of unused alcohol by state excise department

Expired or alcohol non-compliant with IP is treated as "waste" liable for duty forfeiture and destruction to prevent diversion. No explicit "pharma exemption" exists; recovery/redistillation needs special approval. State excise officers are empowered to order destruction if alcohol is deemed "unfit for human consumption or permitted use," after quality tests show sub-standard results, to protect revenue and public safety, treating all alcohol as potential potable liquor unless proven otherwise. Unused expired IP-grade alcohol or alcohol failed in quality tests in the pharma industry, stored in tanks or drums, is destroyed by state excise departments through supervised High temperature incineration or chemical neutralisation. Confiscated liquors are mostly destroyed by Road-Roller Crushing.

It is suggested that pharma alcohol or seized or confiscated liquors should always be sent to government distilleries for recovery instead of destruction.

Inherent contradiction in treatment of xyz year old liquors and unused alcohol in pharma industry.

There seems to be an inherent contradiction in how confiscated/seized/aged liquors and unused alcohol in the pharma industry are treated, primarily due to differing regulatory frameworks, safety standards, and economic incentives. Liquor regulations prioritise revenue control and public safety from adulteration, while pharma focuses on therapeutic efficacy and controlled disposal. Liquors destroyed by state excise department on account of deterioration.

Reasons for No Expiry Dates on liquors

High Alcohol by Volume (ABV) or High-proof alcohol resists microbial spoilage indefinitely and oxidation is minimal when sealed. Regulations exempt distilled liquors from mandatory dating, treating it as a quality choice, not safety requirement; "best before" is voluntary for liqueurs. Manufacturers leverage this for premium aging marketing. Storage of alcohol in pharmaceutical industry needs careful review in this direction.

Key differences

Excise views liquor as taxable intoxicant, pharma as medicinal input.

State excise departments destroy liquors failing alcohol content or purity checks to prevent unsafe consumption. In contrast, unused or expired pharmaceutical alcohol is typically destroyed even if chemically stable, to avoid liability and boost new sales. Pharma recovered alcohol can be redistilled under license, unlike consumer liquors.

Year wise seizure and destruction instances, vol-

umes and alcohol content

Compiled State wise or all India basis year wise data of sampling and destruction is not available. Sporadic uncompiled data of some states e.g. Nagaland, Maharashtra, Gujarat, Bihar is published.

Legal situation in Scotland

No verified instances exist of Scottish authorities (e.g., Excise or SEPA) destroying legally manufactured alcohol stocks solely due to an expiry date.

Alcohol manufactured in Scotland, such as Scotch whisky or industrial ethanol, does not have a mandatory expiry date assigned by regulatory authorities. The Scotch Whisky Regulations (under HMRC and the Scotch Whisky Association) and the Scottish Environment Protection Agency (SEPA) and regulatory body MHRA, treat high-proof alcohol as stable indefinitely when unopened and properly stored.

MHRA guidelines emphasise purity and contamination risks over arbitrary expiry; it's not routinely destroyed for age alone but for failed quality tests or regulatory non-compliance. Scottish authorities do not systematically destroy alcohol based on an "expiry date," as none is mandated—destructions occur for illicit production, seizures, or environmental disposal of waste, not deterioration from age. No public records indicate pharma-specific alcohol disposals tied to expiry in Scotland.

Liquor manufacturing companies rely on ethanol's natural preservative properties at high concentrations (typically 40 per cent ABV or above). No legal mandate requires expiry dates on distilled spirits, empowering manufacturers to omit them. Standard lab analyses during production, bottling such as ABV Measurement, Contaminant Screening, Clarity and Sensory Evaluation can't confirm stability for decades.

Oxidation, Evaporation and Flavor compound loss are typical deterioration in liquor industry. It is gradual chemical changes that alter flavor, aroma, or appearance over time, but high-proof distilled spirits (=40 per cent ABV) are not prone to significant degradation that renders them unsafe. Pure ethanol itself is chemically stable and acts as a preservative, inhibiting microbial growth indefinitely when sealed.

Storage and stability of alcohol

Alcohol is not prone to deterioration in proper conditions (cool, dark, upright storage): sealed glass/containers prevent ingress, high ABV blocks pathogens. Pharma alcohol gets expiry for contamination risk, but liquor relies on alcohol's inherent stability. 10-year-old sealed liquor is fit if clear and odor-normal.

There are no specific articles in the gathered search that directly describe alcohol (ethanol) stored in tanks specifically for pharmaceutical preparations as having deteriorated or being prone to chemical/microbial degradation though there are few related to industrial/plasticiser/fuel ethanol production.

Pharma alcohol in sealed, nitrogen-blanketed stainless tanks remains stable, unlike industrial /plasticiser/fuel ethanol vulnerable for deterioration.

Ethanol IP, "a pharmaceutical aid solvent" is directed "Store in tightly-closed containers at a temperature not exceeding 30°, away from fire and protected from light" [to prevent evaporation, contamination, and impurity ingress] and Ethanol 95 per cent IP "Pharmaceutical aid (solvent); topical anti-infective" is advised "Store in tightly-closed containers at a temperature not exceeding 30° and away from fire". IP tests verify purity, identity, assay, and impurity limits, strength and safety rather than deterioration per se.

Review of legal texts needed to mitigate phenomenon of expiry

There is need to review or amend the legal text enabling storage of alcohol in more clearly directed storage conditions to eliminate deterioration and destruction or to delay and extend it. Some mitigations measures need to be evaluated.

Mitigation measures to extend shelf life.

- **Nitrogen padding/blanketing:** Use dry nitrogen to fill the headspace of the storage tank, prevent atmospheric moisture from entering and keep the system oxygen-free to prevent oxidation. Use pressure measuring gauges or dials to document positive pressure.
- **Use of stainless steel:** Use ethanol compatible stainless steel (e.g., 316) tanks.
- **Humidity control:** Ensuing proper sealing of the tanks and strict humidity control in the storage area.

There is lot of scope to provide alcohol to pharmaceutical industry having much longer shelf life. Literature is populated stating that pure properly stored ethanol lasts indefinitely. Ethanol IP or Ethanol IP (95 per cent) retesting as per IP methods mandated before use.

Enactments governing State excise departments need amendment to eliminate unnecessary destruction of pharmaceutical alcohol in tanks by adopting science-based stability protocols and clear exemptions in rules, distinguishing it from consumer liquor, as follows:

- **Mandatory stability testing:** Require pharma manufacturers to submit IP-compliant certificates of analysis at stipulated intervals and before use.
- **Designated storage audits:** Define SOP mandating inspection of tanks quarterly for seals, temperature (<25°C), nitrogen blanketing and stainless steel integrity to prevent contamination, rather than presuming expiry or sticking to unuse.
- **Digital tracking:** Implement means to track and trace from distillation to pharma use, auto-flagging non-pharma diversion.
- **Exemptions clause:** Amend state excise rules (e.g., like Odisha Excise Rules) to exclude IP-grade ethanol in licensed pharma tanks from "deterioration" destruction penalties, if tests pass IP monographs.
- **Shelf-life validation:** Allow 5-year renewable permits based on ICH Q1A stability data, overriding consumer liquor 3-month rules.?
- **Joint oversight:** Form excise-pharma-FDA committees for approvals, with provisions for redistillation/recovery under Medicinal Toilet Prep Act.

These changes align with alcohol's inherent stability (>99 per cent pure ethanol resists microbial growth), reducing revenue loss while ensuring safety.

Recover alcohol from unused alcohol or confiscated liquors. Do not destroy. Use it to dilute petrol. Amend enactments to allow such use in prevailing energy crisis and thereafter forever.

The current energy crisis advises creation of provisions to use available infrastructure to recover and repurpose unused alcohol or confiscated liquors for petrol dilution instead of destruction, even after cessation of crisis to save efflux of national wealth forever.

Feasibility of recovery after amendments in legal texts

Pharma alcohol though rarely, may contain traces of solvents/impurities failing fuel specs (IS 15464) and confiscated liquor risks adulterants/methanol, requiring reprocessing. Ethanol recovery via distillation could yield fuel-grade spirit (>99 per cent pure) for E20 blending, leveraging surplus waste ethanol amid Iran-US war oil shocks (prices up 30 per cent+ since Feb 2026).

Required legal amendments

- **Medicinal & Toilet Prep (Excise Duties) Act 1955 (Rule 36):** Amend to permit licensed recovery/redistillation of unused pharma alcohol for fuel use, with excise duty remission.
- **State Excise Acts/Manuals:** Insert clause exempting "fuel-destined" unfit spirit from destruction (e.g., Maharashtra Excise Manual Ch. on Disposal), mandating handover to PSUs like IOCL post-testing.
- **Ethanol Blended Petrol Program Rules (2022):** Expand to accept recovered ethanol from excise seizures/pharma waste, with MoPNG certification.
- **Petroleum Act 1934 & BIS Standards:** Update IS 1606 for blended fuels to include "recovered ethanol" category.

Benefits

- **For India:** Highly beneficial—recycles ~10-20 million liters/year waste alcohol (est. from audits), saves $50-100M import bill amid war crisis, boosts energy security (E30 target by 2027), cuts emissions 5-10 per cent besides generating sustainable aviation fuel significant reduction in landfill, incineration and aligns with net-zero goals. Brazil's model post-1970s shocks proves viability.

Tentative procedure to obtain repurposed alcohol fit to dilute petrol. Benefits in terms of savings and reduced imports of petrol.

Repurposed ethanol for fuel blending (E20/E30 petrol) can be done after purification to meet IS 1606 fuel specs. Pharma alcohol is already near fuel-grade, while confiscated liquor needs more steps due to congeners/additives.

Purification procedure

1. Collection & Pre-Treatment: Transfer to distillation plant under excise supervision; filter solids; denature if potable (add 1-2 per cent gasoline/bitex).

2. Multi-Stage Distillation:

- Azeotropic distillation (95-99 per cent ethanol via molecular sieves).
- Vacuum column removes methanol, aldehydes and fusel oils.

3. Impurity Removal: Ozonation/gas stripping/activated carbon adsorbs volatiles/heavy metals;

4. Dehydration & testing: Molecular sieves for anhydrous ethanol; GC-MS verification.

5. Denaturation & blending: Add approved denaturants; blend at depots for E20 fuel.

One may use better methods. Expected recovery is 80-90 per cent.

Benefits [Figures will change after nationwide compilation of real-time data]

- **Volume potential:** Est. 15-25M liters/year pharma unused + 10M from seizures = 2-3 per cent of India's 1,200M liter E20 demand.
- **Import savings:** Displaces 20-35M liters petrol equiv. (~₹200-350 crore/$24-42M at ₹100/L); cuts 5-7M liter crude imports amid 35 per cent oil spike.
- **Energy security:** Boosts E30 rollout (target 2027), saves $100-200M forex yearly, reduces emissions 8-12 per cent.? Crisis-

viable, scalable, aligns with Brazil's waste-ethanol model.

