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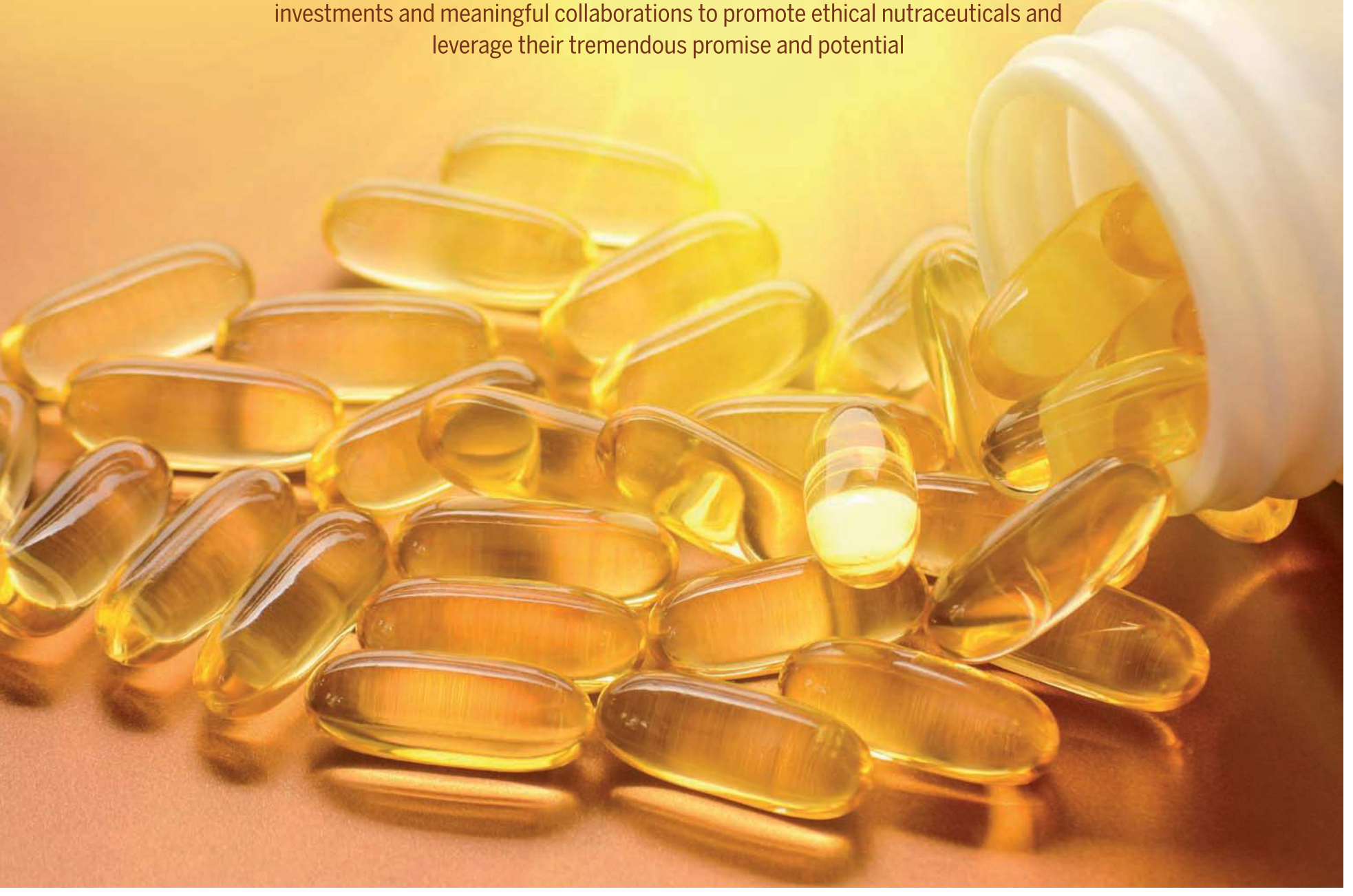

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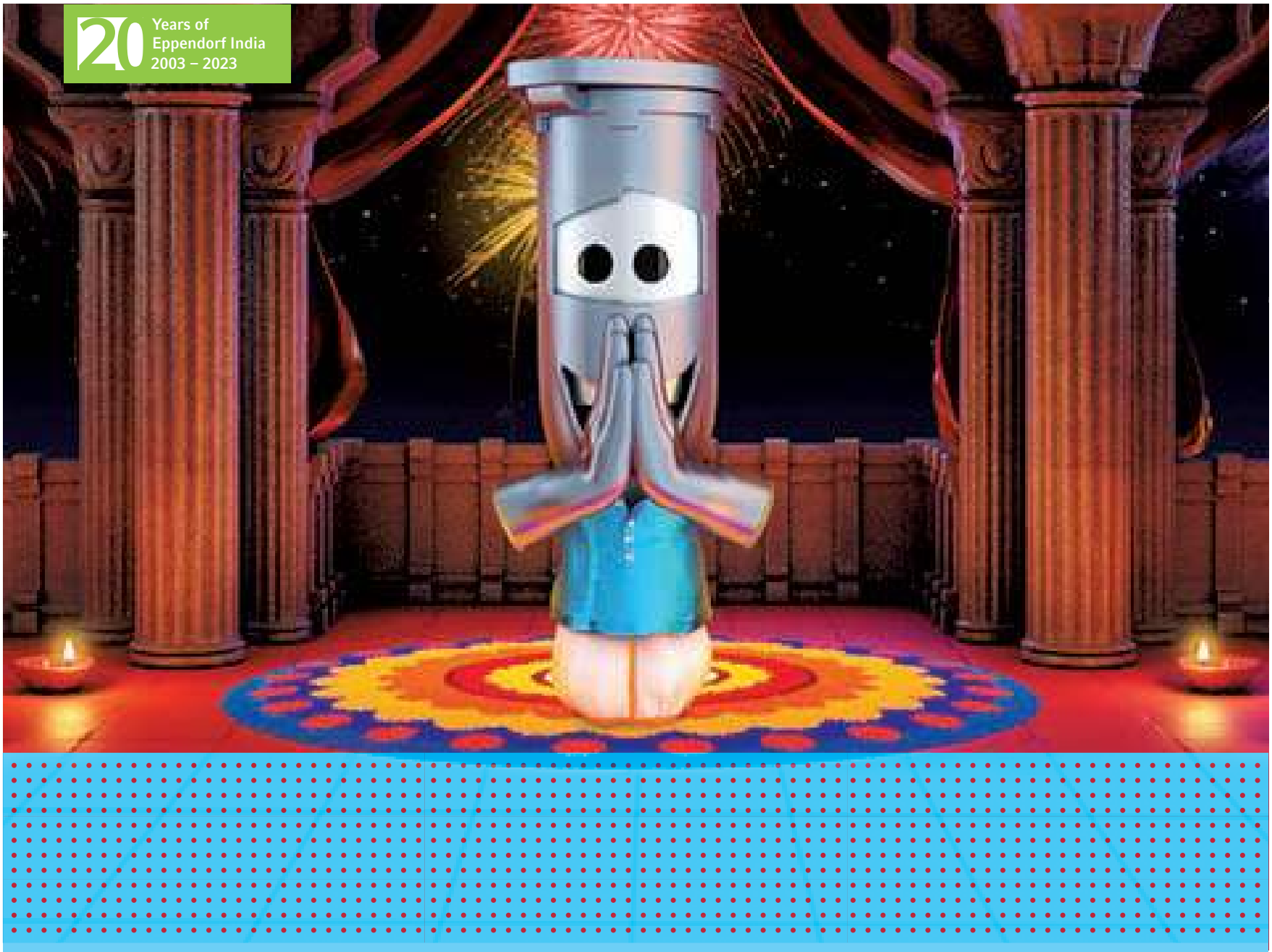

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Express Pharma®

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* Responsible for selection of news under the PRB Act.

