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INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE JUNE 2023, ₹ 40

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VIZAG PHARMA SUMMIT 2023

+

Strategy
JB Pharma:
Betting big on India

Research
Advancing research on human immune system to develop better vaccines

FORTIFYING BRAND INDIA PHARMA

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How to deal with "Oxidation sensitive drugs" with common grades of Polyplasdone™ crospovidone

Saurabh Gupta, Seema Singh and **Nelson Corda**, Ashland Specialty Ingredients, Mumbai, India

Polyplasdone™ crospovidone is a well-known non-ionic superdisintegrant crosslinked homopolymer of N-vinyl-2-pyrrolidone. Polyplasdone™ crospovidone has wicking, limited swellable, and shape recovery properties that provide rapid disintegration and dissolution in oral solid dosage forms. Polyplasdone™ crospovidone particles are porous compared with other superdisintegrants. The high surface area, combined with a unique chemistry, results in high interfacial activity that enhances the dissolution of poorly soluble drugs in a way that is not possible with other disintegrant technologies.

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Because of its porous structure in tablet dosage form, it has good wicking properties and excellent compressibility. Polyplasdone™ crospovidone, with larger particle size grades, i.e., XL/ Ultra, gives faster disintegration and is recommended for immediate-release tablets. However, Polyplasdone™ crospovidone's smaller particle size grades, i.e., XL-10/ Ultra-10, provide a smooth surface and are recommended to use in smaller and orally disintegrating tablets. The particle size of crospovidone strongly affects the disintegration process, and larger particles provide a faster disintegration. As size increases, the intra-particular porosity increases, leading to more considerable water uptake and faster disintegration.

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SAURABH GUPTA
Sr. Technical Business Development Manager Pharma

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grades of polyplasdone™ crospovidone	Typical average particle size range (microns)	peroxide specification (ppm)
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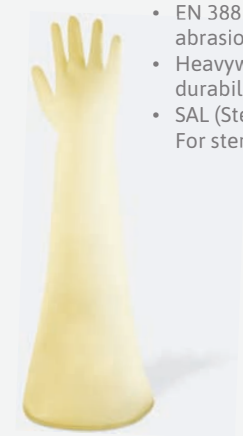

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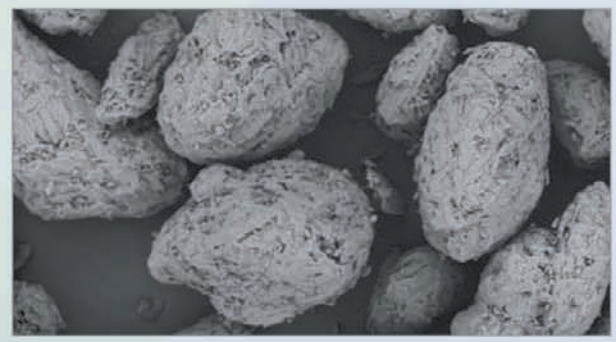

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Express Pharma®

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* Responsible for selection of news under the PRB Act.

Exploring synergies and de-risking strategies

A recent report that Spain may invest in India's bulk drug parks is good news for both countries. The 12th Session of India-Spain Joint Commission for Economic Cooperation (JCEC) held on April 13 in New Delhi saw both governments agree to strengthen their collaboration in several key sectors, including pharma.

The two countries are natural allies in the pharma segment, as they seek to diversify their supply chains for APIs and bulk drugs. As Spain gets set to assume Spanish Presidency of the EU, from July to December 2023, one hopes that both governments can negotiate and finalise the terms of the collaboration, as bulk drug parks are critical to India's hopes of retaining it's reputation as the pharmacy of the world.

There is no doubt that retaining the pharmacy of the world title will only become tougher, as many countries hustle for the same claim to fame.

For instance, even as pharma companies continue the long term process of reducing dependence on outside sources for key input materials, revenues from the US generics market remain subdued. This has forced Indian pharma companies to hedge their bets and focus on RoW markets. Luckily, the India domestic market has some sweet spots. A review of analyst reports on the Q4FY23 and FY23 results show some interesting trends.

For instance, an ICICI Securities report predicts that while there may be some near term green shoots in the US generics market, the macro outlook remains the same. Not surprisingly, the report predicts that pharma companies with specialised R&D skillsets will likely be able to tide over the transformation better.

Giving some relief, the India branded formulations segments seem better placed, with growth predicted to to pick up from Q2FY24. The ICICI Securities report points out how strong brand recall, an asset-light business model and low R&D investments ensure best-in-class EBITDA margins. Companies operating in India are therefore well positioned to benefit by virtue of their lean balance sheet with steady cash flow.

Cutting down on R&D investments is not an ideal strategy for the long term, but it's understandable that faced with tough choices, pharma companies are doing their best to balance short term liquidity with long term R&D investments.

The good news is that while the profitability of the India business was temporarily disrupted due to mandated price cuts on NLEM products and raw material inflation, from April 2023, pharma companies may start taking -12 per cent price hike on products under price control and up to 10 per cent on the rest, thereby improving their margins. Better diagnosis and access to quality healthcare services are likely to boost volumes in India in the near term. The ICICI Securities report expects a 11 per cent CAGR over FY23E-FY25E in India formulations.

As pharma companies continue the process of reducing dependence on outside sources for key input materials, revenues from the US generics market remain subdued. This has forced Indian pharma companies to focus on RoW markets

A second report from CRISIL Ratings offers more perspectives. Predicting some growth in the US generics market, Anuj Sethi, Senior Director, CRISIL Ratings reasons that increased inspections by USFDA after the pandemic and higher withdrawals of abbreviated new drug applications (ANDAs) due to intense competition are leading to moderation in overall supply of existing drugs. Consequently, the double-digit price erosion witnessed in the US generics market during the past couple of years should stabilise at high single-digits this fiscal. To also increase exports, large pharma companies are developing higher-margin complex/specialty drugs and introducing new generics which have only recently gone off patent and where competition is moderate. Thus, he predicts US formulation exports may grow 6-8 per cent this fiscal after an extended period of underperformance.

Pharma companies are deploying various strategies to balance out the loss of revenues from the US generics market. Firstly, a focus on RoW markets. CRISIL Ratings expects domestic pharma companies should be able to register 8-10 per cent growth in revenues from RoW markets, this fiscal.

Secondly, pharma companies are increasingly venturing into tender-based, institutional sales and enhancing marketing channels across the globe.

Thirdly, domestic pharma companies are also expanding into new semi-regulated geographies, with a focus on increased market penetration and faster new product launches given less stringent regulatory requirements.

However, CRISIL Ratings analysts predict that domestic companies may not be aggressive in driving growth in select markets such as Latin America, due to high currency volatility and geopolitical risks.

Thus the de-risking of supply chains and revenue models will continue, as pharma companies look for breakthrough deals to explore synergies. For example, JB Pharma, now controlled by private equity firm KKR, is aggressive about brand acquisitions as a key pillar of its growth strategy. *(Read more in the story, Betting big on India in the June edition of Express Pharma).* Spain's interest in collaborating with India's bulk drug plan, should it fructify, is a huge vote of confidence in India's pharma prowess and the talent pool. Let's hope the industry, and our policy makers, can capitalise on this opportunity.

VIVEKA ROYCHOWDHURY, *Editor*
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FDD Conclave 2023: Making India an epicentre for FR&D

FDD Conclave 2023 will discuss how India Pharma Inc needs to leverage its existing strengths and build new capabilities to develop of innovative and differentiated pharma products, complex drugs or biologics and biosimilars across a range of indications for its next phase of growth

Organised by Express Pharma, Pharma Formulation and Drug Delivery (FDD) Conclave 2023 will be held this year on July 21-22, 2023 at Park Hyatt, Hyderabad It is 'the' platform for leaders, experts and veterans of FR&D to come together confer and converse, on the current and future trends in the industry, their growth drivers and the challenges to tackle them as well as form meaningful alliances to fast-track progress.

FDD Conclave 2023 will bring the FR&D community together to discuss how India Pharma Inc needs to leverage its existing strengths and build new capabilities to develop of innovative and differentiated pharma products, complex drugs or biologics and biosimilars across a range of indications for its next phase of growth.

FR&D leaders will highlight evidence-based strategies and approaches to develop novel formulations and drug delivery systems which will help create intellectual property, enhance life-cycle management, and amplify cost and market differentiation.

The leaders will also examine the impact of recent government initiatives, regulations and policies to help promote innovation in pharma R&D and help India secure and sustain a key position in the global pharma R&D landscape.

Topics/Themes to be discussed

◆ Incentivising pharma FR&D in India: Policies, regulations & initiatives
◆ Fuelling innovation in biopharma FR&D
◆ Building India's FR&D talent pool: Approaches & techniques
◆ Developing cost-effective drug formulations and delivery systems: Opportunities & challenges
◆ FR&D for continuous manufacturing
◆ Predictive approaches for solid formulation
◆ Potential of emerging vaccine technologies
◆ Developments in injectable drug delivery
◆ Impact of additional budgetary allocation for R&D
◆ Role of emerging technologies in drug development

Express Pharma to host the second edition of Chandigarh Pharma Summit 2023 in June

The Chandigarh Pharma Summit provides the opportunity for pharma leaders and game changers to come together and exchange ideas on the most recent trends, challenges, and opportunities in the industry

With the government's focus on the sector, availability of skilled manpower and world-class infrastructure, pharma companies in Chandigarh have a significant opportunity to expand their businesses and become leaders in the industry. Presently, the region is home to several pharma manufacturing units that produce a wide range of products, including generic drugs, branded drugs, and nutraceuticals. These companies have played a crucial role in meeting the growing demand for affordable medicines in India and other countries. They also boost the regional economy by creating job opportunities and attracting foreign investment.

> Presently, the region is home to several pharma manufacturing units that produce a wide range of products, including generic drugs, branded drugs, and nutraceuticals

Therefore, Express Pharma will host the second edition of the Chandigarh Pharma Summit on June 30, 2023, at Holiday Inn, Panchkula.

The Chandigarh Pharma Summit provides the opportunity for pharma leaders and game changers to come together and exchange ideas on the most recent trends, challenges, and opportunities in the industry. It provides a platform to learn and explore business opportunities as well as stay up-to-date with the latest industry trends and developments.

Suggested topics

◆ Making Chandigarh a pharma powerhouse
◆ Tech advancements to improve key pharma processes
◆ Skilled and capability building: Pillars of progress
◆ Policies for positive modification
◆ Strategies for supply chain resilience:
◆ Aatmanirbharta in pharma: A progress report
◆ Drug discovery and development: Make and innovate in India
◆ Changing landscape of clinical research and development
◆ Building a sustainable and ethical pharma business

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JB Pharma: Betting big on India

Our biggest bet is India and the CDMO space, says **Nikhil Chopra**, CEO, JB Pharma, taking stock of the company's ongoing transition as it nears its 50th anniversary in 2025

By Viveka Roychowdhury

Pegged as one of India's fastest growing pharmaceutical companies, JB Pharma's recently released fourth quarter and year ended March 31, 2023 results continue to beat market growth rates.

As per IQVIA MAT March 2023 data, JB Pharma continued to be the fastest growing company amongst the Top 25 in FY23, outperforming the Indian Pharma Market (IPM), growing at 22 per cent versus 8 per cent, aided by the organic business growing at 21 per cent. India business (domestic sales) of the overall sector grew by 15 per cent for Q4 FY23, where as JB Pharma's domestic business grew double at 30 per cent. *(See BOX: JB Pharma Business highlights: Q4 FY23 and FY23)*

Will JB Pharma's dream run continue? And what are the risks of pursuing an acquisition driven growth strategy? As pharma promoters in the India pharma sector contemplate bringing strategic investors on board, JB Pharma's transition strategy and steady rise up the ranks is being closely observed and could well become a success story worth emulating by its peers in the sector.