Quality of repurposed alcohol for diluting petrol and alcohol IP

IP alcohol surpasses basic fuel-grade specs (IS 1606) chemically, making it technically viable for E20 blending after denaturation and included in government fuel programs after additional testing, denaturation processing and MoPNG certification. Government activities (e.g., Ethanol Blended Petrol Programme via OMCs) mandate fuel-grade ethanol produced under specific licenses. Bitrex (denatonium benzoate) is used as a denaturant and aversive agent. Methanol or pyridine may be added if permitted.

Way forward": Pharma ethanol to Fuel Recovery Program" under MoPNG:

1. Inventory audit: Excise+FDA survey pharma firms for unused IP alcohol (>6 months old).

2. License transfer: Issue temporary Fuel Ethanol Supply License (30 days) under EBP Rules.

3. Processing (at govt distilleries): Design SOPs for receipt, processing and supply

- Dehydrate to anhydrous via molecular sieves or other means
- Add denaturants per IS 1606
- QC testing (GC-MS)

4. Handover: Oil Manufacturing Companies (OMCs) purchase at ₹65/L or at price as may be defined by Govt; duty remission via MTP Act amendment or other suitable enactment.

5. Funding: ₹100 crore fund; 80 per cent recovery yield.

"Excise Waste-to-Fuel Initiative":

1. Seizure segregation: Classify confiscations by quality i.e. Extra Neutral Alcohol (ENA)/Rectified Spirit (RS)/liquor).

2. Central recovery plants: 5 PSUs (IOCL/HPCL...) with mobile distillation units.

3. Treatment process: Liquor → Pre-filtration → Azeotropic distillation (95 per cent EtOH) → Molecular sieves (99.5 per cent) → Carbon treatment → Denaturation → Fuel spec testing → E20 or other E blending Volume: 10-15M L/year seizures → 8M L fuel ethanol.

4. Legal: Amend State Excise Acts Rule on "unfit spirit disposal" for fuel diversion.

Benefits: [Figures will change after nationwide compilation of real-time data]: Saves ?300-500 crore imports, utilises 25M L waste alcohol, advances E30 target. High per cent ethanol-blended petrol (e.g., E50 or E85) would likely cost 5-15 per cent less than regular 100 per cent petrol on a pro rata basis, due to ethanol's lower procurement cost compared to refined petrol base.

Recoverable fuel-grade ethanol

Assumed volume recovery post-purification: 70 per cent-80 per cent of starting material.

India can reduce petrol imports and prevent exodus of national wealth. [Figures will change after nationwide compilation of real-time data]

Repurposing seized liquor and unused pharma alcohol would meaningfully help India reduce petrol imports and would yield 10-15 million liters of fuel-grade ethanol annually from seizures alone, displacing equivalent petrol volumes and saving ~?100-150 crore in forex yearly—0.01-0.02 per cent of India's ~?22 lakh crore oil import bill.

Strategically vital for energy security, proving circular economy in fuel policy.

Modified of BS-4 or BS-6 engines to use higher per cent of alcohol in petrol as fuel. Is E100 a dream?

Brazil uses the highest percentage of alcohol blended into petrol, with E100 (100 per cent hydrous ethanol) available alongside E27 (27 per cent anhydrous ethanol in gasoline) for flex-fuel vehicles.

BS-6 (Euro 6 equivalent) petrol engines. BS-6 engines handle E20 (India's 2025 target), require flex-fuel upgrades, factory-level changes for reliability, for higher blends like Brazil's. It is said that India's Toyota Innova HyCross E100 prototype (BS-VI) used similar mods plus hybridisation.

Converting BS-6 or BS-4 engines to run on 100 per cent ethanol (E100).

Petrol/diesel engines designed for low ethanol blends (up to E20 for BS-6) lack ethanol compatibility.

Existing BS-4 and BS-6 engines can be modified to handle higher ethanol blends beyond the current E20 mandate. BS-6 engines are already tuned for E20 compatibility, while BS-4 lines. BS-4 bike engines for E20-E30 may need Ethanol-resistant fuel hoses, seals, O-rings, gaskets, and carburetor jets (for bikes); fuel pump/filter upgrades for cars costing Rs. 3,000-6,000 or more. BS-4 cars may need Rs. 20,000-50,000 or more for E20-E50. BS-6 Bikes/Cars Engines may need ECU remap for richer mixtures, larger injectors (20-30 per cent flow increase), and material swaps costing Rs.10,000-40,000 or more for E20-E85.

BS-4/BS-6 diesel engines need a full combustion redesign (e.g., spark ignition conversion) though prototypes like ClearFlame exist.

Converting BS-6 petrol engine to E85 to E100 friendly one needs Stainless/high-flow Fuel Pump/Injectors, E85-E100 advance/preheat ECU Tuning,12-14:1 optional Compression and possibly additional cost estimate of 2-5 lac. Rising to E85 from E20 i.e. raising blending ratio of Ethanol: Petrol from 1:4 to 17:3 may not substantially reduce the price to the consumer, but would save mammoth sums for India.

Aspect	Brazil Flex-Fuel	India BS-4/BS-6
Ethanol Tolerance	Up to E100	BS-6 tuned for E20 (20 per cent)
Compression Ratio	12-14:1	9.5-11:1
Materials	Stainless steel, ethanol-compatible seals	Standard for low blends
Emission Standard	PROCONVE L8 (Euro 6-like)	BS-6 (Euro 6)

Brazilian flex-fuel designs (introduced 2003) automobile engines are, optimised for 22-100 per cent ethanol blends with higher compression ratios (up to 13:1), corrosion-resistant materials, and direct injection—more advanced than India's BS-4 (Euro 4 equivalent, pre-2020) or models need minor upgrades, i.e. corrosion resistance and fuel delivery, with maximum safe ethanol percentages up to E85 (85 per cent) feasible after tuning. E100 remains ultimate target with major rebuilds. Both may need cold-start aids (fuel preheaters), stainless steel fuel

FDD Conclave – Mumbai Connect: Reimagining formulation R&D

The inaugural edition of FDD Conclave - Mumbai Connect, a city-focused platform brought together FR&D leaders to discuss innovation in formulation science, drug delivery challenges, scale-up imperatives and the need to build future-ready teams, reports **Swati Rana**

Formulation and drug delivery is key to translate scientific discovery into real-world therapeutic impact. As India's pharma sector enters a phase defined by greater complexity, accelerated timelines, and heightened regulatory scrutiny, the role of formulation R&D is being fundamentally redefined.

In this context, Express Pharma hosted the FDD Conclave – Mumbai Connect, around the theme 'Speed, Scale, and Science: Rethinking FR&D,' bringing together key stakeholders from India's pharma and formulation development ecosystem for a day of insightful discussions, strategic dialogue, and knowledge exchange.

L - R : Viveka Roychowdhury, Editor, Express Pharma; Dr Santosh Indraksha, Deputy Drugs Controller (India), CDSCO, DGHS, MoH&FW, Government of India;Dr Pavan Bhat, CEO, Inventia Healthcare; Sumeet Sharma,Vice President - Sales, Cilicant; and Jaynil Doshi, Director – Techno Commercial, Pioma Chemicals

Lighting the path forward

The conclave kick-started with a ceremonial lamp lighting led by Dr Santosh Indraksha, Deputy Drugs Controller (India), CDSCO, DGHS, MoH&FW, Government of India; Dr Pavan Bhat, CEO, Inventia Healthcare; Jaynil Doshi, Director – Techno Commercial, Pioma Chemicals; Sumeet Sharma, Vice President - Sales, Cilicant and Viveka Roychowdhury, Editor, Express Pharma.

Setting the tone for the event, Dr Indraksha brought the regulatory perspective into focus while delivering the Chief Guest address. He stressed that as pharma products become more complex—ranging from modified-release formulations and combination products to advanced drug delivery systems—the regulatory environment is evolving in parallel. Expectations around data integrity, risk management, lifecycle approach, and global harmonisation are becoming more stringent.

Dr Indraksha highlighted the importance of embedding quality-by-design (QbD) principles early in the development process, ensuring that quality is built into the product rather than tested at the end. He also emphasised the need for stronger alignment with international standards, reflecting India's growing integration into global supply chains.

Elevating R&D to strategic core

The transition of R&D from a functional role to a strategic imperative formed a central theme of the conclave. In the session, 'Leadership lens: Making R&D a boardroom conversation,' discussions revolved around how organisations are rethinking the role of formulation development in driving business outcomes.

The session was moderated by Viveka Roychowdhury. She was joined by Dr Pavan Bhat, and Dr Santosh Indraksha. The central thread was that leadership in pharma, particularly within R&D rarely follows a linear path. As highlighted by the panellists, real growth often begins when professionals move beyond narrowly defined roles, taking initiative and embracing opportunities that stretch their capabilities.

The conversation also underscored a critical shift in how innovation is evaluated. While strong science remains foundational, it is no longer sufficient on its own. For R&D to deliver meaningful value, it must align closely with market needs, commercial viability and timing. Innovation, therefore, must be viewed through a more integrated lens—where scientific excellence is complemented by strategic foresight and execution capability.

The panellists stressed the importance of fostering a culture where setbacks are openly discussed and converted into shared learning experiences, reducing the risk of repeated mistakes and strengthening institutional knowledge.

From a regulatory standpoint, Dr Indraksha highlighted the rapid digital transformation underway in India's regulatory ecosystem. Initiatives such as unified licensing systems and single-window platforms are streamlining processes, enhancing transparency, and improving efficiency.

Complexity in modern formulation R&D

As the discussion moved towards more complex products, industry doyens dwelled on the challenges associated with formulation development are intensifying. The panel discussion on 'Managing complexity in modern formulation R&D' brought together experts including Dr Raveendra Pai, Sr VP - Formulation Development, Glenmark Pharmaceuticals; Dr Simta Jadhav, GM, Raay Neo Pharma; Dr Md Rizwan, Formulation Lead, Alkem Laboratories; Preeti Raut, Sr VP - Formulations Development, Cipla; Dr Sunil Pandey, Assistant VP, Head NDDS, Bharat Serum and Vaccines and Dr Premchand Nakhat, Head-Formulation and Technology Transfer, Inventia Healthcare.

The discussion was moderated by Dr Vandana Patravale, Professor of Pharmaceutics, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology.

A key takeaway from the discussion was a reality check on complex generics. While often viewed as the next growth frontier, panellists emphasised that products such as injectables and drug-device combinations are far from easy wins. They demand significant investment, specialised expertise, and longer development timelines, making them high-risk, high-reward opportunities that require careful strategic planning.