Will online pharmacies blink off in India?

The turf war between off-line and online pharmacists continues. Many leading e-pharmacies, including Amazon, Apollo, Flipkart, Tata-1mg and PharmaEasy, received show-cause notices in February for allegedly selling schedule H, H1 and X medicines without valid licenses. The trigger was a warning by the All India Organisation of Chemists and Druggists (AIOCD) that they would launch a country-wide movement if the government failed to take cognizance of their concerns regarding alleged malpractices like unsustainable discounts, misuse of patient data, and fake prescriptions. They also allege that some of the online pharmacies do not have valid licences.

This was followed by a PTI report on the revised draft of the New Drugs, Medical Devices and Cosmetics Bill, 2023, which is currently doing the rounds of various concerned ministries. It seems that the group of ministers tasked with reviewing the revised draft of the bill raised concerns with the proposed draft and made changes. While a previous version of the draft bill required permission to operate an e-pharmacy, a revised version reads that the central government "may regulate, restrict or prohibit the sale or distribution of any drug by online mode, by notification." Thus, while the previous draft allowed for permission to operate an e-pharmacy, the revised draft bill does not have this clause.

After stepping up and meeting patients' needs during the pandemic, online pharmacies were seen as a blessing. COVID-19 patients booked and paid online, and medicines were delivered within 24 hours, if not earlier. Discounts were the cherry on the cake. Investments flowed into the sector as India is a nascent market with room for growth in the under-served tier 3/4 towns.

Online pharmacies seem to have come full circle now, attracting the same mistrust as in pre-pandemic times. Ironically, it is discounts that are tripping up the online pharmacy sector. Going by the dictum, that there are no free lunches, discounts do have a downside. Cut-throat competition forces online pharmacies to keep offering deeper discounts, in the hopes of poaching/attracting and retaining more customers from rivals. This soon became a race to the bottom, with eroding profits of online pharmacies.

The discounts given by online pharmacies cause a lot of heartburn among traditional chemists as they wean away customers, forcing smaller chemists to either shut down or sell out to national chains of online chemists.

Patients too are realising the flip side of discounts. They are never sure how much of the health data they share is being kept confidential. Secondly, they suspect online pharmacy staff push unnecessary medicines, and expensive supplements. Many patients have complained that they try to upsell them to brands giving higher margins, as they are incentivised and need to meet high sales targets.

Tougher regulation, tighter rules, weeding out unscrupulous online pharmacies will ultimately serve the Indian patient better and ensure a more ethical, trustworthy sector, with sustainable revenues

For their part, online pharmacies say that they are open to audits as they have already enough safeguards in place. Global PE investors in online pharmacies too are worried that their investments will go down the drain if the ban comes into effect. Many have reportedly sought meetings with the Commerce ministry to explain their stance, reasoning that they partner with registered offline pharmacy stores with qualified pharmacists to dispense medicines against validated prescriptions.

For example, Devashish Singh, Co-founder and CEO of MrMed, an online pharmacy for super-specialty medicines, reiterates the stance of most e-pharmacy players, saying that MrMed welcomes laws governing e-pharmacies and hopes that these will be drafted keeping patients' well-being first. He points out that today, there is no definition of an e-pharmacy/online pharmacy under any law in India and this needs to be defined.

Underlining the benefits of online pharmacies, he states that MrMed delivers to thousands of towns in India where the availability of medicines that help patients fight cancer, HIV and other life-threatening conditions, is limited. This access to speciality medicines in smaller towns is an important factor amongst a host of others that should be considered in the eventual release of regulations. Singh also hopes that these regulations, amongst other things, will also help address concerns related to data privacy, malpractices, and other issues that have been raised previously. He says his company is looking forward to working closely with regulatory authorities to ensure that their services meet all requirements.

Enforcing regulations has always been difficult, so is a ban on online pharmacies the only fool-proof answer? At an industry level, the government is also bound to realise that this ban might hurt many start ups in the sector and increase unemployment. At a policy level, it might send the wrong signals to global investors.

The rollback of unconditional support for online pharmacies during the pandemic could be criticised as indecision and policy paralysis of regulators. But it is actually sound governance. Tougher regulation, tighter rules will ultimately serve the Indian patient better in the long run. Weeding out unscrupulous online pharmacies will ensure a more ethical, trustworthy sector, with more sustainable revenues.

This is a storm that has been brewing for quite a few years. It is time all stakeholders get together, share concerns and find a middle path, keeping patient/consumer interest as the top priority.

VIVEKA ROYCHOWDHURY, *Editor*
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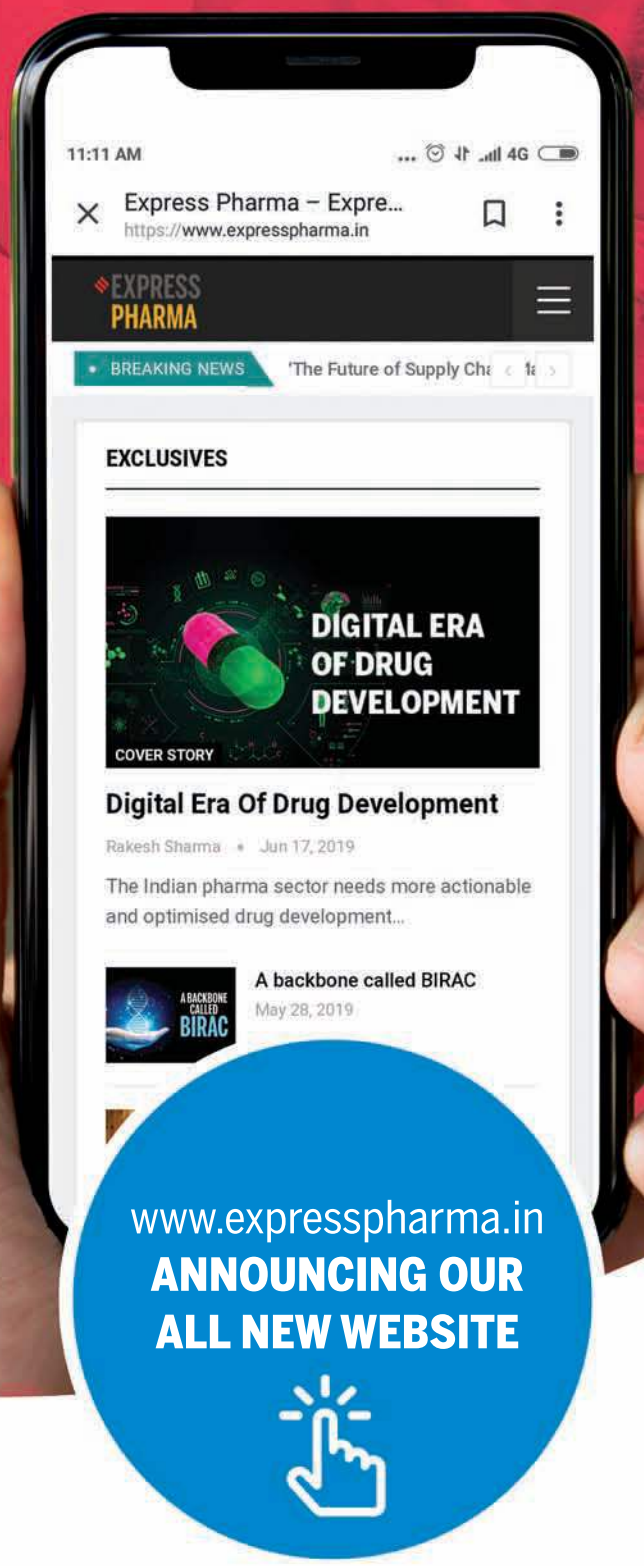