Nikhil Chopra, CEO and Wholetime Director, JB Pharma commented that this "market-beating performance" is "pivoted around their strategy to make big brands becoming bigger, and significant demand acceleration in the acquired portfolio." He pointed out that each of their top seven brands (Rantac, Cilacar, Cilacar-T, Metrogyl, Nicardia, Azmarda and Sporlac) have ascended through the ranks. Further, Sporlac, the acquired business in probiotics and pediatric segment, is the newest entrant to IQVIA's Top 300 brands from their portfolio.

JB PHARMA BUSINESS HIGHLIGHTS: Q4 FY23 AND FY23

- Revenue growth of 22 per cent to Rs 762 crores in Q4 FY23; grew 30 per cent to Rs 3149 crores in FY23
- Operating EBITDA increased by 21 per cent to Rs 181 crores in Q4 FY23
- One of the few Indian pharma companies employing the OROS (Osmotic-controlled Oral delivery System) technology.
- One of world's top three manufacturers of medicated and herbal lozenges.
- Fastest growing company among the top 10 players in the cardiology segment with acquisitions of Azmarda for heart failure and Razel franchise (Rosuvastatin).

Flashback

Till 2020, JB Pharma was like many promoter-driven pharma companies. Started in 1976 by the late JB Mody as JB Chemicals & Pharmaceuticals Laboratories (JBCPL), the company made a name for itself with brands like Metrogyl (1977), Nicardia (1980), Rantac (1989), Cilacar (2007). Overseas, the company's Doktor Mom and Rinza brands were able to tap into the Russia and CIS OT market.

Founder JB Mody carefully steered the ship through the choppy seas of evolving regulations, spiraling prices and increasing price control. Cut to July 2020, when the JBCPL founders sold controlling stakes to private equity firm Kohlberg Kravis Roberts and co (KKR).

With KKR at the helm, and a new management team headed by Chopra, the company jumped nine ranks in two years, from rank #32 in MAT 2021, to #23 in 2023. The company's prescriptions continue to grow at a market beating pace; with the company ending FY23 ranked #15 in the IPM.

Building blocks of a successful transition

Analysing JB Pharma's transformation strategy post KKR acquiring majority controlling stakes in the company, Chopra highlights three major initiatives.

1. Transformation of India business by establishing a new go-to-market model, making big brands bigger.

After KKR came on-board in July 2020, Chopra reveals how they took up a restructuring exercise both internally and externally. Showing its aggressive intent, the new management had initiated a series of measures to transform the entire business.

He narrates how the management put forth an accelerated growth strategy where they would not only build upon core competencies but also leverage strengths to enter into new therapeutic areas. Backed by over 5,000 employees including a 2,500-strong sales force, Chopra says JB Pharma has put in place a new 'go-to-market' model, where they focus on life-cycle management for big brands and evaluate new growth opportunities to further enhance productivity.

Giving more granular detail, Chopra explains how their focus on making "big brands ... bigger was substantiated by launching line extensions of existing franchises and focussing on sales force excellence and automation. Furthermore, expansion into tier 4 and rural towns helped India business in increasing the reach and availability for current brands."

Chopra analyses how one of the pillars of strategy has been acquisition-led growth. JB Pharma completed four major acquisitions (brands from Sanzyme, Azmarda, Razel franchise and paediatric portfolio from Dr Reddy's Laboratories), thus foraying into the fast-growing probiotics, paediatric and the niche of the heart failure segment. These portfolios offer deep geographic and distribution synergies along with prescriber overlap. In six months, Sporlac now is among the top three brands in the probiotic segment, providing significant opportunities to expand through line-extensions.

A 'beyond the pill' marketing approach

Chopra revealed that he emphasised a 'beyond the pill' marketing approach in the Indian pharma industry, which involved organic and inorganic initiatives to enhance patient awareness, education, diagnosis and adherence through various 'phygital' initiatives.

Other areas of expertise include digitalisation of the pharma field force and engagement with doctors, nurturing talent and creating cross-functional collaborations and propagating technology in improving healthcare access and awareness.

He stresses that for JB Pharma, the domestic formulations business remains a key focus area and it has been consistently growing at better than industry growth rate over the last several years.

He also refers to another trend in the IPM. While India has historically been a market dominated by acute therapies, the trend has been shifting to a larger contribution from chronic drugs in the consumption base. As per IQVIA IMS data, the share of chronic therapies in the IPM has expanded from 31 per cent to 36 per cent in the period between FY13 and FY21. This is in line with the trend in several global economies that have seen a larger incidence of lifestyle diseases on the back of improved diagnoses and better compliance by patients.

JB Pharma's international business contributes around 50 per cent of the total revenue, comprises three segments: export formulations, API and contract manufacturing. The business grew by 16 per cent to Rs 382 crores in Q4 FY23 versus Rs 330 crores in Q4 FY22. The international formulations business was at Rs 255 crores in Q4 Fy23 versus Rs 218 crores in Q4FY22 recording growth of 17 per cent.

JB Pharma operates distinct operating models across multiple international businesses with a direct presence in Russia and South Africa as well as distributor relationships in the US and a large number of markets across Asia, Africa and Latin America. According to Chopra, JB Pharma has a leading global position in the contract manufacturing market driven by marquee client relationships.

2. Development beyond financial metrics to a new cultural identity

JB Pharma also recently marked one year of a new corporate identity as JB, centered on being "simple, reliable and agile" while building on the strong foundation of "integrity, trust and reliability" nurtured over the past 45 odd years.

Explaining the vision behind the new identity, Chopra said, "The company offerings and capabilities are becoming more diverse to cater to the evolving needs of customers, manufacturing processes are becoming more robust, and lean, and our vision of looking at the healthcare industry is becoming more progressive globally. We are adapting ourselves to become more responsive to the needs of the healthcare world. In sync with the evolving healthcare industry and the changing need of customers, JB has re-visioned the cause of spreading good health in India. JB aims to support healthcare providers and enrich patients' lives in innovative new ways while remaining committed to its core values of integrity, trust and reliability built over 45 years."

This was inculcated in terms of initiatives within the organisation that made employees and departments

agile, and cultivated a cross-collaborative culture. As CEO, Chopra reportedly played an active role in developing this and led leadership culture building exercises such as One-JBWay (a leadership transformational programme). Furthermore, the same OneJBWay culture is cascaded to the second in line of leaders (N-2) through a forward looking leadership training and excellence programme called LEAP.

3. Publishing inaugural sustainability (ESG) report

Chopra explains how the ESG report was prepared following the international reporting standards framework, the Global Reporting Initiative (GRI) as its Core Standard, and linkages with the Sustainable Development Goals (SDGs).

> We will be looking for acquisition opportunities, buying out brands or mid-sized companies. The other strategy is to grow our big brands such as Cilacar, Cilacar-T, Rantac, Metrogyl, Nicardia and Azmarda. In the next three years, we want to increase our market share by being among the top 20 companies in the IPM market

As per Chopra, from FY 2020 to FY 2022, the organisation has reduced energy consumption by 9.2 per cent and augmented green energy through solar power. Additionally, its Scope 1 and Scope 2 emissions have reduced by 14.6 per cent and 10.7 per cent during the same period. During the reporting period, waste sent for co-processing stood at 757.65 MT. All sites are Zero Liquid Discharge.

JB Pharma's strategy for FY24 and beyond

Looking ahead, Chopra is emphatic that "our biggest bet is India as 50 per cent of our revenue comes from here. We will continue to leverage opportunities that lead us to organic growth and diversify into newer categories that can be in generic formulations, wellness etc. We will also be looking for acquisition opportunities, which are a strategic fit and assure returns within the payback period. The other strategy is to grow our big brands such as Cilacar, Cilacar-T, Rantac, Metrogyl, Nicardia and Azmarda."

Spelling out the goals for the next few years, Chopra says that they plan on accelerating towards their 50th year in 2025. "In the next three years, we want to increase our market share by being among the top 20 companies in the IPM market. Under the new strategy, our major focus is to strengthen our core therapy

segments i.e., hypertension, respiratory, gastroenterology, nephrology, cardiology, dentistry, and paediatrics.

If FY21 was about realigning the structure and portfolio to ensure sustainable growth and focussing strongly on the lifecycle management of their flagship brands, the next priority is to scale up R&D and business development initiatives towards building a progressive portfolio for the US, Russia, South Africa, and API. Chopra says that they will focus on consolidating their business areas through a deeper presence in existing geographies and this will be aided by multiple new launches over the next two to three years.

Building a cohesive entity

With four brand acquisitions in 15 months, and close to 1500+ appointments, across businesses and geographies in the last year, JB Pharma's new identity is evidently an attempt to ensure common brand values across a rapidly expanding workforce.

Chopra says that each brand acquisition came with a sales force from different companies that was relevant to their existing salesforce team and gave geographical synergies. This added almost 500-600 people across divisions of heart failure, hypertension, wellness, respiratory etc.

And Chopra reveals that there could be more acquisitions, as the company will continue to evaluate (further brand acquisition) opportunities and see if there are assets available within the space of pediatrics, cardiology, metabolics, respiratory, and anti-infectives.

It will be interesting to observe how JB Pharma is able to assimilate the 'acquired' sales force into a cohesive entity. Talent retention will be a key component, given the cut throat competition in the IPM. According to Chopra, the company's continuous focus/endeavours on talent retention led to 200+ promotions in FY23. Most pharma companies struggle to increase productivity per sales professional, leading to high attrition rates.

Chopra reiterates, "Our current philosophy has a strong foundation of the legacy brand on which the new identity has been built and carried forward. This is highlighted best in three aspects – our people, our results and our products. We are the fastest growing company with fast tracked growth for careers as well. This is supplemented by strong learning and development programmes across levels and locations. Last but not the least, a healthy work-life balance is critical to increased productivity which is catered to by our wellness initiatives. We are also in the process of introducing a competency matrix which would aid in talent retention."

JB Pharma's transition from a promoter-driven to a private equity led entity is part of a larger trend not just in India, but across the globe. Balancing the legacy of the founders with management strategies of the strategic investors will be crucial in the quarters ahead.

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VIZAG
PHARMA
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2023
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FORTIFYING BRAND INDIA PHARMA

Lessons and insights on measures and approaches to drive innovation, quality and growth in India's pharma sector from industry leaders and policy makers at Vizag Pharma Summit 2023

By **Lakshmipriya Nair**

India's pharma market is rapidly gaining momentum and witnessing significant growth globally. However, in this promising landscape, it is imperative for the industry to embrace a paradigm shift from a conventional, volume-based business strategy to a value-driven approach.

Therefore, the overarching theme for this year's Pharma Summits organised by Express Pharma is "Volume to Value Leadership: Opportunities and Challenges for India Pharma Inc." After the resounding success of Ahmedabad Pharma Summit 2023, Express Pharma recently hosted the fourth edition of Vizag Pharma Summit on May 19, 2023 at the Hotel Taj Gateway in Visakhapatnam. The event served as a catalyst, offering an environment that is conducive for participants to share their experiences, exchange knowledge, and forge partnerships to fuel growth in the pharma sector. Key stakeholders, industry leaders, policymakers and innovators came together to drive discussions that will shape the trajectory of India Pharma Inc.