Dr Santosh Indraksha, Deputy Drugs Controller (India), CDSCO, DGHS, MoH&FW, Government of India

Dr Vivek Jha, Head - R&D, Cilicant; Dhairy Sharma, Manager - Business Development (Healthcare Division), Cilicant

Dhairy Sharma, Manager - Business Development (Healthcare Division), Cilicant

Jaynil Doshi, Director – Techo Commercial, Pioma Chemicals

L-R: Dr Santosh Indraksha, Deputy Drugs Controller (India), CDSCO, DGHS, MoH&FW, Government of India; Dr Pavan Bhat, CEO, Inventia Healthcare; Viveka Roychowdhury, Editor, Express Pharma (Moderator)

L-R: Prof Vandana B. Patravale, Professor of Pharmaceutics, Institute of Chemical Technology(Moderator); Dr Raveendra Pai, Sr VP, Formulation Development, Glenmark Pharmaceuticals; Dr Simta Jadhav, VP, Raay Neopharma; Dr Md Rizwan, DGM, Alkem Laboratories; Preeti Raut, Technical Consultant, Cipla; Dr Sunil B Pandey, AVP – R&D (NDDS-Formulation & ADL), Bharat Serums & Vaccines (Subsidiary of Mankind Pharma); Dr Premchand Nakhat, Head-Formulation and Technology Transfer, Inventia Healthcare

Kumar N Fadadu, Technical Manager (F&D), Vikram Thermo (India)

The conversation also touched upon the growing role of digitalisation, particularly the gradual integration of artificial intelligence into formulation development. AI-driven predictive tools are beginning to support scientists by forecasting impurity profiles, excipient compatibility, and product behaviour, even before experimental work begins. While still evolving, these capabilities are expected to enhance decision-making and reduce development uncertainties over time.

However, technology alone cannot solve the challenge of speed. The panel strongly emphasised that faster time-to-market is fundamentally driven by collaboration. Cross-functional alignment between formulation, analytical, and process teams—combined with experienced talent—plays a crucial role in navigating complexity efficiently and avoiding costly delays.

Panellists also highlighted that strong, well-structured documentation is often underestimated, yet it is essential for successful technology transfer

Dr Abhijit V Gothoskar, Technical Expert, Sigachi Industries

S Mukherjee, GM - Marketing, Dhara Lifescience

Dr Ravleen Singh Khurana, MD, Nitika Pharmaceutical Specialities

L-R: Dr Kour Chand Jindal, Pharma Consultant (Moderator); Minoo Biju, Head - Regulatory Affairs, Piramal Pharma Solutions; Rahul Rajmane, Associate Director R&D/ BD, Cipla Health; Dr Kavita Inamdar, Chief Technical Officer, Indoco Remedies; Vijayendrakumar Redasani, Founder & CEO, DelNova Healthcare; Vinod Raghuwanshi, Sr GM and Head Technical Services, Macleods Pharmaceuticals; Dr Shripad Gadhinglajkar, Sr GM - R&D, Franco Indian Pharmaceuticals; Rajesh Kulkarni, Pharmaceutical and Technical Consultant

L-R: • Dr Ashok Omray, Pharma Consultant (Moderator); Dr Vinay Patil, Sr VP - Pharma (R&D), Raptakos Brett & CO; Avinash Velhal, Pharma R&D Leader; Dr Kuntal Ganguly, Head R&D, Albert David; OS Sadhwani, Former Joint Commissioner and Drugs Controller, Food and Drugs Administration, Maharashtra; Dr Samarth Kumar, Head Formulations Development – Injectables, Cipla; Babasaheb Aware, Sr GM - Formulation and Development, Indoco Remedies; Dr Prashant Kumar Choudhari, GM -Head Formulation Development, Hyloris Pharmaceuticals

and commercialisation. Clear communication of processes, parameters, and learnings helps minimise errors, reduce repeat work, and improve overall efficiency during scale-up.

Collectively, the discussion highlighted that managing complexity in formulation R&D is not about any single lever—it requires a synchronised approach across science, technology, collaboration, and strategy.

Formulation frontiers: Coating, packaging and nitrosamine focus

FDD Conclave - Mumbai Connect saw several technical sessions that informed the audience on issues pertinent to the current times.

S Mukherjee, GM – Marketing at Dhara Lifescience, through his presentation shed light on the evolving advantages of faster coating technologies and the critical considerations that guide product selection in today's competitive pharmaceutical landscape.

He emphasised that choosing the right coating solution goes beyond a single parameter. Instead, it requires a balanced evaluation of quality, service reliability, cost competitiveness, supply consistency, and product efficacy. Overall, the session reinforced that while faster coating technologies offer clear operational advantages, their true value can only be realised through informed selection, rigorous evaluation, and uncompromising compliance standards.

The next session was led by Dr Vivek Jha, Head - R&D, Cilicant and Dhairy Sharma, Manager - Technical Sales, Cilicant. Their presentation on 'Can FREXIL minimise nitrosamine risk?', discussed how packaging is becoming an integral part of product design. From ensuring stability and extending shelf life to improving patient compliance and usability, packaging is playing a far more active role than ever before.

The discussions highlighted the importance of early integration between formulation and packaging teams, enabling more holistic product development. This approach not only enhances performance but also reduces the risk of late-stage challenges, which can be costly and time-consuming to resolve.

Another presentation by Dr Ravleen Singh Khurana, MD, Nitika Pharmaceutical Specialities, addressed the growing concern around nitrosamine impurities and the critical role of excipients in risk mitigation.

He stressed that excipients, often considered inert, can contribute to nitrosamine formation due to the presence of precursor substances such as nitrites and amines, even at trace levels. As a result, controlling nitrosamine risk has emerged as a significant industry challenge, demanding greater scrutiny across the formulation lifecycle.

Dr Khurana emphasised the need to proactively integrate nitrosamine risk mitigation strategies during excipient development itself, rather than

addressing the issue downstream. This includes robust design approaches to control reactive species and minimise impurity formation.

His insights underscored a key shift in formulation thinking—where excipients are no longer passive components, but active contributors to product quality and safety.

In another insightful session, Dr Abhijit V Gothoskar, Technical Expert, Sigachi Industries, drew attention to the often underappreciated role of excipients in influencing formulation performance and impurity risks. He noted that excipient functionality is not always fully understood, despite its critical impact on product quality.

Highlighting microcrystalline cellulose (MCC) as a time-tested, multifunctional excipient, he emphasised the need to revisit its role in the context of nitrosamine concerns. Dr Gothoskar pointed to co-processing MCC with antioxidants as a promising approach to help control nitrosating agents, signalling a shift towards more proactive and design-driven excipient strategies.

In another presentation on 'Modulation of drug release by methacrylate copolymers in matrix systems', Kumar N Fadadu, Technical Manager (F&D), Vikram Thermo (India), discussed the role of methacrylate copolymers in controlling drug release within matrix systems.

He highlighted that polymers such as Drucoat RL and RS can effectively function as binding agents to modulate drug release, with combinations of these polymers offering better control. Importantly, he noted that drug release is inversely related to polymer concentration, making precise formulation design critical for achieving desired release profiles.

Jaynil Doshi, Director – Techno Commercial, Pioma Chemicals, also gave a presentation that introduced Hydrocel as a versatile platform of cellulose-based excipients designed for modern formulation needs.

He highlighted that Hydrocel brings together six functional cellulose excipients under a single brand, enabling broad applicability across pharmaceutical formulations. Derived from high-quality wood pulp, these excipients offer high purity, low impurity levels, and consistent performance. Additionally, their regulatory readiness—supported by US DMF certification and pharmacopeial compliance—positions them as reliable solutions for global markets.

> The discussions at the FDD Conclave – Mumbai Connect point to a broader transformation within India's pharma industry and formulation R&D sits at the heart of this transformation

Collaboration as a cornerstone of innovation

The informative sessions were complemented with insightful panel discussions. One of them was on "Strengthening FR&D collaboration with CDMOs and CROs". It explored how companies are increasingly relying on external partners to access specialised capabilities, accelerate timelines, and manage costs.

The panel discussion, moderated by Dr Kour Chand Jindal, Pharma Consultant, brought together industry experts including Minoo Biju, Head – Regulatory Affairs, Piramal Pharma Solutions; Rahul Rajmane, Associate Director R&D/ BD, Cipla Health; Dr Kavita Inamdar, Chief Technical Officer, Indoco Remedies; Vijayendrakumar Redasani, Founder & CEO, DelNova Healthcare; Vinod Raghuwanshi, Sr GM and Head Technical Services, Macleods Pharmaceuticals; Dr Shripad Gadhinglajkar, Sr GM – R&D, Franco Indian Pharmaceuticals and Rajesh Kulkarni, Pharmaceutical and Technical Consultant, to explore the evolving dynamics of working with CDMOs and CROs.

A key theme that emerged was the growing importance of speed to market, particularly in highly competitive generic segments, where timelines can directly impact commercial success. However, speed must be supported by strong fundamentals—panellists emphasised that technical expertise in complex formulations and robust analytical capabilities are essential for selecting the right partner.

The discussion also highlighted the value of a strong scientific talent pool and cross-functional expertise, enabling CDMOs and CROs to effectively navigate formulation, regulatory, and scale-up challenges. Beyond technical capabilities, success increasingly depends on the quality of collaboration. Transparency in communication, data sharing, and regular project monitoring were identified as critical factors in preventing delays and ensuring alignment throughout the development lifecycle.

Equally important is regulatory maturity and cultural fit, which contribute to smoother working relationships and more efficient execution. Panellists stressed that companies should move beyond transactional engagement and instead treat CDMOs and CROs as an extension of their FR&D teams, involving them early in the development process.

The discussion underscored the need to evaluate capacity, infrastructure, and scalability, ensuring that partners are not only capable of development but also aligned with future commercial manufacturing requirements. Overall, the session reinforced that successful partnerships are built on a combination of capability, collaboration, and strategic alignment.

Bridging academia and industry

At FDD Conclave Mumbai Connect, Prof Vandana B Patravale Professor of Pharmaceutics, Institute of Chemical Technology brought an academic perspective to the discussion, emphasising the need for stronger linkages between research institutions and the pharmaceutical industry.

She highlighted that India's academic ecosystem holds immense potential, both in terms of talent and early-stage research. However, unlocking this potential requires structured engagement, translational research initiatives, and alignment with industry needs. By fostering closer collaboration, the industry can not only accelerate innovation but also ensure a steady pipeline of skilled professionals equipped to meet future challenges.

Preparing for formulation R&D's future

The last panel discussion on "Building future-ready formulation teams" addressed the critical issue and explored how organisations can prepare their workforce for the demands of the FR&D's future.

The panel discussion, moderated by Dr Ashok Omray, brought together a cross-section of industry leaders including Dr Vinay Patil, Sr VP – Pharma (R&D), Raptakos Brett & CO; Avinash Velhal, Pharma R&D Leader; Dr Kuntal Ganguly, Head R&D, Albert David; OS Sadhwani, Former Joint Commissioner and Drugs Controller, Food and Drugs Administration, Maharashtra; Dr Samarth Kumar, Head Formulations Development – Injectables, Cipla; Babasaheb Aware, Sr GM – Formulation and Development, Indoco Remedies; and Dr Prashant Kumar Choudhari, GM -Head Formulation Development, Hyloris Pharmaceutical to examine what it takes to build future-ready formulation teams.