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ETHICAL NUTRACEUTICALS NEED OF THE HOUR

India Pharma Inc needs to arm itself with an evidence-based approach, significant investments and meaningful collaborations to promote and propagate ethical nutraceuticals and leverage the tremendous promise and potential they represent

By **Lakshmipriya Nair**

As the world grappled with the COVID-19 pandemic, and now continues to deal with its aftermath, 'immunity' has become the new buzzword and the demand for nutraceuticals across the globe has increased manifold. This, in turn, has opened a huge opportunity for the nutraceuticals industry globally and India is uniquely positioned to become one of the most formidable players in this segment, with a projected $100 billion valued market by 2030. *(Read: https://www.expresspharma.in/six-reasons-why-india-is-poised-to-be-a-global-leader-in-nutraceuticals/)*

However, even as this industry booms and newer players enter the market, serious concerns are being raised about the research, regulation, development and consumption of these nutraceuticals. So, timely and pertinent measures are of essence to leverage the tremendous growth potential and eliminate bottlenecks that hinder the industry's progress.

Express Pharma- Nutrify Today Boardroom series

In a bid to examine and understand the prerequisites for the next leg of growth in nutraceuticals, Nutrify Today and Express Pharma came together to launch the *Express Pharma- Nutrify Today Boardroom series*. The aim was to create and build a platform for pharma industry leaders to initiate a dialogue that would assist the pharma industry to leverage growth through ethical nutraceuticals. It is also an endeavour to enable government bodies to shape effective policies that would help the growth of the ethical nutraceuticals industry in India through effective engagement with the pharma industry.

The first edition of the *Express Pharma - Nutrify Today Boardroom series*, held recently in Mumbai, offered a platform for meaningful dialogues on the vast ocean of opportunities for the Indian pharma sector to be reaped in nutraceuticals, provided the right course is set for long and sustainable growth.

An eminent panel of pharma experts and leaders came together to explore approaches to build an ecosystem for developing scientifically proven, evidence-based nutraceutical products. Dr Meenakshi Singh, Secretary Nutraceuticals Task Force under chairmanship to PSA to Government of India; Rahul Kulshreshtha, Strategic Alliances - Office of the Principal Scientific Adviser to the Government of India; Aditi Kare-Panandikar, MD, Indoco Remedies; Anand Swaroop, President, Cepham Inc; Rajaram Sankaran, Chief Strategy Officer - India, Torrent Pharmaceuticals; Shriram Balasubramanian, Director Marketing and Business Development, Zuventus Healthcare and Amit Srivastava, Chief Catalyst, Nutrifytoday.com were the participants in this round table moderated by Viveka Rowchowdhury, Editor, *Express Pharma & Express Healthcare*.

As the experts dived deep into the challenges in this field and the measures needed to enhance ethical standards in nutraceutical research, industry practices, and use, they also examined how a pharma-like approach in terms of regulation, quality assessment and safety profiles could benefit the nutraceuticals industry.

This article is a summation of the inferences drawn and lessons learnt from the views, concerns and insights shared by experts on this knowledge-sharing platform. And, we understand that gaining success through ethical nutraceuticals

will largely hinge on the following factors:

◆ **A clear and comprehensive regulatory framework:** Experts emphasised that it is inadvisable to let nutraceuticals evolve without a clear regulatory framework since the lack of uniform, consistent or standardised regulations can arrest the growth and adversely impact the credibility of this segment. Therefore, creating a separate set of laws and regulations to guarantee that nutraceutical products are safe, efficacious and meet high standards of quality is very critical. They asserted that strict guidelines and improved techniques must be adopted to ensure that there is enough evidence to validate the health claims made by different products, especially in terms of purity and safety. Discussing various aspects of dietary supplements, nutraceutical supplementation and pharmacological nutrition, experts stressed that while there have been some measures to improve the regulatory landscape in nutraceuticals, there are limitations and bottlenecks to overcome.

◆ **A centralised regulatory body:** Underpinning the importance of single point ownership in the nutraceuticals sector, the experts pointed out that as the sector has often come under the ambit of different regulatory bodies like FSSAI, AYUSH, DCGI, MoFPI etc, grey areas continue to dog the progress of the sector. Time and again, there has been a call for setting up a centralised authority or creating a body like Pharmexcil to integrate government bodies to serve nutraceuticals. As the experts at this round table also discussed the need for such a centralised body, Srivastava, who was part of a meeting held by the Nutraceutical Task Force, informed that the formation of a nutraceutical panel in the Ministry of Commerce to ensure a nutraceutical industry-specific agenda is underway.

◆ **Sound R&D and manufacturing policies:** Speaking on the need for policies and regulations-led interventions to

We need a lot of R&D collaborations with institutes such as CSIR, ICMR, ICAR and so on to collect clinical data about nutraceuticals. The pharma sector has a very crucial role in building the nutra sector, given their expertise in clinical studies and science-based background. So, the Nutraceuticals Task Force supports endeavours to engage the pharma industry such as the Express Pharma-NutrifyToday Board Room Series

Dr Meenakshi Singh Secretary
Nutraceuticals Task Force under chairmanship to PSA to Government of India

We are working closely with NutrifyToday to shape the responsible nutraceuticals industry and to nurture the growth of the industry into a $100 billion sector by 2030. The Nutraceuticals Task Force is working on solving the hurdles which face the industry. For instance, we are creating a separate space for nutraceuticals in the Commerce Ministry and also shaping up a PLI scheme for nutra. We look forward to getting feedback from the industry through the Express Pharma-NutrifyToday Board Room Series

Rahul Kulshreshtha
Strategic Alliances - Office of the Principal Scientific Adviser to the Government of India

We should not get bogged down by too many issues and focus on three important aspects when it comes to nutraceutical products – quality, efficacy and safety. As a sector which understands and deals with quality issues every day, the pharma sector is very well positioned to be an advisory on the quality side. Pharma will not prefer any claim that cannot be substantiated