This article is a compilation of the valuable perspectives and insights imparted by the esteemed speakers during the Vizag Pharma Summit 2023.

We need collaborative strategies that will fuel innovation and value-led growth

The keynote speaker, K Raja Bhanu, Deputy Director & Joint Director (FAC), Drugs Control Administration, Visakhapatnam Region of Andhra Pradesh shared his insights for the progress of the pharma industry from a regulator's perspective.

Filled with a lot of food for thought for the pharma industry, his session comprised a summary of India Pharma Inc's growth trajectory and several milestones achieved by the "Pharmacy of the World". He urged the industry to scale new heights and become a value-driven leader in the global pharma market. He also gave an overview on why Vizag is key to the Indian pharma industry.

Bhanu went on to say that India's pharma sector needs to be more self-dependant and resilient for value-led growth. He said that now India needs to be able to anticipate future needs and work with all stake holders to create and implement strategies which will foster innovation and promote research in high value products such as antibiotics, biosimilars, oncology medicines etc.

Bhanu was emphatic about the importance of meaningful partnerships and collaborations to grow and thrive in an era of disruptions. He advocated the need to embrace positive change, cultivate a growth mindset, encourage a culture of quality and compliance, and sustain an environment of trust amongst all stakeholders for future progress.

We need a cultural shift and a growth mind set to evolve continuously, and hone our strengths to become future ready

K Raja Bhanu
Deputy Director & Joint Director (FAC),
Drugs Control Administration,
Visakhapatnam,
Region of Andhra Pradesh

AI and digitalisation are bringing in sweeping changes across functions in the pharma industry, be it drug discovery, development, supply chain or manufacturing processes

KV Sreenivasa Babu
VP-Operations,
Natco Pharma

Be careful about operational costs, keep pace with market demands, innovate to stay ahead in the race, leverage advanced technology, and learn from failures

Dr Bikash Kumar Nayak
Plant Head,
Aurobindo Pharma

Prioritise quality to improve performance and boost profitability

Among the many pertinent sessions at Vizag Pharma Summit 2023, one of them was on 'Elevating pharma performance: Regulatory compliance and quality assurance' by Ravi Chander Katta, Site Quality Lead (SQOL) – Vizag, Pfizer Global Supply – Global Sterile Injectables.

At the outset of his presentation, Katta outlined the differences between quality assurance and regulatory compliance. He explained that while their objectives can overlap, quality assurance is optional and non-obligatory but regulatory compliance is compulsory and must be followed by any firm manufacturing pharma products. However, he emphasised that prioritising high-quality standards often has a direct impact on performance and profitability of organisations, especially in the life sciences sector.

His session comprised several takeaways on how India Pharma Inc has fared during inspections by regulatory authorities and which aspects need improvement. Speaking on measures to boost the sector's growth and performance, he pointed out how digitalisation of control processes can be vital to profitability, optimal use of human resources and time, risk mitigation, improving quality of final products etc.

An important inference from this session was that it is pivotal to invest in emerging technologies and leverage them effectively to gain key, real-time data insights and make better decisions across operations. This will help the industry and businesses to anticipate and resolve problems, improve quality performance and adapt to new realities.

Review and revamp growth strategies to stay relevant and future-ready

An insightful presentation from Dr Bikash Kumar Nayak, Plant Head, Aurobindo Pharma, on 'Mapping innovation and building a cost leadership strategy' enlightened the audience about the need to constantly learn and adapt to evolving circumstances to stay ahead in the game. He cited a lot of interesting, real-life cases of successful strategies adopted by renowned brands such as Amazon, Walmart, McDonalds and RyanAir to tackle certain challenges and offer more value than their competitors.

He opined that pharma companies need to study successful brands/organisations from other sectors and examine their marketing and pricing strategies, customer engagement tactics, distribution channels, digital initiatives, messaging and more to look for patterns and best

practices that can be adapted and adopted to their operations and activities.

Dr Nayak underscored the importance of researching the competition and understanding their operations, to improve your own process and reduce costs as well. He also stressed on the importance of building a culture of 'Right First Time' to prioritise quality.

A key inference from his session was agility and adaptability to changing market dynamics and emerging trends, along with an innovation-driven mindset is key for businesses to position themselves for continued success and maintain a competitive edge.

Building a future-ready workforce is an imperative for progress

In a brief and succinct session, KV Sreenivasa Babu, VP-Operations, Natco Pharma showcased both, emerging trends and challenges in the pharma industry. Speaking on trends such as automation, digitalisation, continuous manufacturing, advanced data analytics, AI, predictive maintenance, and more, he highlighted how these technologies offer significant advantages to the pharma industry, including increased efficiency and accuracy, improved regulatory compliance and traceability across functions.

He detailed the power and potential of these technologies to minimise the risk of human error in various critical processes, like drug discovery and manufacturing, quality control, supply chain and packaging.

Babu also outlined the current challenges in the industry currently such as gaps in the supply chain, lack of required skill sets, employee retention, data security, resistance to change, regulatory approvals, and lead time from development to commercialisation.

A key message from his session was that the industry needs to overcome its resistance to change and adopt a growth mindset to stay relevant and future-ready.

Use of real time data analytics, AI will drive process excellence in pharma and elevate regulatory compliance

Ravi Chander Katta
Site Quality Lead (SQOL) – Vizag,
Pfizer Global Supply – Global Sterile Injectables

Quantum computing, proteomics, digitalisation, cryogenic electronics microscopy will change the face of drug discovery

Dr Girish Dixit
Executive Director,
Eisai Pharma

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AI and ML will drive the future of drug discovery

The valedictory address at Vizag Pharma Summit 2023, addressed another vital topic, 'Designing strategies for enhancing drug discovery and development processes.' Dr Girish Dixit, Executive Director, Eisai Pharma pointed out that the cost and timeline of developing new drugs have significantly increased, posing challenges to the pharma industry. Moreover, despite substantial investments in research and development, the discovery of successful molecules has proven largely unfruitful.

Some of the challenges faced in the drug discovery process such as length, complexity, uncertainty, data and cost of drug discovery, unknown pathophysiology of disorder, limitations of animal models, heterogeneity of the patient population and lack of validated diagnostic and therapeutic biomarkers. He also offered solutions to the existing challenges such as utilisation of human genomics which enables the treatment of diseases based on individual genetic markers, use of technologies like AI, ML and digitalisation to make the drug discovery process faster and more efficacious, leveraging the potential of randomised clinical trials to enhance clinical research and refine many processes including patient identification, selection, trial conduct, and capture of data etc.

A key takeaway was that innovative approaches and technologies like artificial intelligence and machine learning, will be crucial to enhance the efficiency and effectiveness of the drug discovery process, as well as accelerate timelines and reduce costs.

Shaping the future

Thus the fourth edition of Vizag Pharma Summit had great insights and lessons for all the participants. It is to be hoped that the event will help to drive innovation and collaboration and bring about positive change through the collective expertise of the experts and leaders. Transformative projects and initiatives will pave the way to capitalise on the opportunities that lie ahead.

Express Pharma's next 'Pharma Summit' will be held in Chandigarh on June 30, 2023 at The Holiday Inn, Panchkula. Stay tuned and join us at these Summits to be a partner in progress and ensure that India Pharma Inc remains at the forefront of innovation, manufacturing excellence and global leadership in the years to come.

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Next-gen solutions for India Pharma Inc

The Vizag Pharma Summit 2023 featured a range of sessions and presentations that highlighted the latest advancements in the life sciences and showcased products and solutions specifically tailored for this industry. Here is an overview of the key sessions conducted during the summit, shedding light on the innovative solutions discussed

Polymer solutions for pharma industry

The Vizag Pharma Summit 2023 comprised some crucial technical sessions from the event's partners, including a session by Ami Polymer. Vaibhav Datke, Sr Manager - Business Development, and Radhakrishna A, Sr Manager – Sales & Marketing, from Ami Polymer delivered a comprehensive presentation on the applications of polymer solutions in the pharma sector.

The speakers delved into various types of polymers, tubings, hoses, and gaskets, highlighting their distinct features, advantages, and applications in the life sciences industry. They emphasised how different drugs and dosage forms require specific solutions tailored to their unique requirements and elaborated on why certain applications are particularly suitable for these products. Additionally, the speakers discussed the crucial role of polymeric products in ensuring regulatory compliance.

They also introduced the company's newest offering - Single-use Bags: 2D/3D/Liner. Datke and Radhakrishna provided details on the features of

Vaibhav Datke, Sr Manager - Business Development, Ami Polymer and Radhakrishna A, Sr Manager – Sales & Marketing, Ami Polymer

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Hoses for sanitary application, traceability and gaskets

Another technical session at Vizag Pharma Summit 2023 focused on 'Hoses for sanitary application, traceability and gaskets' presented by Garet Jacob Fernandes, Sales Executive at CSE India.

Fernandes provided a detailed overview of different types of hoses and their applications, emphasising the importance of selecting the right hose for specific applications to ensure optimal performance and safety. He highlighted that each type of hose has its own unique properties and advantages.

Fernandes stressed the significance of proper hose maintenance to extend their lifespan and ensure optimal performance. He advised regular hose inspection to identify potential problems before they become serious safety hazards. He further mentioned that CSE India and Gecitech manufacture and stock a wide variety of gaskets, O-rings, and seals made of high-quality hygienic elastomers and fluoropolymers, meeting FDA and USP Class VI requirements.

Additionally, Fernandes discussed the traceability solutions offered by Gecitech, which can be adapted to

Garet Jacob Fernandes, Sales Executive, CSE India

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Polymer solutions...

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these bags, including their multilayer structure with an inner inert PE fluid contact layer, low extractables/leachables, and absence of animal-derived components. They mentioned that the film thickness of these bags is 0.325mm and extractable and leachable reports are available upon request.

The speakers also shared insights into their company's journey, achievements, and significant milestones. Regarding future plans, they mentioned the upcoming manufacturing facility equipped with the latest technology for manufacturing permanent implant rubber-based medical products. The presentation concluded with an assurance to the audience that AMI Polymer is well-equipped to provide appropriate tubing and hosing solutions for drug manufacturing processes.

Ami Polymer, apart from offering a wide range of new age polymeric solutions, also provides quick customisation, technical documentation support, quick delivery support

Hoses for sanitary...

Continued from Page 28

various equipment, providing identification through RFID chips, operations scheduling with a deadline alert system, and a comprehensive event history.

He concluded his presentation by stating that his organisation is committed to product quality, safety, regulatory compliance, and service.

GLIMPSES OF VIZAG PHARMA SUMMIT 2023

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Advancing research on human immune systems in India to develop better vaccines

Dr Rama Akondy, Associate Professor of Biology, Ashoka University highlights that by fostering clinical and research partnerships, investing in infrastructure and regulatory frameworks, and supporting local production of research reagents, India can pave the way for significant advancements in understanding the human immune system

The vaccine efforts of the COVID-19 pandemic highlighted our knowledge about gaps in the immune system. Reductionist systems, such as genetically identical inbred mice, have long been the choice for immunology research, which focuses on studying the cells, tissues, and organs that make up the immune system. However, the spotlight has shifted to unravelling the complexities of the human immune system. This article outlines the challenges of conducting human immunology research in a developing country.