A key takeaway was that the role of formulation leaders is rapidly expanding. Beyond core formulation expertise, leaders must now integrate quality, regulatory, manufacturing, and commercial perspectives to drive end-to-end product success. This shift is being accelerated by the industry's move towards biologics, nanotechnology, and advanced drug delivery systems, which demand new capabilities and interdisciplinary thinking.

Despite these changes, the panel underscored that strong scientific fundamentals remain indispensable, forming the base for solving increasingly complex formulation challenges. At the same time, digital tools, AI, and data-driven development are becoming integral to R&D, moving from optional enhancements to core capabilities.

The discussion also highlighted the importance of continuous upskilling, particularly as emerging areas such as gene therapy and nanomedicine reshape the innovation landscape. Alongside technical skills, maintaining regulatory excellence and compliance remains critical to sustaining India's global leadership in pharmaceuticals.

Panellists further emphasised that innovation thrives in environments where teams are encouraged to experiment, take calculated risks, and learn from failure. Ultimately, organisations that invest early in people, skills, and capability building will be best positioned to lead the next phase of formulation innovation.

Road ahead

Thus, the discussions at the FDD Conclave – Mumbai Connect point to a broader transformation within India's pharma industry and formulation R&D sits at the heart of this transformation. It is the bridge between molecule and market, determining how effectively a drug can be developed, delivered, and commercialised.

The conclave concluded with a strong message that the future of pharma will not be built on scale alone, but on the ability to formulate smarter, collaborate deeper, and innovate faster.

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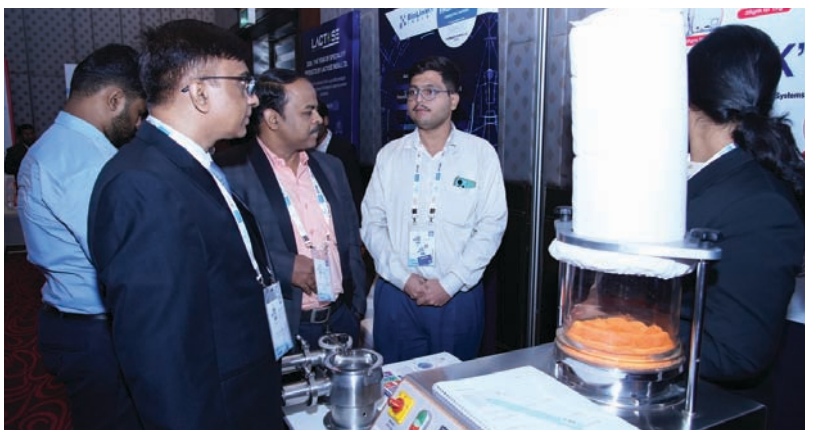

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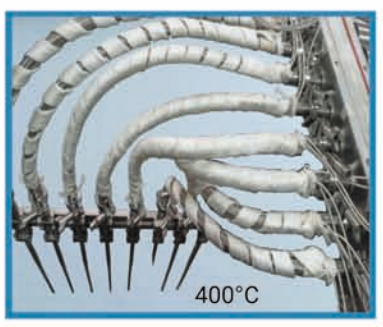

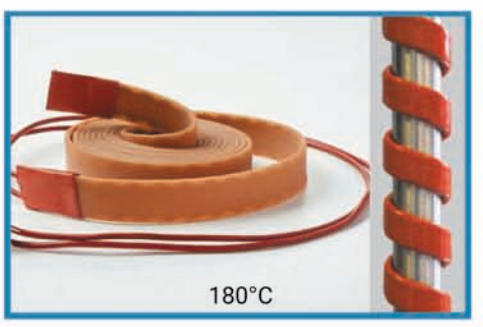

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Eppendorf introduces SpinPro® centrifuge series to streamline life science research

New centrifuge series supports sample processing, workflow integration and laboratory operations across research settings

Hamburg, Germany, 20 March 2026

Effortless every time – Redefine centrifugation with SpinPro® 6 R

Eppendorf, a leading international life science company that develops, manufactures, and distributes instruments, consumables, and services for use in laboratories around the world, today announced the commercial launch of the SpinPro® 6 R centrifuge, the first in the Company's new range of SpinPro floor-standing and benchtop centrifuges. With an advanced user-interface and ergonomic operation, the SpinPro 6 R provides a flexible, and scalable solution for sample separation.

Building on Eppendorf's established range of benchtop centrifuges, the refrigerated SpinPro 6 R benchtop centrifuge offers additional smart features to streamline workflows including new rotors with universal adapters. These rotors can be interchanged within various models of the upcoming SpinPro line, reducing inventory and minimising costs. With a wide range of compatible vessels, the rotors can support applications such as cell culture harvesting, processing of biological samples and isolation of proteins across pharma, biotech, food, and agriculture sectors. Radio Frequency Identification (RFID) chipped rotors enable instant recognition, increasing safety for both samples and users. All new fixed-angle rotors are equipped with Eppendorf QuickLock® Pro lids for fast and easy one-handed operation.

Designed with ergonomics in mind, the SpinPro 6 R is simple to use and easily integrated into existing workflows. Its intuitive software and adaptive 7-inch touch-based display ensure straight-forward set up, while the one-touch operation electric lid drive allows for ergonomic interaction with the device. The SpinPro 6 R is ACT 2.0 labelled, using CO2–based cooling technology without F-gases and full transparency on consumption, production, and sourcing, to contribute to laboratory environmental targets.

> Eppendorf has launched the SpinPro® 6 R as part of its new centrifuge series, designed to support sample separation, workflow integration and laboratory operations across research settings

Dr Tim Schommartz, Global Marketing Manager at Eppendorf SE said; "I see the new SpinPro 6 R centrifuge as a great addition for busy labs worldwide. It combines powerful performance with our latest sustainable CO2-based cooling technology, intuitive Eppendorf QuickLock® Pro lids, and advanced compliance features such as documentation and seamless LIMS integration. The SpinPro range is all about making centrifugation more convenient, more reliable, and more efficient – allowing scientists to concentrate on their research!"

Badrinarayanan, Product Marketing Manager at Eppendorf India, said; "Eppendorf proudly introduces the SpinPro 6 R centrifuge, engineered to elevate laboratory efficiency and compliance. Featuring innovative CO2-based sustainable cooling, Eppendorf QuickLock® Pro lids, and advanced compliance capabilities such as documentation and seamless LIMS integration. The SpinPro 6 R sets a new standard for reliability and operational excellence. This next-generation SpinPro range minimises risk and error, empowering scientists to accelerate research with confidence while supporting sustainability and regulatory requirements."

For more information on the SpinPro 6 R, visit: www.eppendorf.link/spinpro6r

About the Eppendorf Group

Eppendorf is a leading international life science company that develops, manufactures, and distributes instruments, consumables, and services for use in laboratories around the world.

The product portfolio of the business divisions includes Liquid Handling & Consumables and Separation & Instrumentation as well as the Bioprocess vertical includes, for example, pipettes, pipette tips, centrifuges, mixers, ultra-freezers and bioreactors for cell and gene research. In addition, Eppendorf offers a wide range of high-quality consumables. In fiscal year 2024, the Eppendorf Group recorded consolidated revenue of €980.3 million and invested €69 million in research and development (R&D).

Eppendorf products are used in academic or industrial research laboratories, such as pharmaceutical, biotech, chemical, and food industries, as well as clinical, environmental, forensic, and industrial laboratories for process analysis, production, and quality assurance.

Since 1945, the Eppendorf Group has been headquartered in Hamburg, Germany, and today operates production and R&D sites in Europe, Asia and North America and has subsidiaries in more than 30 countries. Today, the Group employs more than 4,000 people worldwide. They all act in accordance with the purpose of the company's founders: to improve human living conditions.

Romaco Group appoints Nicola Magriotis as Chief Sales Officer

New role introduced at group level to lead global sales and service operations

The advisory board of Romaco Holding GmbH has appointed Nicola Magriotis as Chief Sales Officer (CSO) of the Romaco Group. By creating this new managerial post at Group level, the international pharmaceutical machinery manufacturer is strengthening its global sales and service organisation.

Nicola Magriotis has been appointed Chief Sales Officer (CSO) by the advisory board of Romaco Holding GmbH, and in this role will be responsible for the sales and service organisation of the international Romaco Group. He joins Jens Torkel (Chief Executive Officer) and Ann-Xiaoyan Li (Chief Financial Officer) on the management team of the pharmaceutical machinery manufacturer based in Karlsruhe, Germany.

As of 2020, Nicola Magriotis has served as Managing Director of the Romaco S.r.l. business unit in Bologna, Italy, and will continue in this role alongside his appointment as CSO. Since joining the company in 2007, he has held various management positions, including Product Manager, Sales Director, and Director of Sales and Service. During his almost 20-year tenure at the Italian production site for Romaco's Macofar and Promatic brands, his responsibilities have continually expanded with each new role.

Since the beginning of 2026, Nicola Magriotis – who has a degree in mechanical engineering and an MBA (Master of Business Administration) from the Bologna Business School – has been overseeing the Romaco Group's international sales and service activities as CSO at Group level. This strategy is supported by the parent company Truking Technology Ltd. In future, the two firms will work even more closely together to expand existing markets and tap into new ones.

Nicola Magriotis, CSO of the Romaco Group

"My many years of work at Romaco have played a decisive role in shaping my leadership style," explains Nicola Magriotis, CSO of the Romaco Group. "I would like to thank my mentors and the management of Romaco and Truking for the great trust they have placed in me, and am very much looking forward to taking on the challenge of being the first Chief Sales Officer in the history of the Romaco Group. As a one stop solutions supplier, we operate in an extremely complex market environment, in which we constantly must prove ourselves as a reliable partner. Building lasting trust through personal customer relationships, well-founded technical and application-specific expertise and excellent services – this is what I will be focusing on in my new role."

"Nicola Magriotis' strong ties to Romaco, as well as his many years of experience and wide-ranging expertise in sales and service, make him particularly well-suited for the position of CSO," emphasises Jens Torkel, CEO of the Romaco Group. "Mr. Magriotis builds bridges – and this is a quality of enormous importance in an international organisation such as the Romaco Group, with its extensive and varied sales network and global customer base. He is also taking on a key role in the collaboration with our parent company, Truking, to make even better use of existing opportunities for synergies in the future."

Romaco Group

Romaco is a leading international supplier of processing and packaging equipment specialising in engineering technologies for pharmaceutical products. The Group provides individual machines, lines and turnkey solutions for manufacturing, filling and packing powders, granulates, pellets, tablets, capsules, syringes, liquids and medical devices. The company also serves the food and chemical industries. Through its various technologies, Romaco is committed to sustainable production and to systematically reducing CO2 emissions.