Aditi Kare-Panandikar
MD,
Indoco Remedies

If we don't implement or adopt responsible nutrition now, it will create chaos. And, the only way to do that is to bring all stakeholders on the same page through industry collaborations and meaningful dialogues. India is in the right position to start moving towards responsible nutrition and the pharma industry is the best partner in this trajectory

Anand Swaroop
President,
Cepham Inc

To bridge nutritional gaps in an ethical way, pharma companies need to start investing in clinical data on nutraceuticals. We have to collaborate with HCPs to narrow down the claims made by different products, set up an ecosystem to collect and monitor adverse events data and try to prioritise areas for research where it is critical to have more data and clarity

Shriram Balasubramanian
Director Marketing and Business Development,
Zuventus Healthcare

The journey towards ethical nutraceuticals starts with awareness across all stakeholders. We should have a compendium or a guideline about the right dosages for the various dietary supplements, vitamins or nutraceuticals that are prescribed as adjuvants

Rajaram Sankaran
Chief Strategy Officer - India,
Torrent Pharmaceuticals

Reputed journals like PubMed and BMJ reveal that over 30,000 patients annually are admitted to the emergency ward due to the adverse impact of nutraceuticals in the US. So, the government is clear that nutraceuticals is not a consumer game. They are engaging deeply with the industry to evaluate if an advisory body can be created to create policies for nutraceuticals

Amit Srivastava
Chief Catalyst,
Nutrifytoday.com

ease the growth of this industry, stakeholders of the pharma and nutra industry also discussed the value of incentives to encourage research in ingredients and formulations to drive ethical nutraceuticals. Apart from addressing the need to design and implement policies that encourage product standardisation, minimise product adulteration, and ensure that recommended daily allowance (RDA) and Tolerable Upper Limit (TUL) are met, the experts also discussed how the government's plan to introduce a Research Linked Incentive (RLI) Scheme and Production Linked Incentive (PLI) scheme in nutraceuticals could give an added impetus to the sector's growth by enabling sizeable investments.

◆ **A robust nutrivigilance system:** The experts at the round table unanimously believe that indiscriminate access and consumption of nutraceuticals without the support of the medical fraternity could turn into a huge health disaster. This view is supported by studies published in reputed journals like PubMed and BMJ that reveal that over 30,000 patients annually are admitted to the emergency ward due to the adverse impact of nutraceuticals. This, in turn, led to a discussion on the role and importance of a surveillance system akin to the pharma industry to monitor and record adverse events associated with nutraceuticals. The experts at the round table vociferously supported setting up a dedicated nutrivigilance system which can promote and implement a systematic, scientific and consistent approach to assess the risk–benefit ratio of nutra products, build up scientific evidence and proof of concepts, as well as initiate and chart risk alleviation strategies.

◆ **Evidence-based practices:** The dearth of precise scientific data or *raison d'être* for the use of dietary supplements and nutraceuticals can have an adverse impact, caution industry experts. They recommend stringent guidelines to collect and propagate validated data on the safety, efficacy and claims made on the labels of nutraceuticals products. Long-term studies for clinical validation of ingredients or formulations in nutraceuticals, effective approaches to understanding the toxicology of active ingredients, interactions between drugs and dietary supplements, purity, and bioavailability of nutraceuticals etc are also imperative to drive ethical growth in the sector. Drawing comparisons between R&D and manufacturing practices in the

pharma and nutra sectors, the experts said that nutraceutical manufacturers should ensure that only potent ingredients with the right dosages backed by clinical studies are used in their products. Better standardisation, cGMP practices and evidence-based approaches to ensure better product quality, stability, functionality, safety, solubility and acceptance among patients will be vital to the advancement of this sector. This, in turn, will help the nutra sector deal with increased scrutiny and surveillance from global regulatory agencies as well.

◆ **Effective use of technology:** Emerging technologies will play a crucial role in shaping the discovery, design and development of responsible and ethical nutraceutical products, opined the panellists at the first edition of *Express Pharma-Nutrify Today Board Room series*. They also examined how technology can be leveraged and effectively deployed to provide specific dosages and ingredients as per patients' varying needs. For instance, AI can be deployed to select ingredients by matching data points from studies on nutrition and nutraceuticals and provide insights on commercial patterns, industry trends, etc. Automation and IIoT can enhance efficiency, cut costs and get products to market faster. A case-in-point discussed at the round table was NutrifyToday's NutrifyGenie, an AI-powered engine that can prioritise safety, efficacy and traceability in nutraceuticals.

India Pharma Inc's tryst with nutraceuticals

Thus, amid the clarion call for better regulations, a clear road map and empirical data to validate claims of efficacy and safety made by the slew of products entering the market to build a clear and robust roadmap for the nutraceuticals sector in India, India Pharma Inc, backed by its science and research-oriented approach, has several comparative advantages when it came to nutraceuticals. Especially, since ensuring transparency and ethical approaches to making and marketing nutraceuticals will be pivotal to the long-term growth of the sector.

However, over the last few years, the pharma industry's forays and experiments with nutraceuticals have evinced a mixed bag of results. The sector looks at the nutraceutical segment as an avenue to expand product portfolios by leveraging scientific credibility. But, the excitement to leverage the growth potential in nutraceuticals has been countered by challenges like the lack of an effective approach/guideline for clinical proofs, clinical trials, factory audit standards, bioactive standardisation, method validations, etc.

Companies like Dr Reddy's, Sun Pharma, La Renon, and Zuventus have made sizeable investments and witnessed noteworthy growth in their nutraceuticals portfolio, but many others are still struggling to find the best approach to succeed in this space.

But, armed with the right partners and a robust entry strategy, the nutra space offers a great opportunity for the pharma sector to fill gaps for certain health conditions and problems, improve profit margins, increase customer base and grow in new markets.

However, pharma players, industry bodies and policymakers need to align and adopt a cohesive approach to bring more clarity to this industry and make it mainstream to make the most of its tremendous potential.

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BRIDGES TO $100 BILLION NUTRACEUTICAL INDIA

A recent survey report by Nutrify Today titled, 'Bridges to $100 billion Nutraceutical India', identified the gaps to be filled for India to realise its nutra potential as a $100 billion industry by 2030. The survey covered the Indian nutra industry and community, including senior and middle management professionals and owners of nutra firms and businesses. Other stakeholders, such as academia and investors, were also included in the group.