A different approach to study the human immune system

While model animals are valuable tools, it is apparent that they may not always accurately predict the behaviour of the human immune system. The TGN 1412 trial serves as a great example, where a drug deemed safe in animals resulted in life-threatening consequences when tested at a much lower dose in humans. Another reason to focus on human immunology is the heterogeneity in immune responses, which may not be accurately reflected in model organisms. Therefore, it is particularly valuable to characterise the baseline as well as the breadth of immune responses in India, which includes people from different ethnic groups, ages, dietary patterns, and socioeconomic backgrounds. Lastly, India faces a significant burden of tropical diseases, such as dengue, chikungunya, and malaria, and also faces a threat from emerging or rare infectious diseases. Thus, understanding the human immune system is crucial for improving disease management strategies and being prepared for future outbreaks.

Studying immune cells

The most accessible source of immune cells is blood, and a significant portion of human immunology research has been conducted using blood samples obtained from participants in regulated, ethically conducted studies with informed consent. Studying immune cells in the blood can provide insights into their behaviour and role in pathogen control. However, blood cells do not present the entire picture. Many immune cells in tissues may look and behave differently from cells in the blood, and some immune cells never enter the circulation and reside in tissues. Characterising immune cells in human tissues, such as lymph nodes obtained from surgical waste during living donor transplants or biopsies remaining after clinical use, has proven useful in addressing this gap. More recent studies have also utilised samples from recently deceased organ donors who consented to research. The advantage of using such samples over surgical explants or biopsies has been highlighted in the work by Dr Donna Farber's group (PMID 28719147), which is not discussed in detail here.

Immunology studies in India: Steps we can take

Human immunology studies in India require several key components to support high-quality research, including a regulatory framework, effective clinic-research lab partnerships, infrastructure, and funding. Recognising this, some upcoming research institutes in India have invested in these aspects to support scientists interested in human immunology.

A robust regulatory framework is necessary to address the ethical and biosafety considerations unique to human sample research. While regulatory bodies for this purpose already exist, it is essential to establish rigorous yet reasonable rules governing human subject research. High-quality training modules, contextualised for scenarios encountered in India and available in multiple languages, are crucial for training personnel at all levels to execute research with high standards. Institutional support, such as expert consultants, essential document templates, and protocols for regulatory submissions, is also vital. Finally, public engagement in research has to be sought through informal group sessions communicating the purpose of the human research in plain language.

Similarly, institutes that facilitate connections between local hospitals and research institutes play an essential role. India boasts a large community of qualified physicians and scientists, but fostering more synergistic associations between the two is necessary. This can be achieved through the creation of short-term paid positions for clinicians to train with research groups

and for research groups to engage in medicine or public health-related community service. Although collaborations of this nature already exist, they tend to be concentrated in major cities. To enhance outbreak preparedness and gain valuable local information, it is important to extend these networks to smaller research institutes and hospitals in towns and rural areas.

The requirement for infrastructure encompasses not only specialised equipment but also the substructure necessary to support that equipment over an extended period. For example, frequent power outages can impact the lifespan of equipment, and backup power may not be sufficient to support power-consuming instruments. Purchasing energy-efficient equipment, rather than solely considering the lowest cost, could potentially reduce strain on power consumption.

Human immunology research in India is considered too small a market. To break this cycle of no supply-no demand, increased funding for local production of research reagents by academic units (when intellectual property is not a concern) is necessary, not just for point-of-care devices or novel technologies

Immunology research heavily relies on consumable reagents, such as fluorochrome-coupled monoclonal antibodies, MHC tetramers, and various types of tissue culture tubes and plates. Currently, these reagents are mostly imported through distributors, adding significantly to the cost of experiments (due to refrigerated shipping costs and import duties). Another hidden cost is the time taken for reagents to reach the lab, or in some cases, the reagents not clearing customs at all. To alleviate these challenges, local production of such reagents would reduce costs, shorten delivery times, and stretch research budgets further. However, one hurdle to local production is that reagents not involving innovation or point-of-care products are not considered market-worthy. Moreover, human immunology research in India is considered too small a market. To break this cycle of no supply-no demand, increased funding for local production of research reagents by academic units (when intellectual property is not a concern) is necessary, not just for point-of-care devices or novel technologies.

Way forward

Human immunology research holds promising potential in India, but it requires a collective scientific will, collaborations and increased clinical and research partnerships to gain momentum. By fostering these partnerships, investing in infrastructure and regulatory frameworks, and supporting local production of research reagents, India can pave the way for significant advancements in understanding the human immune system. This knowledge will not only contribute to better disease management strategies but also ensure preparedness for future outbreaks, benefiting the health and well-being of the Indian population and beyond.

Why IP certification should be made mandatory

Repeated news of deaths due to substandard Indian cough syrups, time to make licensing and regulation more stringent than ever: Mandating usage of duly-certified isopropyl alcohols or IPA in medicines could be a first step, opines **Vikas Biyani**, Retd. Assistant Commissioner, FDA, Maharashtra

Recently, it was widely reported how the WHO had raised a 'product alert' on cough syrups made in and originating from Punjab, a fact confirmed by the CDSCO. The cough syrups were found to have contained 'unacceptable amounts' of toxic diethylene glycol and ethylene glycol. This was reminiscent of a similar incident last year in October when the WHO had issued a medical alert over cough syrups coming from another state in India and potentially responsible for children's deaths in The Gambia, a West African country.

Even as it confronts and attempts to navigate through these adverse developments, the government must also turn its attention to the continuing violation of protocols on the usage of isopropyl alcohol, or IPA, under Section 16 and the Second Schedule of The Drugs and Cosmetics Act 1940. IPA, a colourless, flammable liquid with a strong odour, is a widely-used solvent or excipient in the making of bulk drugs and drug formulations apart from also finding usage as a common ingredient in products such as hand sanitisers, antiseptics, and disinfectants.

However, just as cough syrup makers have been illegally using diethylene glycol and ethylene glycol as a cheaper substitute for glycerine and propylene glycol, the other Indian drug manufacturers too regularly make use of cheap and imported IPA, a product that fails to meet various critical parameters covered in Pharmacopeia Standards such as UV absorbance test, identification of unsaturated hydrocarbons and rapidly carbonisable material.

It must be remembered that since solvents such as IPA, Toluene, Acetone, and others are imported in bulk and stored in commingled tanks at different ports, the likelihood of contamination through different handling stages is very high

That the usage of such substandard non-pharma grade IPA adversely affects the quality and safety of the drug is hardly an overstatement.

It must be remembered that since solvents such as IPA, Toluene, Acetone, and others are imported in bulk and stored in commingled tanks at different ports, the likelihood of contamination through different handling stages is very high thereby posing a huge risk to the health and life of the end-user using any pharma product containing these ingredients.

Moreover, the imported IPA stored in commingled tanks at Indian ports does not meet the pharmacopeia standards. In fact, traceability of source which is one of the important parameters carefully pursued by the pharma industry is a missing link when it comes to comingled storage of solvents. Importantly, the US Pharmacopeia hasincluded UV absorbance test for IPA in USP which will be effective from December 2023. This will make IPA USP standard more stringent and ensure that only the right quality of IPA goes to pharma applications.

Incidentally, only days before the Punjab news came out, the CDSCO came out with a circular with a view to ensure that drug manufacturers comply with the standards of identity, purity, and strength as specified in the Indian Pharmacopoeia or the Pharmacopoeia of any other country. Around the same time, the Central Drugs Standard Control Organisation (CDSCO) flagged 48 commonly used medicines as they failed the latest drug safety alert issued by the drug regulator. Earlier in March this year, the government had cancelledthe license of 18 pharma companies for making spurious and adulterated medicines and breaching of good manufacturing practices (GMP).

The Indian pharma sector consumes roughly 170,000 MT of the overall India IPA demand of around 230,000 MT in FY23. Of the 170,000 MT of IPA consumed by the pharma Industry, only about 15-17 per cent is pharma grade, meeting Indian and other Pharmacopeia Standards. The rest is non-pharma grade.

"To repeatedly witness these tragic eventualities on foreign shores on account of frequent slip-ups through the Indian drug regulatory system is not only embarrassing from a diplomatic and moral standpoint. If we do not take corrective measures, it can turn out to be immensely damaging for India's pharma export interests. In fact, these unfavourable instances should serve as a policy trigger for the government to also come down hard on manufacturers who do not observe the standards for solvents and excipients such as IPA and others, as laid down in the Indian Pharmacopoeia. Admittedly, there has been no reported incident related to IPA as yet. But this doesn't rule out a disaster from eventuating in the future.

With a view to improve the quality of API sold in the Indian market by Indian manufacturers, the DCGI in its letter dated 21.04.2023 issued direction to all state/UTs Drug Controllers and all zonal/sub-zonal offices of CDSCO to ensure compliance with government-prescribed standards. Earlier, a fewstates had also issued circulars requiring all pharma manufacturers to procure solvents complying with pharmacopeial standards. However, such responses cannot be reactive and of an ad hoc nature. The central authority should simply make it mandatory for all drug manufacturers and under all circumstances, to only procure and use IPA and all other solvents that are manufactured and imported by registered licensees and that conform to Indian pharmacopeial standards, or other country's standards as the case may be.

How AI and ML are transforming pharmacovigilance

Intelligent automation driven by AI and ML in pharmacovigilance presents compelling alternatives to optimise product quality, improve treatment plans, reduce IT costs and replace legacy processes and workflows for enhanced patient safety, emphasises **Mukul Singhal**, SVP, Global Head – Life Sciences (Delivery and Operations), Birlasoft

Pharmacovigilance is crucial in monitoring the safety and efficacy of drugs. It plays a pivotal role in assessing, detecting, and analysing drug-related issues by processing crucial data for medical companies. However, as data becomes more complex and abundant, it's becoming challenging to analyse and interpret it all. With the rise of artificial intelligence (AI) and machine learning (ML), pharmacovigilance has become more efficient and effective in identifying potential safety concerns and improving patient safety.

A report by Market Research Future reveals that the global pharmacovigilance market size is expected to be worth $14.95 billion by 2028 at a CAGR of 14.1 per cent. The use of big data analytics, artificial intelligence, machine learning, and other digital technologies has revolutionised the pharmacovigilance industry by assisting in pulling out data insights to facilitate intelligent information. Intelligent automation driven by AI and ML in pharmacovigilance presents compelling alternatives to optimise product quality, improve treatment plans, reduce IT costs and replace legacy processes and workflows for enhanced patient safety.

AI and ML for data insights

AI is a powerful tool that can quickly analyse large datasets, including electronic health records, and clinical trial data to identify patterns of potential safety concerns. By automating the analysis of data, AI can identify safety concerns faster and more accurately than traditional methods. It can be used to identify previously unknown adverse events or drug interactions. ML can then be used to develop models that predict the likelihood of adverse events occurring, allowing healthcare professionals to take proactive measures to mitigate the risks associated with specific drugs. By analysing the data collected from patient records, drug trials, and other sources, AI can identify trends and correlations that may have gone unnoticed by human analysts. This can help researchers to understand how drugs work and identify potential new applications for existing drugs.

> AI and ML can improve the efficiency of clinical trials. By using predictive modelling to identify which patients are most likely to respond to a particular treatment, trial designers can target enrollment specifically at those patients. This can save enormous amounts of time and money and reduce the number of patients exposed to ineffective treatments

Improving the efficiency of clinical trials

Moreover, AI and ML can improve the efficiency of clinical trials. By using predictive modelling to identify which patients are most likely to respond to a particular treatment, trial designers can target enrollment specifically at those patients. This can save enormous amounts of time and money and reduce the number of patients exposed to ineffective treatments. By automating the recruitment process, AI can also help to ensure that trials are more representative of the wider population, reducing the risk of bias and improving the generalisability of the results.