The Romaco Group has its headquarters in Karlsruhe (Germany) and is part of Truking Technology, a globally operating high-tech enterprise based in Changsha (China). Truking's core competency is handling and filling pharmaceutical liquids.

Romaco operates from six production sites worldwide, with a broad portfolio comprised of seven established product brands. Noack and Siebler (Karlsruhe, Germany) supply blister, heat-sealing and rigid tube filling machines. Macofar (Bologna, Italy) markets technologies for filling sterile and non-sterile powders and liquids. Promatic (also Bologna, Italy) specialises in cartoners, track & trace systems and case packers. Kilian (Cologne, Germany) is a leading manufacturer of tablet presses. Innojet (Steinen, Germany) is in the business of granulating and coating fine solid particles. Tecpharm (Barcelona, Spain) offers tablet coating technologies.

More than 930 highly skilled and committed Romaco employees are dedicated to the development of future product technologies and to the continuous implementation of internal improvement processes. The Romaco Group's multi-brand system solutions are sold worldwide through ten Sales & Service Centers and a dense network of local agent organisations. Over 12,000 installations delivered by Romaco are currently in use in more than 180 different countries.

For more information on Romaco, visit our website and social media channels: www.romaco.com – Showroom – LinkedIn – YouTube

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Optima advances digital twins to boost efficiency in pharmaceutical turnkey machines

Virtual testing, training and simulation tools enhance performance in complex manufacturing environments

The potential is clear. If digital twins can fully replicate the functionality of turnkey systems, project timelines can be significantly shortened. Specialised digital twins for complex fill-and-finish systems, including isolators and freeze-drying units are already available. This article explores the efficiency boost these digital tools provide.

The concept of the digital twin has been widely known for years, but what it truly entails is interpreted differently due to the diverse fields in which digital twins are applied. Today, they are already being used in logistics, personalised medicine, and even marketing.

Even within mechanical and systems engineering, there are numerous "types" of digital twins. The complexity of the system to be digitised plays a key role in determining how easily it can be digitally mapped. In addition, the potential application scenarios for a digital twin are equally diverse. Whether these varied tasks can ultimately be fulfilled depends largely on the level of detail the digital twin is able to achieve.

Bringing the vision to life

In the medium term, Optima's digital twins will represent all relevant details of a comprehensive turnkey system. These models are fully functional and operate in real time. A single, centralised model integrates all core components, including fill-and-finish processes, isolators, and, where applicable, freeze-drying systems with loading and unloading, as a complete turnkey solution.

The digital twin serves as a complete virtual mirror of the entire process that containers or liquid pharmaceuticals undergo within a system, including all supporting processes. This can then be used, for example, to conduct flow simulations across the entire isolator-protected area, both during operation and with all moving system components in place. Software testing, as well as other simulations, can be conducted using this centralised digital model, even before the physical machinery is built. That's the vision – and it's almost within reach.

Every day, a dedicated team of experts at Optima is working to make digital twins viable for both current applications and future innovations. These efforts are already yielding results. What began as a development initiative has evolved into a new service offering now available to Optima's customers. The first pharmaceutical companies are already commissioning digital twins of their actual equipment, highly complex and large-scale systems. One key distinction from the long-term vision is that these digital twins are currently specialised for specific application areas, rather than being centralised models of entire systems.

CAD data produces a 3D model, but only by integrating digitised mechanics, kinetics, sensors, servo motors, and software does a digital twin emerge that accurately represents the processing workflow

Preliminary testing of control software on the digital twin offers substantial time savings and efficiency improvements – capabilities now included in Optima's portfolio

Digital twins, operated through original HMIs, are already being successfully utilised for training purposes

Practical application: Preliminary PLC testing using the digital twin

"Today, we already identify several areas where digital twins can be applied" says Waldemar Mayer, Group Leader Development Digitalisation at Optima. One of the key development goals is to use the digital twin to conduct virtual testing of a system's control software (PLC) in advance. "We see enormous potential for time savings here. If we can fully test the program code for an entire system in a virtual environment, rather than on the physical machine, it marks a significant milestone. Our customers benefit from faster, more efficient commissioning processes," Mayer explains.

With this type of digital twin, Mayer's team sees itself close to the finish line, particularly when it comes to highly complex turnkey systems. The objective is to develop a model in which the PLC cannot distinguish whether it is operating a real system or its digital counterpart. Ideally, this would allow the program code developed on the digital twin to be transferred to the real system with little to no modification. As a result, time-consuming iteration loops on the physical system, which were previously almost unavoidable, could be eliminated.

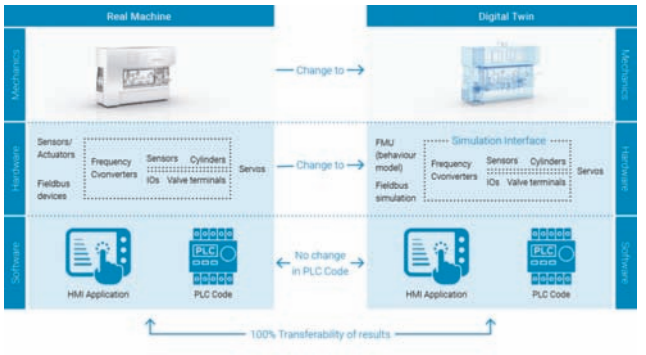
Another key application for this type of digital twin is the testing of firmware updates from PLC and component manufacturers. Rather than deployment directly to the physical system, updates are first tested on the digital twin. Only after successful validation are they rolled out to the real system. Similarly, any functional changes or enhancements developed jointly by Optima and the customer can be virtually tested in advance. This approach eliminates the need for prolonged production downtime and significantly reduces the risk of errors, offering an additional layer of security.

From training to hands-on operation

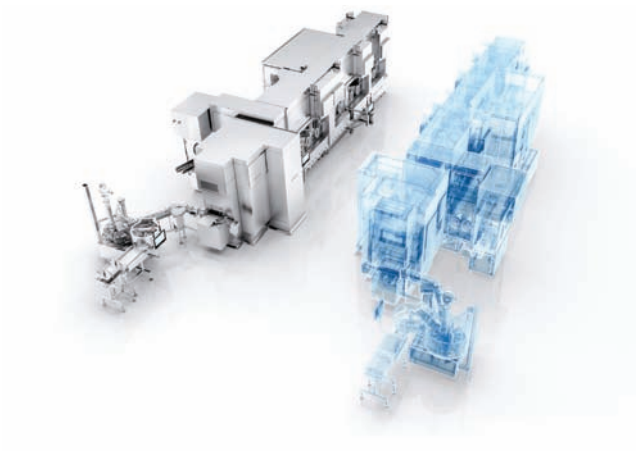
When new functions or modules are developed within a project, functional testing is typically conducted on the physical hardware using test benches. If

modifications are required, a redesign is implemented, the test bench is reconfigured, and new components may need to be ordered, explains Mayer. However, if a digital twin of the module or function is already available, it can reveal potential areas for improvement without the need to order parts or rebuild test benches. Additionally, this visualisation proves especially valuable when dealing with highly complex processes within the systems. According to Mayer, these interrelated processes can be better understood on screen with the aid of moving components.

Training new employees using digital twins offers significant time savings because operators in training are not permitted to work on the actual system during production. Consequently, production systems must be "set aside" for training, leading to potential production losses or delays in sales. Since the digital twin features a fully functional HMI, it allows trainees to practice tasks like starting the system or performing format changes. Individual processes and the impact of these format changes can be realistically observed within the digital twin.



How does Optima create a digital twin? One key element is the simulation interface, which digitally replicates the behavior of hardware components such as sensors and valves. Ultimately, the goal is for the PLC code developed and tested on the digital twin to be transferable to the physical machine with minimal effort



Ambitious vision: A centralised, fully representative digital twin that visualises movements and processes in real time, accurately incorporating physical dynamics

Physics and the digital twin

Despite the well-founded enthusiasm surrounding digital twins and their potential, considerable challenges remain. Mayer points out that, to date, there is no central tool for creating digital twins. Substantial manual effort is still necessary to develop a digital twin that meets system requirements. Similarly, the development tools themselves are still evolving. Optima has implemented one key advancement – a simulation interface compatible with both Rockwell and Siemens control software. However, support from component manufacturers continues to offer room for improvement.

The level of detail is a key differentiator and ultimately a measure of quality for digital twins. Optima's ongoing development of its digital twin explicitly aims to represent processes as realistically as possible. This objective goes hand in hand with the increasing integration of physical phenomena into the models. Physics encompasses many effects, such as drive slippage or compensatory movements in motor mounts. In these cases, if a load is not applied precisely as introduced, the deviation may seem negligible in isolation, but the sum of such slight inaccuracies will be noticeable in the digital twin.

Digital support

Another aspect of digital twins involves developing and integrating behavioral models for the many hardware components, aiming for the highest possible level of differentiation. Mayer uses cylinders in systems as an example: Do they simply open and close digitally, or do they also simulate dampening effects as in the real system? Optima is committed to achieving the most precise simulation possible and ensuring the control software can be transferred seamlessly from the digital twin to the physical system. Consequently, the digital model incorporates dampening effects in cylinders.

What remains on the developers' agenda is the integration of previously separate digital elements into a comprehensive, higher-level model. Current models, tools, and computational capabilities are not yet sufficient to fully support this. For instance, the dosing behavior of liquids in vials could eventually be incorporated into a centralised model. While isolated simulations of this behavior are already feasible, representing it accurately as a component within an overall system model is still out of reach. This would require including factors such as laminar flow and, where applicable, simultaneous dosing and transport processes involving acceleration and deceleration.

First projects: Comprehensive

Optima's initial digital twin deployments are already being delivered for complex systems. One ongoing project involves creating a digital twin of an Optima turnkey system including the fill-and-finish line, isolators, and four freeze dryers.

These large, complex pharmaceutical systems are hardly comparable to other "twin projects" in mechanical engineering, Mayer explains. A pharmaceutical line, like the one currently being developed both physically and as a digital twin at Optima, can consist, for example of nine machines connected inline. In total, up to 150 servo motors, sensors, and other components operate together and are software controlled. This complexity surpasses that of a digital twin of an entire production hall with 30 robots performing relatively simple tasks, Mayer notes.

Adding to the complexity of digital twins in the pharmaceutical segment are the stringent regulatory requirements specific to this industry, particularly those affecting software. For instance, any software changes must be verifiable and fully traceable. Additionally, different software modules must be secured against unauthorised access and may only be modified by authorised personnel.

Optima is making significant strides in the technological advancement of digital twins, which demands substantial investment. High-performance computing power and the latest graphics cards have been acquired to meet these requirements. However, advanced development tools are only effective when paired with qualified personnel who have the expertise to utilise them properly.