Some of the gaps identified by the survey are as follows:

- ❑ 48.2 per cent of respondents underscored the lack of a dedicated nutra department in the government
- ❑ 40.1 per cent raised concerns over the evolution of regulatory policy
- ❑ 38.6 per cent pointed out the dearth of clinical studies in the industry in India
- ❑ Over 50 per cent believe lack of consumer awareness is still the biggest hurdle to nutraceuticals in India
- ❑ 70.6 per cent highlighted the paucity of trained professionals in nutraceuticals

STEPS TO BOOST THE NUTRA SECTOR

- ❑ **Nutraceutical Task Force:** The government of India set up a 14-member Task Force in 2021 with a term of two years, under the chairmanship of Dr K Vijayaraghavan, principal scientific adviser (PSA) to the government of India. The task force's objectives are to identify challenges to the nutra sector and chalk out growth strategies, including policy initiatives. Sources reveal that talks are underway to modify the task force to enable participation from pharma leaders to incorporate their concerns while framing policies for the nutra sector.
- ❑ **PLI Scheme in nutraceuticals:** The government is planning to introduce a production-linked incentive (PLI) scheme for the nutra sector as well. The scheme will identify the top 10 products to catalyse growth in this sector. This scheme aims to stimulate investments, enable growth in domestic and international markets, and make India a major manufacturing hub for nutraceuticals.
- ❑ **Centres of Excellence:** The task force is also evaluating how to set up Centres of Excellence (CoE) at select locations to undertake advanced R&D and innovation in nutraceuticals. Reportedly, a consensus has been formed to create India's first nutraceutical incubation hub at IICT and CCMB.
- ❑ **FSS Regulations 2022:** Food Safety and Standards Authority of India (FSSAI) has drafted a new framework termed Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, and Food for Special Medical Purpose, Prebiotic and Probiotic Food) Regulations 2022. It claimed that the rationale is to remove ambiguities in the regulation of nutraceuticals, help companies to innovate and import a broader range of supplements. In November 2022, FSSAI notified that FSS Regulations 2022, as per provisions specified in its earlier directives of March 29, 2021, and May 5, 2022, is re-operationalised as of October 1, 2022. The regulation in its final form is still awaited.
- ❑ **DGFT brings nutraceuticals under SHEFEXIL:** The Director General of Foreign Trade (DGFT) recently released a notice informing that nutraceutical products will be included under the jurisdiction of the Shellac & Forest Products Export Promotion Council (SHEFEXIL) in the Appendix 2T of the Foreign Trade Policy (FTP) 2015-2020.
- ❑ **Nutrify Today Academy:** Nutrify Today is working with industry, academia and policymakers to help design and develop industry application courses for postgraduate students in pharmacy, nutraceuticals, food tech and chemical engineering. Currently, IIT Jammu, Montreux University Switzerland, and Centurion University are backing the certification courses. Nutrify Today also intends to take these courses, through government bodies, to other universities to fuel the national growth of trained nutraceutical professionals.

Emergence of RWD and RWE – Are they an alternative to RCTs?

Venkatesan Balu, Associate Director, Global Data Sciences, Navitas Life Sciences says that though hybrid clinical studies that utilise RWD have the potential to support regulatory decisions in the absence of RCT data, further work is needed to better understand the settings in which RWD analyses can accurately replicate the results of RCTs

Randomised clinical trials (RCTs) have long been considered the most reliable method of producing evidence on a medicine's safety and efficacy prior to its marketing authorisation. However, RCTs can be expensive, take time to conduct, and often focus on relatively homogenous patient populations with strict inclusion/exclusion criteria, limiting generalisability and not always providing answers about the drug in question.

Real-world data (RWD) consists of data relating to a patient's health status or the delivery of healthcare that are gathered from various sources, while real-world evidence (RWE) is clinical evidence about how a medicine is used and what benefits or risks it may have based on analysis of RWD.

Advent of digital technology

The proliferation of digital technology and the availability of electronic health data have allowed for RWD to play an important role in healthcare decision-making. Regulatory bodies often use pharmacoepidemiology methods and principles as the basis for using RWE in post-authorisation regulatory decision-making[1,2].

In addition to this, post-authorisation safety and effectiveness studies based on pharmacoepidemiology methods

and principles, are often considered the foundation of the use of RWE for post-authorisation regulatory decision-making by regulatory bodies around the globe. RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, and RWE is the clinical evidence about the usage and potential benefits, or risks of a medical product derived from analysis of RWD[3].

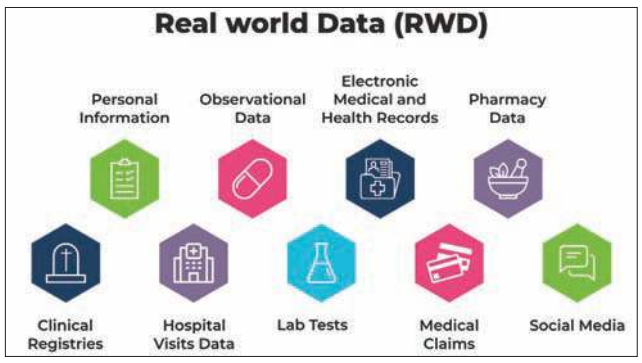
In recent years, there has been an effort to increase the use of RWD studies in regulatory decision-making. In particular, the US Food and Drug Administration (FDA) was mandated by the twenty-first Century Cures Act to provide guidance on when manufacturers can use RWD for approval purposes; meanwhile, investigators from the European Medicines Agency (EMA) also shared their views on this topic[4].

SOURCES OF RWD AND RWE

Source	Type of Data	Available medium
Clinical Trials	Data Generated out of Clinical studies	**Regulatory Agencies:** FDA, NIH, DCGI, etc., Pharma/Device companies **Data storage:** CTRI, clinical trials.gov, 3rd party storage
Hospitals/ Pharmacy	Prescription data, Sales data, Lab Tests, HER Data, Specimen/Tissue Pathology data	Pharmacies, Doctors prescription, Clinical Labs, Private Genetic Test Companies, Profession society of Clinical Registry etc.,
Patient Centred	Patient Reported/Centred Outcome, social media	Patients, Patients communities/Social Network, Patient powered networks
Claims	Medical Claims, Prescription Drug Claims	Insurance companies, CMS, FDA Sentinel, Claim Databases

LIST OF DOCUMENTS PUBLISHED BY REGULATORY AND OTHER ORGANISATIONS WITHIN EACH GEOGRAPHICAL REGION

Europe	Innovative Medicines Initiative (IMI) IMI Get Real project European Medical Information Framework (EMIF) European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
USA	FDA's RWE Framework Duke-Margolis RWE Collaborative Bipartisan Policy Center
Canada	Canadian Agency for Drugs and Technologies in Health



RWD – Implementation and strategy

RWD studies are unquestionably the trials of the future – the near future. As this dynamic field evolves, we use experience-based approaches to guide you through effectiveness, efficiency, and sustainability when it comes to using real-world data.

A new era of healthcare innovation may be possible by merging multiple sources of patient data to generate RWE. Evidence from "real world" practice and utilisation – outside of clinical trials – is seen to tailor healthcare decision-making. These insights are more closely associated with the characteristics of individual patients, and thus are a step towards making health care more personalised and effective. Robust RWE will not only tap increasing volumes of data, but weave together different sources of data, such as clinical data, genomic data, and socioeconomic data, to yield a better picture of individual patient characteristics and improve medicine's ability to treat individual patient needs.

Today, legislators and policymakers are actively engaging in dialogue on the value of real-world data. The FDA is developing specific guidelines for using RWE to support regulatory decision-making – a critical step to understanding real-world patient care and outcomes in the drug-approval process. The EMA has begun similar initiatives, and in the Asia-Pacific region, interest in leveraging real-world data in clinical research is dramatically on the rise.