Despite the many benefits of AI in pharmacovigilance, some challenges need to be addressed. One of the main challenges is ensuring the quality and accuracy of the data used to train AI algorithms. It is crucial to ensure that the data is representative of the population and that there are no biases in the data that could affect the algorithm's performance.

By enhancing the transparency and interpretability of AI algorithms, healthcare professionals and researchers can better comprehend how the algorithms generate their outcomes, leading to more precise and reliable data. By implementing MLOps methodologies, such as data validation, version control, and model monitoring, researchers can ensure that the data sets used for training AI algorithms are accurate and up-to-date, which can enhance the overall quality of the data.

In addition to addressing challenges in AI and ML, there is a need for collaboration between pharma companies, regulators, and other stakeholders to maximise the potential of this technology. By working together, they can ensure that the benefits of AI and ML in pharmacovigilance are realised and that patients worldwide receive the safest and most effective treatments possible.

Moreover, it is essential to ensure that the ethical implications of AI and ML are considered in pharmacovigilance. Healthcare professionals must ensure that the use of AI and ML does not replace human decision-making, but rather augments it, ultimately benefiting patient outcomes. It is also crucial to consider the impact of AI and ML on patient privacy, as large amounts of patient data are used to train algorithms. Ensuring that patient privacy is maintained will be essential to building trust.

In conclusion, AI and ML are transforming pharmacovigilance by improving the speed, accuracy, and efficiency of identifying potential safety concerns as well as helping healthcare professionals make better-informed decisions about drug safety. While there are challenges that need to be addressed, the benefits of AI-powered pharmacovigilance are clear. As AI technology continues to evolve, it will undoubtedly play an increasingly important role in ensuring the safety of patients worldwide.

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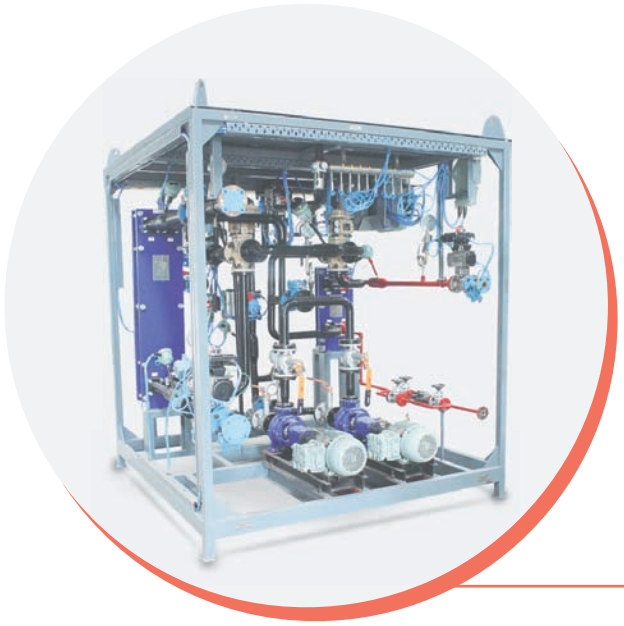

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Reusable cleanroom apparel and the contamination risks

Based on a recent study[1], the Bacterial Filtration Efficiency (BFE) of reusable cleanroom apparel degrades significantly after the garment has gone through wash and irradiation cycles. This poses a real yet invisible contamination risk to aseptic manufacturing environments.

Contamination risks posed by reusable cleanroom apparel

A significant cost to pharma manufacturing is process contamination. Nothing is more serious than a contamination event in a cleanroom. Contamination can lead to expensive shutdowns and increased production expenditures, as well as recalls and potential loss of life. People are the largest contributor to particle contamination in any cleanroom, accounting for 46 per cent of all particle contamination[2]. Humans shed and spread millions of particles throughout the day. Body regenerative processes, such as skin flakes, oils, perspiration, and hair can contribute to cleanroom contamination.

Wherever there are people, there is a risk of microbial contamination

This risk can be mitigated by using sterile cleanroom apparel that protects the environment from viable particles such as bacteria and yeast, and non-viable particles such as hair, dead skin cells, and dandruff. For this reason, it's essential that cleanroom operators select apparel that provides the highest levels of contamination control.

Choosing the right type of apparel is paramount. But what if the garment itself poses a hazard to the cleanroom environment? Testing by Kimberly-Clark Professional™ found that the barrier on reusable protective apparel declined after multiple washing,

drying and sterilisation cycles. This barrier decline poses a significant contamination risk for cleanrooms.

Cleanroom apparel: Cleanroom apparel falls into two main categories: single-use disposable apparel and reusable laundered apparel.

Single-use apparel: Single-use apparel is made from two types of fabric:

1) Flash-spun polyethylene fabric, which provides filtration efficiency for sub-micron sized particles and microorganisms and is suitable for light splash protection from non-hazardous liquids, and

2) Spunbond melt blown spunbond (SMS) fabric, which has outer layers of spunbond polypropylene for strength and cloth-like comfort, and middle layers composed of a matrix of microfibers, which creates a strong barrier for particles and liquids.

Reusable apparel: Reusable cleanroom apparel is typically made from woven polyester-blend fabrics, which may degrade after multiple laundering and sterilisation cycles. Testing1 conducted by Kimberly-Clark Professional™ used garments that were randomly selected from pharmaceutical customers. The testing results showed a decline of more than 25 per cent in Bacterial Filtration Efficiency (BFE) after an average of five washings. This presents a real yet invisible contamination risk to aseptic manufacturing environments[3].

The testing[1] also found:

◆ 100 per cent of the worn sterile reusable garments tested showed a decline in BFE after washing.

◆ The filtration efficiency of the reusable garments was typically less than 70 per cent.

◆ Fabric degradation was visible at the sub-micron level – enough to allow bacteria to penetrate the material. The product declined more rapidly than expected and that decline continued through multiple wash cycles.

◆ The total cost of ownership for reusable cleanroom apparel was much higher than projected.

◆ The average number of wash cycles was much lower than expected.

Results confirmed by additional testing

Kimberly-Clark Professional™ conducted comparative testing[1] of disposable and reusable cleanroom apparel. The testing method involved covering a container with a swatch of reusable apparel material and another with a swatch from a Kimberly-Clark Professional™ disposable apparel fabric[4]. The containers were then sprayed with an aerosolised form of Staphylococcus aureus bacteria. After 24 hours, the material was removed and the number of colony-forming units of bacteria were counted to measure the number of bacteria that penetrated through to the test medium. The results[1]:

◆ The disposable fabric maintained its 95 per cent BFE.

◆ The reusable fabric had a 68 per cent BFE.

Additional concerns

The laundering process for reusable cleanroom apparel involves multiple processing steps – such as sorting, multiple wash cycles, drying, cool-down and inspection – which all put the fabric under additional stress. This is repeated each time the gown is serviced. Therefore, the laundering process itself creates channels for bacteria to pass through. Test data for the BFE of reusable apparel is typically based on new apparel, not on apparel that has been washed and sterilised multiple times. The filtration efficiency and the lifespan of the apparel do not appear to be consistent with what is being observed in use.

Single-use apparel benefits

Disposable apparel offers a few other advantages over reusable apparel, including:

◆ **Predictability** – These garments are washed once to guarantee optimal, predictable performance for each garment.

◆ **Data transparency** – Data on disposable garments is available

◆ **Ease of donning** – Unlike reusables, some disposable apparel is designed with innovative features that keep the garment from touching the floor during the donning process

◆ **Comfort** – The Kimberly-Clark Professional™ SMS fabric is cool and breathable

◆ **Consistent Performance** – Single-use apparel provides performance and consistency to ensure that the highest levels of sterility are being met

◆ **Vacuum-sealed** – This method ensures sterility

Conclusion

The test findings detailed here cast doubt on the efficacy and reliability of reusable protective apparel and its ability to meet cleanroom standards after laundering. All sterile reusable apparel tested showed a decline in Bacterial Filtration Efficiency (BFE) after washing. By contrast, single-use disposable apparel is washed once, guaranteeing optimal, predictable performance for each garment.

When selecting apparel for an aseptic manufacturing environment, it's essential to choose cleanroom apparel that offers the highest level of BFE. Purchasers would be wise to consider these study results and choose sterile, disposable apparel for their facilities.

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PharmaEdge: Control, Monitor and Analyse – One solution does it all

The integrated PharmaEdge solution helps users optimise the performance of their automation systems while simultaneously improving cost and energy efficiency

In today's fast-paced world, the pharma industry is undergoing a remarkable transformation fueled by market outlook and the determination of manufacturers to embrace digital innovation. This exciting era has witnessed a surge in the introduction of cutting-edge solutions and progressive approaches to manufacturing. Such advancements have been made possible through a deep understanding of emerging technologies and their rapid integration into the industry's workflow. As a result, pharma manufacturers are now able to meet market demands by harnessing the power of niche technologies across machines, production lines, plants, and factories. The identification of technology's role in enhancing operations, efficiency, and customer service has prompted a systematic analysis and exchange of substantial amounts of data. This analytical capability enables manufacturers to improve production efficiency, accurately target customer needs, revise productand business models, and determinenew distribution channels. The pharma landscape is evolving, and technology is driving the way towards a more innovative, sustainable, and customer-centric future.

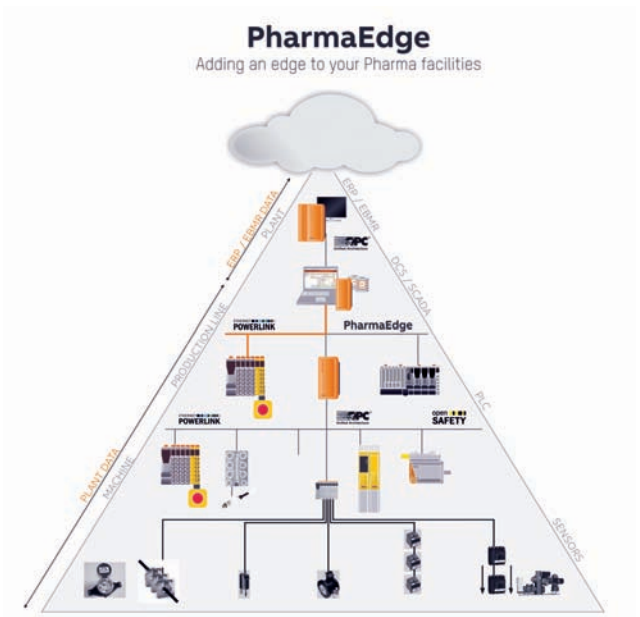

Fig: PharmaEdge is an integrated solution for the pharma industry – all the benefits of SCADA and a powerful control system in one device

Fig: Features offered by PharmaEdge include data archiving and retrieval, electronic signatures, batch reporting, access protection and central user management as well as audit trail and change management

The demand for digital Innovation

The Indian pharma industry offers tremendous opportunities for the automation sector. With needs of higher productivity, superior quality and competitive market demands, more companies are becoming open to digitalisation for different pharma processes, from drug discovery to manufacturing and packaging. On top of that, compliance with regulatory requirements opens new opportunities and challenges for machinesuppliers. Digital revolution is all about creating seamless connectivity between machines, processes, and people within and beyond manufacturing facilities to increase quality, productivity, and profit from the power of advanced data analytics. With these next-generation automation solutions, pharma manufacturing companies can digitise their operations, increase efficiencies, enhance product quality, and fulfill regulatory compliances. Pharma companies are usually tasked with examining data at every stage of their manufacturing process, right from the time raw materials arrive until the final product is packed and sent for distribution. In traditional pharma facilities, the references and information about drug formulation, production, equipment, and data of QA-QC are manually entered in data sheets, which are prone to human errors and can even be manipulated. With such non-real-time information, it is hard for businesses to make correct actions and suitable decisions. However, with connected plant and Industrial IoT (IIoT) solutions, manufacturers can access data in real-time to monitor production, quality, OEE, and equipment condition. It also enables mass customisation and batch size one with cost-effective production. IIoT is presently in its nascent stages of adoption and started gaining interest in the Indian pharma industry while some big players have already started to take the first movers advantage. IIoT helps in the standardisation of the manufacturing process along with data integrity. By systematically controlling, monitoring, and analysing large volumes of data, manufacturers can benefit from improved production efficiency, productivity, reliability, and quality, thereby increasing overall operational efficiency.