Since July 1st, Nicholas Alexander Schloer has been leading Optima's "Digital Twins" department. Additionally, Optima's experts collaborate with specialists across company boundaries when necessary. "To accelerate development, we evaluate each situation individually to determine the most efficient and effective path to achieve our goals," explains Mayer.

Turnkey advantage

Considering Optima's development objectives and the complexity of pharmaceutical systems, one point stands out: Optima's turnkey approach provides optimal conditions for creating digital twins. All relevant information integrated into a digital twin is directly accessible without company boundaries or restrictions. The greater the level of detail in the digital twin, the more effectively numerous functions can be digitally coordinated. Additionally, having program code developed by a central provider for all plant components offers a distinct advantage. The ability to digitally test this program code for the entire system beforehand marks a significant step forward. At Optima, the digital twin has not only found its footing but is taking major steps toward a promising future. Its appeal lies not only in its development potential but also in the tangible benefits it has already delivered, benefits that validate and encourage its deployment in customer projects.

A key development objective is leveraging the digital twin for virtual testing of a system's control software (PLC) prior to physical commissioning.

Optima's ongoing development of its digital twin explicitly aims to represent processes as realistically as possible.

Important for you

- Optima offers digital twins for even the most complex turnkey systems
- A key milestone is the programming and testing PLC code on the digital twin at an early stage
- Additional applications include training and firmware updates, and functional system upgrades
- Significant efficiency and time savings are already being realised
- The Vision: A centralised, detailed digital twin encompassing all simulations and tests

SEW-EURODRIVE India opens Drive Technology Centre in Chennai

Facility expands assembly and service capabilities to support industrial operations in southern and eastern India

SEW-EURODRIVE India has inaugurated its new Drive Technology Centre (DTC) in Chennai, one of South India's fastest-growing industrial hubs. Conceived with a long-term perspective, the facility is designed as a robust platform built for generations. It strengthens SEW-EURODRIVE's ability to serve customers across southern and eastern India with higher responsiveness, reliability, and long-term support.

Spread across 12.27 acres, the 21,350-sqm assembly and service facility provides the scale and flexibility needed to support customer growth, evolving application requirements, and future expansion. It reflects SEW-EURODRIVE's commitment to sustainable development, technology leadership, and long-term partnership with Indian industry, combining global engineering standards with strong local execution.

The facility complies with green building norms, incorporating natural daylight, solar power generation, and rainwater harvesting. Energy-efficient construction and advanced climate control reduce shopfloor temperatures by up to 3°C, supporting stable production conditions, consistent quality, and improved working environments.

At its core is a 15,000-sqm assembly shop with digitisation-ready, high-productivity assembly cells based on a single-piece flow concept, along with SEW-EURODRIVE India's first semi-automated painting booth to ensure consistent surface quality and higher throughput.

With this DTC, SEW-EURODRIVE reinforces its role as a trusted partner, investing in capabilities that support customers' long-term industrial growth in India.

Complete environmental monitoring solution – testo Saveris Pharma

There are several critical applications in the industry like research and development that demand for continuous & reliable monitoring of important environmental parameters. From medical, biotechnical, chemical and pharmaceutical laboratories to cleanrooms, biobanks up to blood and tissue banks, a holistic monitoring system is very necessary which reliably records different measurement parameters in these rooms and at equipment. Wherever there is a need to adhere to necessary standards, ensure traceability and audit compliance, especially Pharma, these solutions become crucial in the facility operation.

The most efficient way to address this requirement is the implementation of fully automated environmental monitoring system testo Saveris Pharma. It monitors and documents temperature, humidity, differential pressure, and other parameters without interruption and compliantly with GxP so that audits and inspections are conducted smoothly. As a complete solution, testo Saveris Pharma combines

- High-precision measurements with secured data communication
- Intuitive and pro validation software
- Comprehensive services.

The system consists of following components

Data logger and communication modules

Data loggers are the components that measure / log the data continuously at different locations in the facility. They communicate with the base unit to transfer the recorded data. Because there are numerous tasks to fulfil in research and development, there are various models of data logger to measure different parameters.

Another important task is data transfer and for that communication modules are used. Each data logger can be flexibly connected to one of the three communication modules.

- WLAN Module
- LAN Module
- Radio via Testo Ultra range communication Module

testo UltraRange ensures that a strong and robust radio signal is available even over long distances or in closed rooms. All data loggers can be exactly calibrated, and depending on the model, can record temperature and relative air humidity. As per the applications, Data Loggers are selected for Environment Monitoring for Warehouse, Analytical/ Microbiology Lab, Animal house or Equipment Monitoring like Refrigerator, Freezer, Chiller, Walk in chamber, etc.

The base station

The base is literally the heart of testo Saveris Pharma system. It can connect with 1000 different Data Loggers at a time. It collects measurement values and analyse it limit value violation or any other critical event occurs. It plays an important role in prompt alarm management. The base unit can be positioned centrally at a given facility location or office. Base station delivers alarms to users via an alarm relay and an LTE stick that enables alarms by SMS as well in addition to visual and audible alarms.

Digital and analog sensors

The instrumentation utilised to measure parameters like temperature and humidity is in the form of variety of digital and analog sensors that are easy to handle and install. The Digital sensors has advantage over analog sensors as it can be quickly exchanged during continuing operation for calibration or defect correction. Calibration of Digital Sensor is independent of its Logger. Thus, it ensures no gap in the measurement values or documentation. The measuring ranges of the temperature probes extends from -200 °C to +1300 °C, covering almost any possible scenario in the field of research & development.

The integration of other measurement parameters such as differential pressure, particles etc. also work smoothly with the analog coupler as a standardized interface.

System software

Once the data is recorded by Loggers and analysed by the base station, the testo Saveris Pharma software comes into play where all readings are collated, stored, visualized, and backed up seamlessly. Automatic reports are generated and sent over email to concerned users. Some important features are applied like electronic signature, Electronic Record, Access Control, Audit Trail, Alarm Logs. There are two versions of the testo Saveris software;

- testo Saveris PRO software- It is suitable for the automated and uninterrupted data monitoring with less stringent regulations, normally other than Pharma Industry.
- testo Saveris CFR software – It guarantees unconditional adherence to US 21 CFR Part 11 as well as Annex 11 of the EU guidelines for GMP. In addition to the range of function of the PRO version, it offers Audit Trail and electronic signatures.

In addition, we provide Web access to the data with testo Saveris Pharma Cockpit - a web based and intuitive user interface which allows data access from different end devices. Alarms can be identified and acknowledged via a smartphone, tablet or PC at any time. It also supports features like digital signature post any action as well as a mandatory comment on the event.

Comprehensive services

The most important aspect of any solution is after sales service. This is one of the strongest values offered by Testo to its customers. Testo extends its support from site survey, Installation commissioning, IQ-OQ documentation to annual maintenance work and recalibration. So, all the end-to-end services are offered under one roof as an OEM by Testo. Thus, user do not have to run pillar to post to get support, Testo ensures rich user's experience throughout life cycle of the system.

Areas of application

- Area Monitoring in Labs, Production, Warehouse, Animal House in Pharma
- Equipment monitoring for QA/QC, Microbiology in Pharma
- Clean room area Monitoring in Pharma
- Refrigeration and deep-freezer applications in Pharma
- Uninterrupted cold chain monitoring & controlled freezing in blood and bio banks
- Applicable for lab equipment from laboratory extractor to water bath
- Data centre Area Monitoring
- Calibration and Testing Lab area monitoring

For more details, login to our website www.testo.com or write back to us on info@testo.in

Redefining humidity control in pharma manufacturing

Bry-Air systems reflect shift towards material-based humidity control in pharma manufacturing

In pharmaceutical manufacturing, environmental control has evolved from a supporting function to a critical determinant of both operational efficiency and product quality. As energy costs continue to rise and sustainability targets become more stringent, maintaining precise humidity levels is no longer just a technical requirement but a significant operational challenge. Manufacturers are increasingly under pressure to achieve consistent environmental conditions while minimising energy consumption and controlling operating costs, making efficient humidity management a key focus area across modern pharmaceutical facilities.

Humidity plays a significant role across multiple stages of pharmaceutical production. From material handling and granulation to coating, packaging, and storage, even small fluctuations can influence product characteristics, affect hygroscopic materials, and introduce variability in processing conditions. In cleanrooms and API manufacturing environments, uncontrolled moisture levels can lead to issues such as agglomeration, degradation, electrostatic challenges, and long-term stability concerns.

Traditionally, desiccant-based systems have been widely deployed to manage humidity in pharmaceutical facilities. These systems have provided reliable performance over the years and continue to form the backbone of environmental control strategies. However, as manufacturing priorities expand to include energy efficiency, sustainability, and operational optimisation, there is increasing attention on how humidity control can be achieved with lower energy demand and improved process integration.

This shift has driven interest in newer approaches to dehumidification, particularly those enabled by advancements in material science. Emerging adsorption materials with highly engineered porous structures are enabling more efficient interaction with water vapor, allowing systems to deliver consistent environmental control with reduced operational burden. These developments are also facilitating better integration with modern energy systems and supporting broader sustainability objectives within pharmaceutical operations.

As environmental control becomes more closely linked with process performance, the emphasis is moving beyond achieving target conditions to maintaining them with greater stability and efficiency. This is particularly relevant in high-sensitivity manufacturing environments, where even marginal deviations can have downstream effects on product quality and yield.

In this context, manufacturers are increasingly adopting advanced dehumidification platforms based on next-generation adsorption materials, with companies such as Bry-Air introducing systems like the P80°x to address these evolving requirements. Such solutions reflect a broader shift toward material-driven innovation in humidity control, where improved adsorption characteristics enable more efficient and stable performance under demanding operating conditions.

As pharmaceutical manufacturing continues to advance, environmental control is no longer viewed as a standalone utility, but as an integral component of process integrity—requiring solutions that align with both operational demands and sustainability goals.

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Gandhi Automations elevates loading bay efficiency with advanced dock leveler solutions

Engineered systems from Gandhi Automations Pvt Ltd enhance safety, durability and seamless material flow

At Gandhi Automations, we are proud to be recognized as India's No.1 Entrance Automation and Loading Bay Equipment Company. This achievement is the result of our relentless pursuit of excellence, innovation, and a steadfast commitment to delivering quality. Over the years, we have earned a reputation for providing reliable solutions backed by exceptional customer service. Our dedication to maintaining the highest standards is reflected in our certifications, including EN ISO 9001:2015, EN ISO 14001:2015, and ISO 45001:2018, accredited by TÜV Austria.

Since our inception in 1996, we have been at the forefront of manufacturing, importing, distributing, and installing products that are both reliable and user-friendly.