Inclusion of RWD in hybrid clinical trials

The RWE program covers both clinical trials and observational studies, and the key to successful hybrid design lies in their study designs. For the assessment of the efficacy and safety of an experimental product, the presence of a comparator (control) group is critical to understanding what happens to patients with similar characteristics and who would be subject to the same conditions and procedures as in the experimental treatment group, but who do not receive the experimental treatment[5]. In RCTs, randomisation is conducted to allocate treatments to trial participants based on the presumption that all measured (observed risk factors) and unmeasured (unseen risk factors) co-founders would be equally distributed among the treatment arms in a study, satisfying the independent assumption of treatment assignment and ensuring that each participant has the same probability of receiving the experimental treatment or active control (or placebo)[5].

There are some clinical circumstances where randomisation is impossible to undertake—due to ethical concerns and a state of clinical equipoise that may not exist. Evaluated during the planning of a randomised study, clinical equipoise is the state of uncertainty about not knowing which treatment or intervention would work better for study participants[6]. These may include clinical settings with no available standard of care treatment or life-threatening diseases with limited treatment options. There may be circumstances where randomization is impractical or infeasible. For example, in disease settings with high unmet needs, a control arm may be perceived as a suboptimal treatment option by patients leading to challenges in the conduct of randomisation—due to the unwillingness of patients to enrol in or continue an RCT or due to the anticipated crossover of patients from the control arm to the experimental treatment arm during a study.

Barriers to utilising RWE in clinical trials

There are multiple factors that affect the sustainable use of real-world data, limiting access to the potential benefits.

◆ **The authenticity of data:** Most sources of RWD are not collected for research purposes. Many researchers become "data janitors," forced to "clean" gaps and inconsistencies in data through methods that may not yet have gained wide acceptance for statistical validity.

◆ **Cost:** While the cost of collecting and maintaining data may be an established cost of doing business for manufacturers (clinical trial and outcomes data) and payers (claims data), financial models for data maintained by other stakeholders (patient groups, professional societies, providers) are much less certain, particularly to the extent that they rely on government funding.

◆ **Patient data protection:** Repeated data breaches in the healthcare industry undermine patient confidence in data privacy. Meanwhile, there is no clear law or regulation on when and how often patients must give consent for the use of their data.

◆ **Disparate rules on stakeholders:** FDA-regulated entities, like pharmaceutical and medical device companies, are generally prohibited from making claims or commenting on uses of their products that are not part of FDA-approved labelling and not supported by evidence from RCTs. Other stakeholders with access to "Big Data," like insurers and providers, do not face similar restrictions. RWE from

disparate sources needs to be developed and evaluated in an open transparent manner by all stakeholders.

◆ **Navigating the regulatory framework:** RWD and RWE are largely applied during early discovery, post-market phase of safety surveillance, and for comparative effectiveness evaluation. Health authorities are moving in the right direction but must provide greater clarity on the acceptability of RWE in decision-making. There is a need for guidance on standards and best practices for methodology and analysis when integrating RWE for regulatory submissions.

The 21st Century Cures Act was passed in 2016 with the remit to accelerate the discovery, development, and delivery of 21st-century cures, and for other purposes. Subtitle C – Modern Trial Design and Evidence Development[1] contain a section describing the potential use of real-world evidence to help support approvals for new indications and support or satisfy post-approval study requirements. This act also laid the framework for FDA's Real-World Evidence Program. Additionally, international clinical research networks and agencies are key players in determining RWE's position in regulatory decisions. Current programs and frameworks can help provide support for harmonising the rules and guidance for RWE generation.

◆ **Statistical tools used to collect RWD:** RWE is not just "Big Data" – it's the integration of multiple sources of clinical data. Typically, RWD is not going to be structured in the same way as the static SAS datasets found in clinical trials. There are multiple types of data that may be available like very large datasets, streaming data, unstructured and unformatted data, or cloud-based systems for data collection and storage. Similarly, the needs for programming tools are different as well and require a set of skills pertaining to the Julia, Python and R programming languages, in addition to SAS and others that can handle big data. Meshing the domain expertise of clinical programmers and statisticians with the advanced data science capabilities of skilled data scientists may require a period of learning for all involved. By leveraging scripting languages, everyone involved can quickly gain the necessary knowledge and skills to create powerful, meaningful insights.

Moving ahead with RWD and RWE

The potential benefits of RWD and RWE in establishing external controls to support regulatory decision-making are plentiful. By utilising RWD and RWE, it is possible to provide evidence in circumstances where traditional RCTs are either unethical, impractical, or infeasible. Furthermore, RWD and RWE can be used to support evidence development for marketed medical products, increasing the efficiency of evidence development for regulatory purposes and expediting access to medical products to patients. Additionally, RWD and RWE can enable supplemental evidence

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Synthetic lipids: Paving the path for better drug delivery systems

Arun Kedia, MD, VAV Lipids informs that as seen in the new mRNA-based COVID-19 vaccine delivery systems, synthetic lipid nanoparticles are providing stability throughout the delivery process and helping generate a stronger immunogenic response

In a world where 'natural' and 'organic' have become synonymous with sustainability, labeling a product 'synthetic' seems antithetical. From a pharma perspective however, synthetic chemistry has been transformative for the healthcare of humanity. It has powered new drug discovery for years, preventing epidemics and saving lives.

Pharma breakthroughs today are coming from targeted drug delivery systems based on synthetic lipids. The technology is opening a wide medicinal platform with the potential to deliver a whole range of therapeutics, encompassing genes, RNAs, peptides and diagnostic imaging agents. It is offering hope for improving the therapeutic index, pharmacokinetics, and pharmacodynamics of several drugs.

How do synthetic lipids help with drug delivery?

Lipid-based drug delivery systems possess great potential to deliver drugs, biologics and nutrients through various administration routes due to their biocompatibility, slow-release rate, high stability, and low toxicity. Some of them like solid lipid carriers (SLC) and nanostructured lipid carriers (NLC) are among the most widely studied. These systems are based on phospholipids. Working with phospholipids extracted from natural sources is however, not easy. Due to the presence of a wide range of unsaturated fatty acids in natural phospholipids, they produce a variety of components in mixed ratios that could vary from batch to batch. The resulting differences in physical, chemical, and biological properties make it difficult to develop robust, reproducible, controlled release drug delivery systems.

Modern synthetic phospholipids can help overcome this hurdle.

They are easier to standardise, being single, well defined molecules. Under suitable conditions, they permit a controlled adjustment of physical, chemical, and biological properties especially where more physically stable liposomes with increased stability in blood plasma or phospholipids with more powder-like properties are desired. Since they lack antigenic properties, they can also be metabolised easily in the body. They are less toxic and have a higher degree of solubility, thus making them better candidates for liposomal-based drug delivery systems, especially for parenteral administration and inhalation dosage forms.

Synthetic phospholipids like Dioleoyl Phosphatidylcholine (DOPC), Dimyristoyl Phosphatidylcholine (DMPC), Distearoyl Phosphatidylcholine (DSPC) and Distearoyl Phosphatidylglycerol (DSPG) among others are usually preferred in lipid-based drug delivery systems.