PharmaEdge: More than just SCADA

When it comes to control and monitor, Manufacturer are often presented with multiple systems which become difficult for them to handle. B&R has developed an integrated single-PC solution for users in the pharma industry to control, monitor and analyse their entire operations, which also meets the increasing demands of FDA compliance. PharmaEdge is an out of the box solution for the pharma industry providing all the benefits of SCADA and a powerful control system in one device. With possibilities to add energy monitoring, condition-based predictive maintenance, and MES/ERP connectivity, it enables implementation of smart machines for the future of the industry. Quality, regulatory compliance, safety, easy track and trace and efficient data access are the trademarks of a world-class pharma facility. PharmaEdge provides a quick and easy way to implement and customise audit trails. System manufacturers and end users benefit from maximum security without having to implement organisational measures. Features offered by PharmaEdge include data archiving and retrieval, electronic signatures, batch reporting, access protection and central user management as well as audit trail and change management. This solution is compliant with FDA 21 CFR Part 11. The integrated PharmaEdge solution helps users optimise the performance of their automation systems while simultaneously improving cost and energy efficiency. Instead of deploying separate control systems for process control, SCADA, energy monitoring and condition monitoring, users get all this functionality in a single integrated system with built-in cybersecurity. With this one-box solution, users will be able to monitor and analyse as well as control their entire operations.

VIVAPHARM® ALGINIC Acid: Natural Hydrocolloid Super-Disintegrant

VIVAPHARM® ALGINIC Acid is obtained from a sustainable seaweed harvest, free from allergens, clean label friendly and offers high batch to batch consistency

Due to its viscosifying, gelling and film forming properties VIVAPHARM® ALGINATES are one of the most versatile hydrocolloids. The versatility is reflected in different applications using alginates, from medical and dental care to nutraceuticals and pharmaceuticals, such as thickener in syrups, controlled release in tablets, tablet disintegrant, enteric coating for capsules, wound dressing with hemostatic properties, or a physical raft against reflux.

Alginates are biopolymers that have been investigated for their use in food and medical fields. However, minimal information is available regarding their potential application as tablet superdisintegrant.[1]

Alginates generally occur as hydrophilic polysaccharide composed of linear copolymers.

Alginate is an unbranched block copolymer composed of homopolymeric ß-D-mannuronate M and α-L-guluronate G blocks, which have no regular repeating units. The proportion and arrangement of these uronic blocks provides unique physicochemical properties to the alginates and vary, as mention above, to a large extent depending on their source and extraction method.

The proportion of the three types of blocks — MM, GG and MG plays a critical role on the physical properties of alginates.[2]

Alginates obtained from different algae species, season and place of harvesting differ significantly in their chemical composition (mannuronic/guluronic (M/G) ratio), structural/block organization, and physicochemical properties (molecular weight, rheological characteristics, moisture content, particle size distribution, purity, etc.). The extraction method and process parameters (temperature, time of extraction, alkali concentration and pre-treatment) have also shown an impact on the properties of the produced alginate.[2]

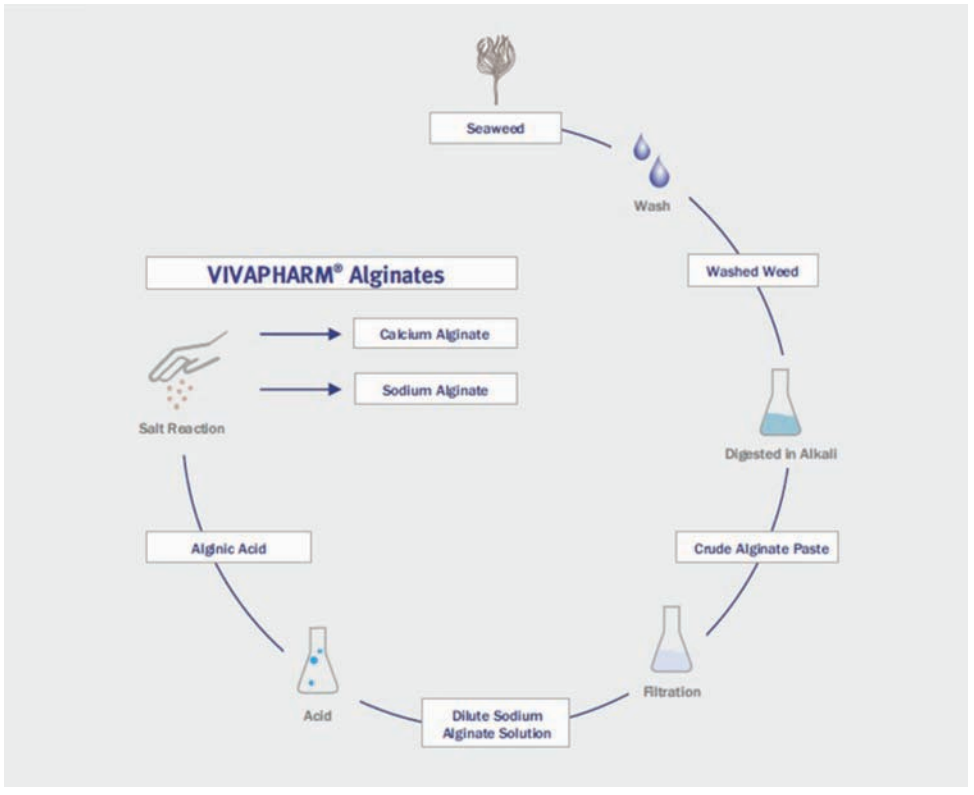

Fig.2 Manufacturing process of VIVAPHARM® ALGINATES: Alginic acid, Sodium alginate, Calcium Alginate

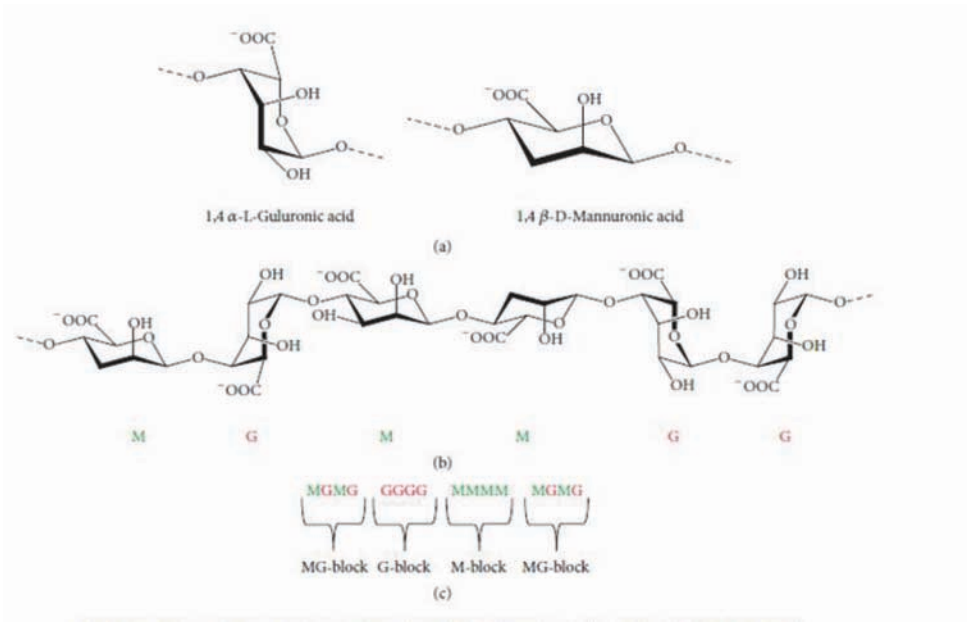

Fig. 1 The structure of Alginates: monomers (a), chain conformation (b), and blocks distribution (c) 5

Chemical properties of VIVAPHARM® ALGINIC ACID

The performance of Alginic acid is affected by the content of G and M. Different ratios of G units and M units in the molecule determine its molecular structure. Different structures and diverse conformations determine the biology of Alginic acid characteristics.

Alginates rich in GG blocks have higher water solubility than those rich in MM blocks. At low pH, alginates with more MG/GM blocks are soluble, whereas MM or GG block–rich alginates are insoluble.[3]

The presence of free carboxylic acids in the Alginic acid which also favours polymer hydration and therefore increases its water uptake kinetics this capability of materials to interact strongly with water is essential for disintegration functionality. [2]

Acid resistance: Sodium alginate will gradually form an Alginic acid gel when the pH value is lowered; when the pH value is increased, the Alginic acid will dissolve and restore the original viscosity.

Gel formation: When the pH is lowered, Alginic acid will form a gel. The gel strength of this gel is weak, the formed gel is soft, and it is soluble in the alkaline solution; when a small amount of Ca2 + is added to the solution, Ca2 + replaces some of the H + and Na + in the alginate to

form a calcium alginate gel. In this three-dimensional network structure, in the middle of the Ca2 + image structure, it forms an "egg-box" structure with the G block The gel formed by calcium alginate is heat-irreversible, which is an obvious advantage of sodium alginate over other colloids.[3]

Why use VIVAPHARM® ALGINIC ACID?

1) Obtained from a sustainable seaweed harvest
2) A short distance from sea to plant for optimal product quality
3) Natural based hydrocolloid free from allergens, clean label friendly
4) High batch to batch consistency

VIVAPHARM® ALGINIC Acid and its role in OPTIZORB™ technology[4]

Panadol® with Optizorb™ technology is a paracetamol based analgesic, that provides fast, suitable, effective relief of pain and discomfort associated with headache and migraine. However, sometimes standard paracetamol tablets slowly dissolve and absorb, and can sometimes takes a long time to impart its effects. Panadol® with Optizorb™ technology dissolves quickly (in the stomach) due to super-disintegration which causes the tablet to swell even more, and speeds up the break up process aiding in quick absorption. [4]

Optizorb™ technology contains three main ingredients which are: Alginic acid that draws fluid from the stomach into the tablet causing it to swell and break apart; calcium carbonate that works together with Alginic acid to boost the disintegration of the tablet and, crospovidone which acts as a superdisintegrant. [4]

Optizorb™ disintegration technology is five times faster and shows action more quickly. It gets easily dispersed in stomach and work faster, relief faster. Optizorb™ technology is based on the use of super-disintegrant such as Alginic acid and Calcium Carbonate that makes it act within five minutes.

Optizorb™ technology can be applied where rapid onset of action is required, for example Analgesics and Anti-inflammatory Agents, Anti-bacterial Agents, Anti-Arrhythmic Agents, Anti-depressants.