Among our range of innovative solutions, our dock levelers play a crucial role in enhancing the efficiency and safety of loading and unloading operations. We offer Electro-hydraulic, pneumatic, and mechanical Dock Levelers, each designed to ensure fast, smooth, and safe transitions between vehicles and loading bays. Designed to meet EN 1398 standards, our dock levelers are engineered for the most demanding environments. The platform surface features an MS almond-shaped anti-slip checkered plate, with a robust 12+2 mm thickness, providing enhanced durability and safety for optimal performance. Available in capacities of 6, 9, and 12 tonnes, our dock levelers are versatile enough to meet a wide range of operational needs.

To meet diverse loading needs, we provide a comprehensive range of dock levelers:

a) Radius Lip Dock LevelersAvailable in various sizes and capacities, our Radius Lip Dock Levelers connect the dock with the truck bed, facilitating easy drive-on and drive-off operations for forklifts and other equipment. Their self-cleaning lip-hinge system prevents the accumulation of dust and dirt, ensuring smooth operation.

b) Telescopic Lip Dock LevelersIdeal for situations where vehicles cannot dock closely, such as sea containers or side-loading railway wagons, these levelers come with an extendable lip that can reach up to 1 meter, providing flexibility in various loading scenarios.

c) Edge-of-Dock LevelersCompliant with the latest EN 1398 safety standards, our Edge-of-Dock (EOD) Levelers are ideal for facilities without an existing pit, where the height difference between the loading dock and the truck bed is minimal. These levelers are particularly suited for environments with consistent truck heights, such as warehouses, distribution centres, and retail facilities. EOD levelers offer an efficient, space-saving solution for quick loading and unloading in locations where installing a pit-style leveler is not feasible. They offer reliable performance and safety for efficient loading operations.

d) Forklift Roll-Off Barrier Lip Dock LevelersOur newly introduced Forklift Roll-Off Barrier Lip Dock Leveler includes a run-off protection feature that prevents accidental forklift roll-off when the overhead door is open and no trailer is present. This leveler combines the benefits of hydraulic dock levelers with the added security of a robust barrier.

All our dock levelers can be seamlessly interlocked with existing doors and vehicle restraint systems, ensuring top-notch performance and security in every loading operation.

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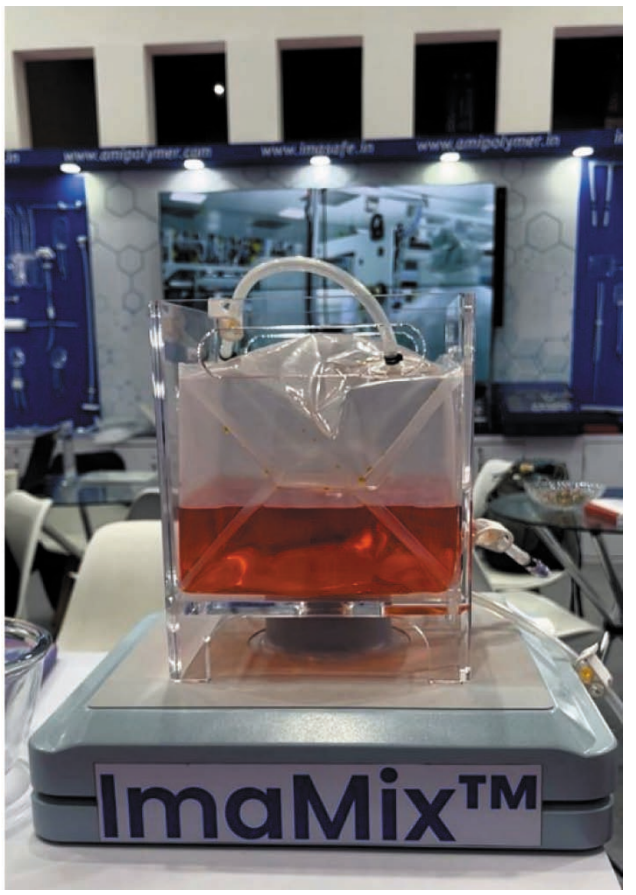
Ami Polymer strengthens biopharma processing with single-use mixing systems

Advanced polymer-driven solutions support sterile, scalable and efficient upstream and downstream operations

IntroductionMixing systems are a critical component of modern biopharmaceutical manufacturing, ensuring sterility, product consistency, and process efficiency. With the rapid shift toward single-use technologies, mixer bag systems have become an innovative and reliable solution across upstream and downstream applications.

Designed for single-use disposable and biopharmaceutical industries, these systems are manufactured in controlled cleanroom environments (ISO Class 7 / ISO Class 8), ensuring strict quality control from raw material selection to finished product delivery.



Ami Polymer is advancing single-use mixing systems designed for biopharma applications, enabling sterile processing, consistent product quality and efficient operations across upstream and downstream workflows

Key features & benefits

- Tailored designs for specific process applications
- Integrated precision impeller for consistent and uniform mixing
- High burst strength for durability and operational safety
- 100 per cent integrity tested with pressure leak validation
- Superior protection of product molecules and components
- Easy inlet and outlet connections
- Scalable sizes: 50L | 100L | 200L | 500L | 1000L

Applications in biopharma

Upstream processing

Single-use mixing systems play a vital role in:

- Media preparationEnsures uniform dissolution of powders and nutrients in WFI, directly impacting cell growth and productivity.
- Buffer preparationProvides accurate and homogeneous mixing for pH control during cell culture and fermentation.
- Cell culture applications-Maintains sterility and consistency in media preparation and storage.
- Process & fluid transferEnables safe, contamination-free handling of process liquids.

Downstream processing

Mixer systems are equally critical in:

- Buffer & reagent preparationSupports chromatography and filtration processes with reliable mixing performance.
- Process intermediatesUsed for holding and mixing intermediate bulk solutions during purification.
- Virus inactivationEnsures proper interaction between product and inactivation agents.
- Final formulationProvides controlled and gentle mixing of APIs with excipients, minimizing shear stress and protein aggregation.
- Fill-finish operationsEnsures homogeneity before sterile filling into vials or syringes.

Compliance & Certifications

Manufactured to meet global regulatory expectations:

- ISO 11137 – Sterilization Validation
- USP <87> – Biological Reactivity (In Vitro)
- USP <88> – Biological Reactivity (In Vivo)
- USP <661> – Plastic Packaging Systems
- Extractables & Leachables Studies

These standards ensure material safety, biocompatibility, and regulatory acceptance in global markets.

The role of advanced Polymer Solutions

High-performance polymer components such as silicone tubing, single-use assemblies, gaskets, and customized molded parts are essential for maintaining sterility and chemical compatibility.

At Ami Polymer, we deliver advanced polymer solutions that support safe, scalable, and compliant mixing technologies for the biopharmaceutical industry.

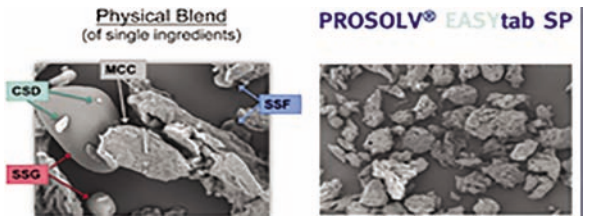
By Sreedhar Chirra
Assistant Manager
(Business Development)

PROSOLV® EASYtab – All-in-one excipient

Designed for direct compression, this excipient can achieve functional tablet properties that cannot be achieved when adding the same components individually to a formulation

Developed using the PROSOLV® technology, PROSOLV® EASYtab is the first lubricated high functionality excipient on the market. It effectively combines four individual components –

◆ Microcrystalline cellulose (filler/binder)
◆ Colloidal silicon dioxide (glidant)
◆ Superdisintegrant
◆ Lubricant



Particle morphology of Physical blend of individual excipients and PROSOLV® EASYtab

As compared in above image, PROSOLV® EASYtab is not a simple physical blend. Instead, it is spray-dried, uniform, lubricant-coated high functionality excipient composite. Compounding with PROSOLV® technology leads to homogenous distribution of individual components throughout the particle and on its surface. All the excipients maintain their chemical identities while synergistically providing increased physical and functional performances due to significantly increased surface area.

Due to this unique combination and favorable particle morphology, it is perfectly suited for dry mixing / direct compression applications.

Advantages of using PROSOLV® EASYtab discussed in brief in subsequent section.

Benefits of PROSOLV® EASYtab:

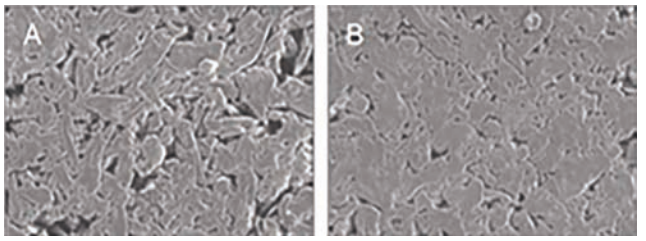
Process benefits

◆ **Simple process steps:** Processing with PROSOLV® EASYtab requires only blending as compared to conventional granulation techniques. This leads to less dust generation and significantly lower cleaning and change over gaps between batches.

◆ **Better flow properties:** Favorable particle morphology imparts excellent flow property when compared with physical mixture and blends.

◆ **Better coating process and film adhesion to core:** Its unique surface structure makes it ideally suited for film coatings, resulting in better film adhesion and crisp logo definitions.

◆ **Blending robustness:** If longer mixing times are required in order to ensure a good blend homogeneity, there is no risk of over-mixing or segregation. This provides robustness in terms of blending times due to its all-in-one unique structure.



SEM images of tablet surfaces. A. MCC, B. PROSOLV® EASYtab

Formulation benefits

◆ **Excellent blend and content uniformity:** No possibility of segregation of individual excipients due to the composite nature. The porous surface helps adhesion of micronized API particles and hence improves uniformities in blend and finished formulation.

Following table shows results of low-dose API (0.6%) formulation with direct compression process, which shows satisfactory uniformity of dosage throughout the compression cycle.

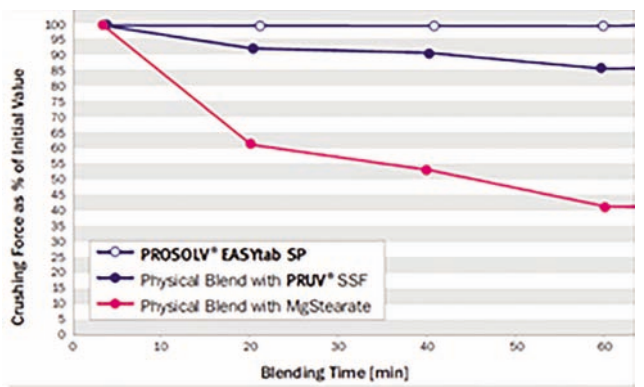
◆ **Improved compactability:** Excellent compaction and lubrication attributes generated due to spray-drying manufacturing process result in tablets with good hardness, less friability at lower compaction forces.