Synthetic lipids can help build improved drug delivery systems

Progress in synthetic lipid nanoparticle-based delivery systems has led to the development of robust drug delivery systems. As seen in the new mRNA-based COVID-19 vaccine delivery systems, synthetic lipid nanoparticles are providing stability throughout the delivery process and helping generate a stronger immunogenic response. The mRNA strand is extremely fragile and susceptible to degradation but when this strand encoded with the key protein is encapsulated in synthetic lipid nanoparticles and used in the vaccine, it is delivered much more efficiently.

Nucleic acid drugs encapsulated in synthetic lipid nano particles (LNP) are being extensively researched for their potential to be used for replicon-based therapeutics in oncology, protein replacement therapy, and to aid gene-editing techniques. The use of ionizable lipids which is the critical component of the LNP helps in determining the potency of the LNP towards target sites and allows for enhanced penetration in the target tissues such as liver and solid tumours.

The use of synthetic cationic lipids like oxime ether lipids containing hydroxylated head groups is known to be superior siRNA delivery agents and offers hope in the treatment of breast cancer using small interfering RNA (siRNA) based gene silencing therapy. Due to their small size, they can easily penetrate the tumor and release the drug in the intracellular space. This target cell site delivery mechanism using LNPs helps in reducing side effects to the surrounding healthy tissues. As the optimum size ranges from 80 nm to 100 nm, these nanoparticles can tide through several bioavailability barriers that are encountered during the treatment phase.

Few of the cationic lipids used in delivery of solid lipid nanoparticles have no long term toxicity, biodegradation or biocompatibility data and induce proinflammatory response.

Why isn't everyone making synthetic lipids?

Synthetic phospholipids with different polar head groups, fatty acid compositions can be manufactured using various synthesis routes. By varying fatty acids incorporated in the phospholipid, differences in the liposome's physical properties can be studied but it involves complicated chemistry, complex characterisation as well as elaborate manufacturing techniques. However, the advantages of using synthetic phospholipids which have relatively high purity is that the delivery system is relatively more stable with predictable release pattern. It also allows targeting. A lot of research is being carried out and it is likely that online libraries will be available soon. This will help to advance the LNP targeting and delivery.

Research and government support will help fully unlock the potential of synthetic lipids

Modifications to liposomal drug delivery systems are constantly investigated to minimise toxicity, increase efficacy, and reduce rapid clearance from the bloodstream. Experimental studies focused on complex multi-functional liposomal formulations are in progress to develop more efficient drug delivery systems.

There currently exist bottlenecks in the clinical translation of synthetic lipid-based drug delivery systems owing to pharmaceutical manufacturing, government regulations, and IP. Quality assurance and costs remain a major challenge. This complex system can be affected by the scalability of the process, the reliability and reproducibility of the final product, stability of the product and lack of in-house expertise. IP of liposomal based drug delivery systems is quite a perplexing challenge and expensive. Clinical trials of liposomal formulations are more complex and time consuming than chemical formulations.

In India, the government has now introduced schemes and incentives for companies that manufacture synthetic lipid nanocarriers by allocating budgets for research and development activities of such manufacturers. State-funded research on the effectiveness of liposomal nanotechnology will go a long way in positively providing support to industry and academia as well. With proper support and awareness, there is no doubt that the pharma industry's use of synthetic lipids will grow rapidly in the next decade worldwide.

Emergence of RWD and RWE...

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development that is more relevant to patients, providers, payers, and policymakers. With the growing emphasis on the role of RWE in decision-making by regulatory agencies, a new optimism has been created to meet these goals and has provided an impetus for a new regulatory framework.

Accumulating evidence from RWD and advances in technology suggest that hybrid clinical studies that utilise RWD have the potential to support regulatory decisions in the absence of RCT data. Further work is needed to better understand the settings in which RWD analyses can accurately replicate the results of RCTs and the settings in which they cannot. Regulatory bodies must carefully consider potential sources of bias when determining if they will accept RWD in place of RCTs.

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INTERVIEW

Indian regulations have evolved positively to favourably support clinical research while balancing patient safety

Emmes, a global, full-service contract research organisation recently announced that it has rapidly expanded its capabilities in India and strengthened end-to-end services, including monitoring, data management, biostatistics, safety and study start-up, with a particular focus on capabilities to get studies up and running quickly and effectively. The CRO has also been involved in several NIH clinical trials globally and recently with many COVID vaccine trials in India. With its network of government connections in the US, a large base of scientists and 45 years of CRO experience, Emmes in India is looking to establish itself as a premier trial organisation. **Archana Sarda**, President, Emmes India in an interaction with ***Express Pharma*** shares her insights on the direction that the CRO industry is taking and how it is shaping the future clinical trials in the country

There is an increased interest now from innovators globally to carry out clinical trials in India - do you see this trend, and if yes, what might be the reason? What percentage of global trials is India's part currently?
During the pandemic, India accounted for an 8.3 per cent share of the global clinical trials.1 So yes, there is an increased interest from innovators in conducting trials in India. The strong regulatory framework, genetic diversity in the large patient population, disease burden, experienced site networks and access to digital technology facilitate the conduct of clinical trials in India. The Indian government has recently launched the largest universal healthcare program in the world, Ayushman Bharat. This will reform the way healthcare is delivered in India and will benefit the conduct of trials here as well.

Is the current regulatory environment in India considered stable enough to inspire this confidence from CROs and trial sponsors?
Yes, the current regulatory environment in India is very robust and comparable to the regulatory frameworks in the US and Europe. There have been numerous updates to the guidelines governing the conduct of clinical research in India. Indian regulations have evolved positively to favourably support clinical research in India while balancing patient safety. The current process for clinical trial application, requirements around consent, ethics committee and the standard of care have brought back confidence in trial sponsors and CROs. This will allow innovative medicines to come to Indian patients at the earliest.

What growth are you seeing in terms of demand for clinical services domestically in the next few years?
Sponsors are looking for CROs to work as partners and provide end-to-end clinical trial services with the highest compliance standards. The need for accelerated timelines in clinical trials will require CROs to provide deep domain expertise, access to robust site and patient networks, and digital technologies that are integrated into all their clinical trial services. There is also an increased demand to support decentralised clinical trials.

What are innovators in India looking for in a CRO?
Innovators are looking for a CRO who can partner with them through the entire life cycle of the clinical trial. They want a CRO with strong therapeutic expertise and an accessible network of clinical sites that can conduct the trial to the highest compliance standards. These capabilities will allow CROs to get their studies up and running quickly and effectively.

Emmes has been conducting and supporting clinical research for 45 years across a variety of therapeutic areas around the globe. We always look to drive better patient outcomes by bringing data, technology, and services together. Our deep domain expertise and patient-centric approach have been the key to our success.

For which therapeutic conditions are International clients interested in conducting trials in India?
Infectious diseases, oncology, respiratory, diabetes, cardiovascular and rare diseases are the most popular.

Infectious diseases and vaccine trials have been carried out in large numbers in India. Do you expect the demand to remain for

these conditions?
Yes, I do believe the demand will continue. COVID-19 has helped the world and India realise the urgent need to develop vaccines at an unprecedented rate and scale. The current disease burden from infectious pathogens is high in India. Government and policymakers in India are encouraging vaccine innovators to conduct trials in India. This will help improve access to vaccines and reduce the burden of life-threatening diseases. In addition, India's diversity in patient population helps embed diversity into the trials, making studies more accessible and inclusive.