Crocin Advance™ Paracetamol 650mg tablet also uses Alginic acid along with Calcium carbonate and Crospovidone.

Disintegrant property of VIVAPHARM® ALGINIC Acid

VIVAPHARM® Alginic acid shows good swelling in all the dissolution media. Its disintegration mechanism follows a combination of swelling and shape recovery. It has been observed that in some cases the disintegration obtained by Alginic acid is comparable with Sodium Starch Glycolate and Crospovidone. [1]

The use of Alginic acid as a tablet superdisintegrant is thus recommended, particularly, in uncomplicated hydrophilic formulations of natural products for the supplement and nutraceutical industries, where the use of all-natural excipients is often becoming a necessity. [1]

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Accurate weighing through GWP® - The Global Weighing Standard

GWP's risk-based approach ensures that all your weighing devices meet your own accuracy requirements and adhere to quality standards such as ISO, GMP and GLP

Good Weighing Practice™ (GWP®) is the science based global weighing standard for the efficient life cycle management of weighing systems. It ensures consistent accuracy, quality and compliance in any weighing process. GWP's risk-based approach ensures that all your weighing devices meet your own accuracy requirements and adhere to quality standards such as ISO, GMP and GLP. It is applicable to new or existing weighing devices from any manufacturer in any industry or workplace.

Regular verification and control of weighing equipment is an essential part of ISO, GLP or GMP quality management systems, ideally conforming to a risk management process. It ensures that instruments continually perform to a high standard, meeting specifications and fulfilling current regulatory demands. This requirement is made clear in the Organisation of Economic Co-operation and Development (OECD) publication, "Principles of Good Laboratory Practice, Chapter 4.2: Use, Calibration, and Maintenance of Equipment", which states that 'Apparatus used in a study should be periodically inspected, cleaned, maintained and calibrated according to Standard Operating Procedures (SOPs). It is the responsibility of test facility management to ensure that instruments are adequate and functioning according to their intended use'. The US Pharmacopeial Convention takes this one step further, with "USP Chapter 41" recommending the adoption of a risk management approach to scheduled calibration and routine testing of weighing equipment.

GWP® Verification helps you assure accurate weighing results as part of your quality management system. Applicable for all balances and scales, it provides an optimised testing and calibrating scheme which may translate to sustainable time and cost savings

The first, and essential, step in any laboratory application or workflow is to ensure that all balances are correctly calibrated and routine testing of equipment is up to date; optimising maintenance procedures and balance verification intervals will help eliminate inaccurate readings and reduce downtime. Generally, laboratory balances are checked on a regular basis for any deviation in sensitivity - the difference between the calibrated weight and the displayed value, ideally measured at the maximum capacity of the balance - and repeatability, defined as the standard deviation of 10 measurements of a weight below 5 per cent of the capacity of the balance. Further testing, including linearity and eccentricity, is best performed by a fully trained service technician during annual / biannual balance calibration procedures.

METTLER TOLEDO developed GWP®, Good Weighing Practice™, as a standardised scientific methodology for secure selection, calibration and operation of weighing equipment.

Benchmark your quality management system

GWP® Verification helps you assure accurate weighing results as part of your quality management system. Applicable for all balances and scales, it provides an optimised testing and calibrating scheme which may translate to sustainable time and cost savings.

Your benefits

- The accuracy of your weighing instruments is matched to your process tolerances.
- A comprehensive summary report provides an overview of the status of all weighing equipment.
- An optimised routine testing and calibration schedule results in sustainable cost savings.
- Audit-proof and up-to-date documentation complements your quality management system.

For your success: you focus on your process, METTLER TOLEDO takes care of the measurement.

For more details:
Visit: www.mt.com/gwp
Email - sales.sales@mt.com
Call toll-free at - 1800 22 8884 & 1800 1028 460

Ensuring pharma compliance with testo data measurement technology

Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharmaceutical products during production, storage or transit of goods

Due to the crucial necessity and its direct impact on human health and welfare, pharma is probably the most important and critical sector among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the Pharma division to ensure safety measures and controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing and measurement sector provides the best in class data loggers and data monitoring systems for the pharma division.

Ensuring end to end climate monitoring – Testo Data Loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. Temperature and humidity data loggers are often used in pharma industries to monitor the conditions in which drugs, medicines, vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is very extensive. A temperature and humidity logger such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi channels for connecting external sensors and thermocouples, like testo 176 are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimisation in QA units and clean room applications. These instruments are the most convenient and pocket friendly solution for all pharma application areas.

The testo Saveris 2 WiFi data logger system is the simple, flexible and reliable solution to humidity and temperature monitoring in cold storage area like blood banks. This innovative monitoring system is ideal for high product quality & eliminates manual work of reading out or documenting measurement data. With a secure online storage of all readings in Testo Cloud the data can be managed and analysed online by the user via smart phone, tablet or PC anywhere and anytime. In case of crises and deviations, it is provided with an alarm by e-mail, or optionally by SMS.

Another important and crucial application of a pharma industry involves validation of sterilisation and freeze-drying processes. Not only that, validating cleaning and disinfecting equipment is equally necessary. In order to allow a seamless operating procedure, the validation process and the documentation work must be as efficient and smooth as possible which could be easily achieved with testo 190 data logger solution that has innovative data loggers for temperature and humidity, smart software and accessories.

Data compliance for audits and inspections

Testo offerings are majorly related to the data security along with comprehensive analysis and evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharma products during production, storage or transit of goods. Real time data monitoring is important for the quality of pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers and data monitoring systems. Our data loggers are EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

Service and calibration made easy

Testo also has an established state-of-the-art NABL accredited service and calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune. Testo service and calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards. The accredited parameters include Humidity, Pressure, Absolute Pressure, Contact Type Temperature, Non-Contact Type Temperature (Infra Red Thermometer, Thermal Imager). In fact, testo's lab is the first and only lab in India to get NABL accreditation for Dew Point Temperature as well.

For more details, login to www.testo.com or write to info@testo.in

MultiUse portfolio: Flexible and high performance

The latest generation of MultiUse systems combines 10-laned processes and the specific characteristic concept of individual packaging

The latest generation of OPTIMA MultiUse equipment processes up to 24,000 containers per hour. The complete MultiUse portfolio covers applications from clinical studies to large batch sizes. The processes are transferrable on a one-to-one scale, up to the highest output, while maintaining precise dosing volumes, and maximising the product yield and flexibility.

When Optima began developing the MultiUse systems 10 years ago, the design team was literally looking at blank pages. Today, MultiUse machines are the safe and economical answer to complex dosing tasks for expensive pharma- drugs and different active ingredients. They are well suited for a wide range of uses from clinical trials to high-speed commercial production processes. The MultiUse portfolio offers identical transferable processes, from one to 10 lanes.

The market demands higher outputs

Many biotech start-ups became notable companies or an interesting takeover candidate. The ratio of pharma produced drugs in Germany is more than a third. At the same time, specialised contract development and manufacturing organisations (CDMOs) for complex pharmaceutical drugs developed into larger enterprises.

New drugs receive additional approval for supplementary therapeutic applications and reach new markets. Conclusion: A dynamic and growing market demands MultiUse applications with a high-performance ratio.

The latest generation of MultiUse systems combines 10-laned processes and the specific characteristic concept of individual packaging. The output can reach up to 24,000 containers per hour. All features like 100 per cent in-process control for vials, ready-to-use syringes and cartridges, as well as product savings are still available with a high output. The MultiUse portfolio includes all performance categories for small, medium and large batches.

MultiUse line with process paths for liquids and freeze-drying

Easy scale-up from the lab to high-performance filling

Optima Pharma places great emphasis on process transfer to all new systems and for all concepts. Scale-up is easier when processes can be "inherited" by the next generation of high-performance MultiUse systems. This includes guide-lines for system adjustments in the millimeter range, homing function and more support processes. Validation of identical machine functions is possible and already validated processes are the basis for new systems.

Nested containers are unpacked automatically. Bulk containers such as non-pre-sterilized vials can optionally be fed via a second product path

version by relieving the production machinery and using its potential to its fullest.

Turnkey: Many process paths – for maximum flexibility

The MultiUse portfolio provides the option to configure different processes within one machine. For example, a bulk

Transfer of the containers into the highly flexible transport system. There is no glass-to-glass contact at any time in the MultiUse lines

Currently, Optima Pharma is designing a MultiUse machine complementary to the single-lane MultiUse machine for laboratories and for batches up to 2,000 containers, typically used for experimental purposes and stability tests. With this MultiUse version Optima offers identical functions that can be used within an isolator, but with a very small footprint. The processes can be transferred to the MultiUse production system later. Users benefit from the laboratory path for non-sterile vials that are transported from the washing machine and sterilising tunnel to the filling station. Parallel a RTU-path for pre-sterilised syringes, cartridges and nested vials or vials in trays can be integrated leading to the same filling station. A freeze dryer can follow and lead to a joint crimping station that processes both liquid and lyophilised vials.

The MultiUse portfolio adapted with the comprehensive scientific process

engineering (CSPE) approach for different combined processes in one system is especially profitable. Machines are completely integrated and tested before the FATs (iFATs) with isolators and loading and unloading systems in the CSPE center. Subsequently, Optima Pharma performs a cycle development in-house, in order to save the customer time until production start.

Digital technologies and robots increase process safety

To comply with pharma requirements, Optima Pharma selected a different, innovative approach for automation. Depending on the assignment, a typical six-axle robot can be a disadvantage for pharmaceutical systems. Robotic arm movements, particularly, above open containers have to be avoided to maintain pharma integrity. In addition, the large space requirements of the robot, the possible disturbance of the laminar air flow, as well as lower speeds during the transport through the machine, call for specific robotic and pharmaceutical solutions.

For these reasons, the MultiUse system contains different robotic types and kinematics and in part, newly designed robots. This highlights the fully automatic linear transport with a format-free design and ensures the gentle transport of containers throughout the entire machine: from de-nesting to re-nesting containers without any glass-to-glass contact.

Flexible robotic approach

Third-party robots can be used for de-nesting and feeding containers into the transport system. The free-programmable oval transport can also be reviewed as part of this process. Together with "conventional" robots, the oval transport offsets potential empty spaces in the nest and is part of the flexible re-nesting process. All robot functions reduce operator involvement to a minimum.

An additional benefit: Optima Pharma programs all con-tinuous core processes, including all transport systems

Highly precise dosing system, exact filling volume: If a fill volume is inaccurate, the container is immediately refilled instead of rejected – the so-called "re-dosing on request"

Freeze-dried or liquid? MultiUse: Both product paths can be processed at a common crimping station for vials

in-house – this is more than "just" an integration of third-party components. Each MultiUse machine is controlled by central logistics. This full synchronisation forgoes manufacturer specific software sub-systems and reduces the software's complexity enormously. This is especially vital if the standard process has to be changed. For example, if an individual stopper is added, all machine components stop and will be automatically married again to the process. A process that is easily controlled, specifically if coherent software controls the machine operation.

Weighing precision without compromises – up to high performance systems

Highly precise weighing systems are one of MultiUse system's most beneficial features. The transport system's impact on the weighing precision should not be under-estimated. Optima's sophisticated transport and weighing technology

With identical processes from R&D to high-performance The MultiUse portfolio offers maximum flexibility and highest product yield

achieves precise weighing results, avoiding potential errors due to oscillation.

Highly precise weighing results require a certain time to be completed. Optima succeeded in implementing these requirements into the new MultiUse high-performance machinery. In addition, individual weighing cells simplify the acquisition of spare parts.