Sampling point	% API amount
Initial	105.1
Middle	101.4
End	100.5

◆ **Smaller tablets:** Lower excipient level needed when formulated with PROSOLV® EASYtab grades as compared to using individual excipients, which result into tablets with smaller shape and size.

◆ **Rapid and consistent disintegration:** Intricately entrapped superdisintegrant particles ensure rapid and uniform disintegration and ultimately dissolution.

◆ **Improved surface for coatings:** Smooth unique surface helps to get tablets devoid of coating defects and uniform films for aesthetic and functional purposes as well.



Effect of blending times on tablet hardness

◆ **Better suited to pressure sensitive APIs, Enzymes and Probiotics:** Mechanically robust tablets with lower friability produced at comparatively lower compaction and ejection forces when formulated with PROSOLV® EASYtab. This helps to get a better hardness for tablets with APIs exhibiting sensitivity towards hardness for disintegration and dissolution. It also supports to maintain viable cell counts for probiotics. There is no significant reduction in enzyme activity when Enzyme tablets are compressed with PROSOLV® EASYtab.

Cost benefits

◆ **Low setup:** Due to easy process of direct compression, there is no need of comparatively complex and energy consuming equipment line setup.

◆ **Single inventory management:** Being composite of four excipients, only single inventory to be maintained instead of multiple individual grades. The cost is also saved on raw material quality testing.

◆ **Accelerated product and process development:** PROSOLV® EASYtab is most suitable for direct compression applications; Hence, lesser process and formulation parameters needed to be optimized to finalize formulation and take it to market.

◆ **Less number of batches for same output:** When formulated with PROSOLV® EASYtab, batch size is proportional to blender size unlike equipments for conventional granulation methodologies. This leads to higher batch size resulting in less number of batches for same output; results in lower time, lesser testing.

◆ **Higher outputs:** Simpler process as compared to wet and dry granulation results in shorter processing time and higher production. It also shows lower die-fill depths due to better flow and density properties. This makes PROSOLV® EASYtab a choice of excipient for high volume formulations.

◆ **Improved yield:** Lesser number of unit operations results in much lower process loss at every step.

◆ **Low risk of batch failure:** Converting conventional granulation process to dry mixing step minimizes person and process variables, which significantly reduces the risk of batch failure.

◆ **Prolonged tooling and equipment life:** With PROSOLV® EASYtab, sufficient tablet hardness can be achieved at lower compaction forces, which leads to prolonged life of tooling and equipments.

◆ **Best suited for continuous manufacturing:** Because of its all-in-one structure, blending uniformity and blending robustness, PROSOLV® EASYtab is best suited for continuous manufacturing process.

Other benefits

◆ **Patient compliance:** Smaller tablets formulated with PROSOLV® EASYtab may show better patient acceptability.

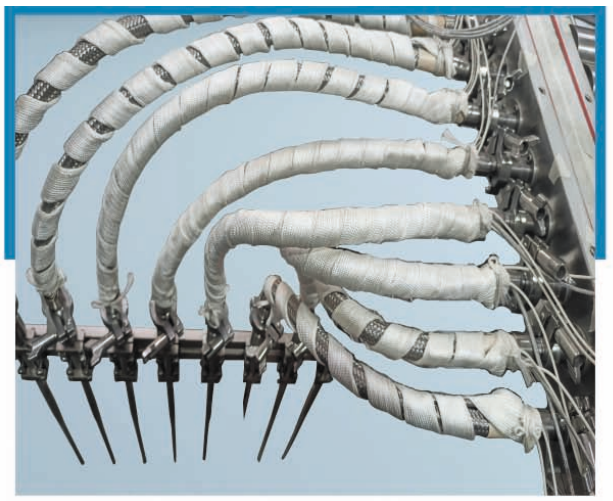
◆ **Complete regulatory support:** QnQ composition revealed for all PROSOLV® EASYtab grades. USDMF is available along with complete regulatory support.

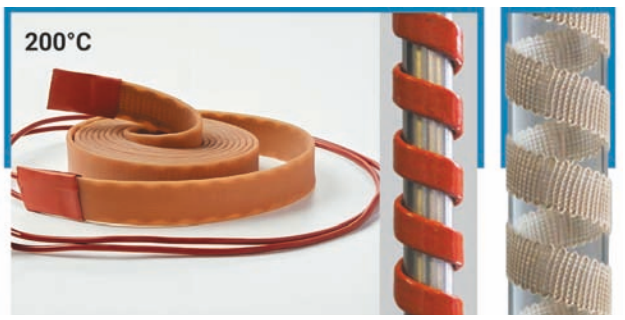
Conclusion

Excipients have come a long way since powdered cellulose, particularly with the introduction of all-in-one excipients such as PROSOLV® EASYtab. Designed for direct compression, this excipient can achieve excellent functional tablet properties that cannot be achieved when adding the same components individually to a formulation. PROSOLV® EASYtab has some special benefits when used in continuous manufacturing applications too.

(The author is Technical Manager, JRS Pharma India. He can be contacted at krishna.patel@jrsindia.com)

Flexotherm heating tapes & cords





Typical Applications of Heating Tapes and Cords in Industrial Solvent Handling

Handling and processing solvents in industrial environments requires precise temperature management. Many solvents are sensitive to fluctuations—too cold, and they may thicken or crystallize; too hot, and they may degrade or evaporate. Tempo's Flexotherm™ heating tapes and cords provide a safe, flexible, and efficient solution for maintaining solvent temperature across a wide range of industrial processes.

Why Tempo Heating Tapes and Cords?

Unlike bulky heating systems, Tempo heating cords and tapes are thin, robust, and easy to wrap around drums, pipes, valves, or vessels. They deliver uniform heating, reduce the risk of cold spots, and can be paired with Tempo's digital or thermostatic controllers for precise monitoring and safe operation.

Typical Applications in Solvent Handling

1. Drum and Container Heating: Solvents stored in poly or metal drums can become viscous at low temperatures. Tempo drum heating jackets and tapes keep contents at the right viscosity for safe pumping, mixing, or decanting.

2. Pipeline and Transfer Line Heat Tracing: Solvent transfer lines are prone to cooling and blockages. Flexotherm™ heat tracing cords maintain consistent flow and prevent condensation or freezing.

3. Valve and Flange Heating: Critical fittings often act as cold spots. Tempo heating tapes eliminate these risks, ensuring solvents move smoothly through the system.

4. Reactor and Vessel Heating: In chemical processing, Tempo customized heating solutions wrap neatly around reactors, tanks, or vessels to deliver controlled, uniform heating.

5. Laboratory Solvent Applications: From Soxhlet extractors to heating mantles, Tempo lab heating products support safe solvent extraction, distillation, and analysis.

6. Gas Cylinder Warming: For solvent-related gases such as SF6, propane, or nitrogen, Tempo cylinder warmers improve pressure stability and minimize losses due to condensation.

Advantages with Tempo Solutions

- **Viscosity Control:** Prevents thickening, crystallization, or freezing of solvents.
- **Energy Efficiency:** Localized heating ensures minimal energy loss.
- **Safety:** Avoids leaks and blockages from cold solvent lines.
- **Flexibility:** Easy to install on pipelines, drums, reactors, or valves.

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Behind Samarat Hotel,
Mira Road,
Mumbai - 401104
Maharashtra, India

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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 DISCRIPTION

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 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 water, 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.

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	-

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/Glutraldehyde 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, humidificator, filters, etc. are often contaminated with loads of bacterial and bio-films.

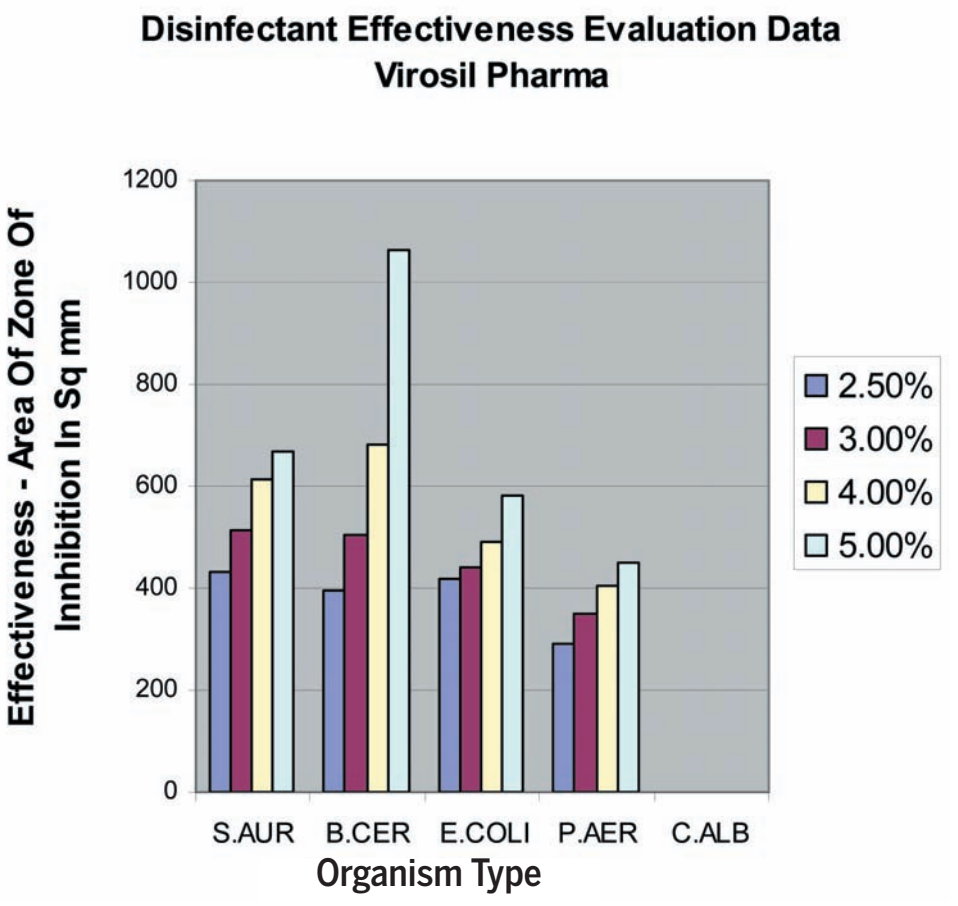
The main aim of Virosil Pharma is to increase productivity by cutting down disinfection time while at the same time providing a totally microbe-free environment.

Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to rewash 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, 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.

A GRAPHICAL VIEW ON DISINFECTANT EVALUATION DATA - VIROSIL PHARMA



	S.AUR	B.CER	E.COLI	P.AER	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

Targets

Sanosil Biotech is marketing this disinfectant under the 'Virosil Pharma' brand name and is targeting the entire industrial belt of India. The company has already set up a distribution and infrastructure network having establishments in Maharashtra, M.P., Hyderabad, Chennai and Delhi.

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