Easy operation and increased innovation

Smart production assistance services from Optima have proven extremely useful for highly flexible systems. Digital technology supports systems during size part changes or the changeover to a new product. All tasks that need to be performed by an operator can be accessed with augmented reality glasses, a tablet or HMI and can be uploaded visually into the machine system, and information immediately implemented by the operator.

A re-printing function to maximise the product yield is a new feature. The vials or tubs can be reprinted, if they are classified as incorrectly labeled by the camera system. This assists bringing pharmaceutical production per batch even closer to the 100 per cent mark. In addition, processing of pre-crimped individual cartridges was accomplished 100 per cent air bubble-free using a multi-staged filling process in combination with vacuum stopper insertion. This means the stopper is always in the correct position, for the final pen application.

This machine design has an additional benefit. Different bio-pharmaceutical products require different handling. The individual handling of the object is the ideal requisite to fulfill individual requirements.

MultiUse – a model for success: Customers utilise its portfolio reliability

The bold decision to establish a new MultiUse machine system proved correct. Since the first customer bought a MultiUse in 2014 (they have since purchased a second Multi-Use machine), the demand has continuously grown, especially since 2019. Today, MultiUse machines are very well established on the market. From laboratory to high-performance machines, the systems are in daily use in the pharma industry. Several customers, including international CDMOs and well-known companies, use the portfolio and operate MultiUse equipment with different outputs.

Important for you

- ◆ Continuous MultiUse portfolio from R&D to high performance applications with identical, transferable processes.
- ◆ New: High output up to 24,000 containers/hour, including complex fill & finish requirements.
- ◆ Flexibility to process different container types: Ready-to-use syringes, cartridges and vials (bulk or RTU in tubs or trays).
- ◆ Unique process varieties with turnkey options: Combination of different process paths in one system, including freeze-drying.
- ◆ Pharmaceutical optimised robotic and best in-process safety for minimized operator interference.
- ◆ Comprehensive functions for maximum product yield.
- ◆ Smart Production Assistance Services provide production and format change support.
- ◆ **Small MultiUse systems up to high performance lines:** A broad portfolio for all outputs and batch sizes with transferable processes.

Waters Corp completes acquisition of light scattering leader Wyatt Technology

Wyatt accelerates Waters' ability to build a high-growth business in bioanalytical characterisation for new modalities

Waters Corporation has completed its acquisition of Wyatt Technology, a pioneer and well-recognised leader in innovative light scattering and field-flow fractionation instruments, software, accessories, and services.

With more than 80 per cent of its rapidly growing revenues tied to large molecule applications, Wyatt accelerates Waters' ability to build a high-growth business in bioanalytical characterisation for new modalities. This includes cell and gene therapies, which represents a significant opportunity with a $1.8 billion total addressable market and 10-12 per cent projected annual growthi. Wyatt's highly complementary analytical technologies, together with Waters' global reach and expertise in simplifying sophisticated techniques for high-volume applications, positions Waters to better serve the fast-growing needs of its global customers.

"We are pleased to complete the acquisition of Wyatt, which is a significant milestone for Waters as we advance our strategy to accelerate value creation and generate faster growth. With Wyatt, we are even better positioned to solve our customers' critical challenges with differentiated bioanalytical characterisation techniques. We welcome the Wyatt team to Waters and look forward to facilitating a smooth integration process and working together to deliver an unmatched set of bioanalytical characterization solutions to our global customers," said Dr Udit Batra, President and CEO, Waters Corporation.

> The transaction is expected to be immediately accretive to Waters' revenue growth and margin profile. Additionally, Waters expects to generate over $70 million in annual revenue synergies by the fifth year following transaction close

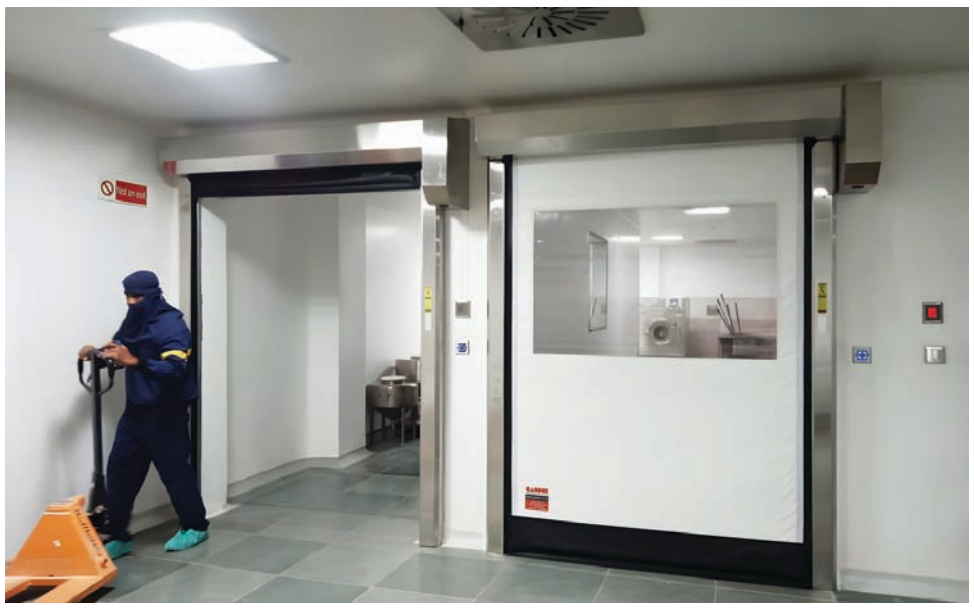
As previously announced, the transaction is expected to be immediately accretive to Waters' revenue growth and margin profile. Additionally, Waters expects to generate over $70 million in annual revenue synergies by the fifth year following transaction close. The transaction is also expected to be accretive to Waters' adjusted earnings per share beginning in Q1 2024 and to deliver a high single-digit plus adjusted return on invested capital in year five, net of tax.

High-speed doors from Gandhi Automations

Gandhi Automations, India's No.1 entrance automation and loading bay equipment company offers high-speed doors that are versatile and solid ensuring long-lasting reliability

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

Fast-moving, functional and reliable doors are needed in industrial and commercial contexts. Gandhi designed and manufactured High-Speed Doors are versatile and solid ensuring long-lasting reliability. The modular structure of the curtains, assembled and joined by anodized aluminium extrusions, provides for a wide range of polyester sections available in a variety of colours. Wide, full-width window panels ensure safer traffic and allow more light in. Their fast and easy replacement, in case of accidental tearing, saves money and time. The alternating metal tubular structure there inserted ensures high wind resistance.



Prime High Speed Doors are the ideal solution for internal and external entrances and effectively operate in any situation, even when strong winds are blowing and in rooms with high volume traffic. Sturdy and dependable, Prime is the intelligent door for medium and large entrances.

High-Speed Doors for the external entrance are equipped with spring steel wind lock in curtain pocket that ensures silent door travel, higher wind loads and curtain stability.

High-Speed Door - Prime Reset

It is a unique High-Speed Self-Repairing Door with the latest technology that prevents downtime of the door system. In case, the curtain is impacted accidentally it will cause the curtain to move out of the guides without damage. The movement of the door is designed in such a way it can be recovered with a simple opening and closing operation. Gandhi Automations manufactures doors of the highest quality that meet the issue for greater flexibility desired by clients. High-Speed Self-Repairing Door in PVC is the most suitable solution in the field industries, it lowers the time of transition from one facility to another, avoiding any human error which can cause damage to the High-Speed Door and all this can be achieved due to the innovative anti-crash system. Gandhi Automations provides a world-class product with great security.

Below are the features of self-repairing high-speed doors offered by Gandhi Automations:-

- ◆ Flexible and self-repairing door
- ◆ Functional, safe, quick and resistant
- ◆ Innovative anti-crash system
- ◆ Can be equipped with PVC vision windows
- ◆ Self-lubricating maintenance-free guide
- ◆ Smooth and silent opening and closing
- ◆ Protects traction unit, enables rapid wiring and safety photocell
- ◆ Flexible curtain in self-extinguishing material
- ◆ Self-resetting without intervention
- ◆ Quickly back to operation
- ◆ Control panel designed for an intensive continuous service

Contact

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B&R and ABB showcase automated solutions for the future of retail at interpack 2023

Highlight how automation can help companies tackle the production and logistical challenges posed by omnichannel retailing

B&R and ABB together have showcased a comprehensive range of solutions for packaging automation at interpack 2023, highlighting how automation can help companies tackle the production and logistical challenges posed by omnichannel retailing. Solutions include automated package handling and intelligent track systems, machine vision, robotic picking solutions, autonomous mobile robots (AMR), as well as digital programming and simulation software. B&R's range of track-based and planar product transport systems, including the ACOPOStrak, SuperTrak and ACOPOS 6D, have been engineered to support new production concepts, such as adaptive manufacturing. At the show, 18 adaptive machines incorporated the ACOPOS 6D, on various stands throughout the exhibition.

Fig: Mechatronic product transport combined with robotics, vision and simulation and powered by B&R's open and integrated control solutions

The growth of omnichannel retailing has challenged manufacturers, distribution centers and logistics warehouses to transform their systems to handle both pallets and packaging destined for retail shelves. At the same time, manufacturers and distributors need to pick and pack highly varied items for shipping direct to individual consumers. ABB and B&R's highly flexible and reconfigurable robotic and automation solutions meet these needs, ensuring companies can continue to respond to consumer demands.

Contact
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Enteric coating | Film coating | Sustained release
Taste masking | Moisture barrier coating

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Thickening agent | Suspending agent | Emulsifying agent
Topical application | Oral care application

KYRON™ **Taste Masking & Super Disintegrant**
Taste masking of drug | Suspension | Dry syrup
Chewable tablets | Mouth dissolving tablets

ACRYSOL™ **Castor Oil Derivative**
Vitamin solubilizer | API solubilizer | Cream emulsifier
Oil & Perfume solubilizer | Dissolution improver

ACRYFLOW™ **Stearate Derivatives**
Tablet Lubricant | Sustained release

NUTRACOAT™ **Natural Coating System**
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IDEAL CURES

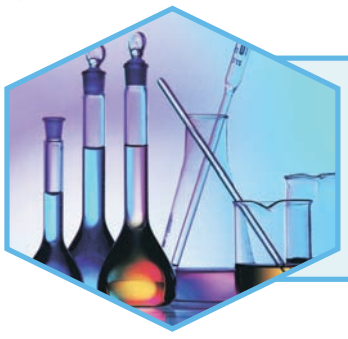
Ideal Cures Pvt.Ltd. is a global pharmaceutical excipient manufacturer.
We specialized in the production of coatings and functional excipients for solid dosage forms.

Support for Customized Formulations:

- Extended development team for customers
- In-house to ready-mix
- Specific ingredients /combinations etc.

Commercial Small Batches:

- Small pack sizes
- Cost effective



Strong Research & Development Capabilities:

- Innovative formulations (Instacoat 4G, Instacoat SFC, Instacoat QD, INSTACOAT T2F, Instaspheres, Ecopol)

Educational Programs:

- Trial support at customer site
- Trial support and guidance at IC laboratory
- Ideal Institute of Coating Technology
- Customer Site Trainings

Our Products Range:

INSTACOAT 4G® | INSTACOAT T2F® Talc & TiO_2 Free Coatings | INSTACOAT SFC | Ecocool® Extended Cooling Booster | ECOPOL® Pharma Acrylic Polymers

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