Emmes has an especially strong pedigree in vaccines and has completed many trials globally, including in India, Bangladesh, and Africa, for tuberculosis, shigellosis, enterotoxigenic escherichia coli (ETEC), polio, human papillomavirus (HPV), yellow fever, respiratory syncytial virus (RSV), influenza, COVID-19 and typhoid.

> The need for accelerated timelines in clinical trials will require CROs to provide deep domain expertise, access to robust site and patient networks, and digital technologies that are integrated into all their clinical trial services

What have been some of the learnings from conducting COVID vaccine trials, globally and in India?
The COVID-19 pandemic has had a tremendous impact on companies globally and in India.

COVID-19 studies had an accelerated timeline that required us to innovate, use technology and launch the study within a week of the protocol receipt. Quick setup times, use of digital devices and digital healthcare care infrastructure to collect data, risk-based remote monitoring and innovative analysis techniques allowed us to meet these timelines and contribute to this global pandemic.

We've seen a rise in the request for decentralised clinical trials (DCTs). I'm sure that the industry and policymakers will collaborate to ensure a push forward in our approach to virtual trials. These innovations will help to reduce patient burden and bring treatments to market faster.

What is unique about Emmes' operations in India and how is Emmes different from other CROs?
Emmes' India operations are headquartered in Bengaluru with an additional office in Ahmedabad. Emmes' presence in India spans 16 years, and the India team has strengthened end-to-end services, including project management, monitoring, data management, biostatistics, safety, and study start-up, with a particular focus on capabilities to get studies up and running quickly and effectively. The team's commitment to quality, customer satisfaction, innovation, and the drive to make a public health impact is what sets us apart from other CROs in India.

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Leveraging CRM to revolutionise pharma industry

Sharda Kumari, Staff Systems Engineer at Airbnb outlines how CRM is a powerful technology that can be applied in various industries such as healthcare, pharma and pandemic management to improve the efficiency and effectiveness of operations, and to ensure that the needs and rights of all stakeholders are protected

The article discusses the role of Customer Relationship Management (CRM) in improving patient outcomes in the pharma industry. The use of CRM software enables healthcare providers to easily access patient data and track their progress, leading to more informed treatment plans and reducing the risk of adverse events. Pharma companies can also use CRM to better understand patient needs and preferences by analysing customer data, increase patient engagement and education through personalised information and support, and comply with privacy and security regulations. The article highlights the importance of adopting a strategic approach to CRM implementation, including defining goals and objectives, selecting the right CRM platform and tools, and investing in employee training and support. The future trends of CRM in the pharma industry include the integration of AI and machine learning and the increasing use of mobile technology to improve patient engagement.

The well-being and health outcomes of patients are paramount in the pharma industry. With the implementation of customer relationship management (CRM) technology, pharma companies are able to gain a deeper understanding of their customers and develop more effective engagement strategies. The use of CRM holds the potential to greatly enhance patient outcomes through enhanced communication, a better understanding of patient needs and preferences, and increased patient engagement and education. In recent years, the pharma industry has experienced rapid changes, and CRM technology has become crucial in enhancing patient outcomes and fostering better engagement between companies, patients, and healthcare providers. The future of CRM in the pharma sector is forecasted to be influenced by various trends and innovations, which will continue to shape the way companies interact with their patients.

> In order to fully realise the potential benefits of CRM in the pharma industry, companies must adopt a strategic approach to its implementation. This includes defining clear goals and objectives for the CRM initiative, selecting the right CRM platform and tools, and investing in training and support for employees

Impact of CRM on improving patient outcomes

One of the key ways in which CRM can improve patient outcomes is by facilitating communication between healthcare providers and patients. With the help of CRM software, healthcare providers can easily access patient data and track their progress over time. This allows providers to make more informed decisions about treatment plans and medication, reducing the risk of adverse events and improving overall health outcomes. For example, a provider can use the patient's medical history, medication history, and current symptoms to create a personalised treatment plan.

In addition to improving communication, CRM can also help pharma companies to better understand patient needs and preferences. By analysing customer data, companies can identify patterns and trends in patient behavior, which can be used to inform product development and marketing strategies. For example, if a large number of patients are expressing dissatisfaction with a particular medication, a pharma company can use this information to make changes to the product, such as reformulating the active ingredient or changing the dosage form. This can help to improve patient satisfaction and increase the likelihood that patients will continue to use the medication as prescribed.

Furthermore, CRM can also help to increase patient engagement and education. By providing patients with personalised information about their medications and treatments, companies can help to increase patient understanding and adherence. This can help to improve health outcomes and reduce the risk of adverse events, as patients are more likely to follow their treatment plans when they have a clear understanding of why a particular medication is necessary. In addition, by using CRM to track patient interactions, pharma companies can identify opportunities to provide additional support and resources, such as educational materials or patient support programs.

For example, a pharma company can use CRM to provide patients with reminders about their medication schedules, as well as information about potential side effects and how to manage them. The company can also use CRM to communicate with patients about the benefits of their medications and to encourage them to ask questions and share concerns. By improving patient engagement and education, pharma companies can help to increase patient satisfaction and improve health outcomes.

Effective implementation of CRM in the pharma industry: A strategic approach

In order to fully realise the potential benefits of CRM in the pharma industry, companies must adopt a strategic approach to its implementation. This includes defining clear goals and objectives for the CRM initiative, selecting the right CRM platform and tools, and investing in training and support for employees.

One of the first steps in implementing a CRM strategy is to identify the specific goals and objectives for the initiative. This may include improving patient engagement and education, increasing patient adherence to treatment plans, streamlining communication between healthcare providers and patients, and reducing the risk of adverse events. Once these goals have been established, companies can then identify the specific CRM tools and functionalities needed to support these objectives.

Another important factor in the implementation of CRM in the pharma industry is the selection of the right CRM

platform and tools. Companies must consider their specific needs, budget constraints, and existing technology infrastructure when making this decision. In many cases, it may be necessary to work with a CRM vendor or consultant to select the right platform and tools. This may involve conducting a thorough review of the vendor's technology, security measures, and support and training offerings.

In addition to selecting the right CRM platform, companies must also invest in training and support for employees. This is critical to ensuring the successful adoption of CRM within the organisation. Employees must be trained on the specific CRM tools and functionalities, as well as the best practices for using these tools to engage with patients. Companies can provide this training through a combination of in-person workshops, online resources, and ongoing support from CRM experts.

Overcoming challenges of implementing CRM in pharma

The use of CRM in the pharma industry is not without its challenges, however. One of the main challenges is ensuring the privacy and security of patient data. Pharma companies must comply with strict regulations, such as the Health Insurance Portability and Accountability Act (HIPAA), to protect patient information. In addition, companies must ensure that the CRM systems they use are secure and that only authorised personnel have access to patient data.

> The use of Big Data is also expected to play a significant role in the future of CRM in the pharma industry. Companies will be able to analyse large amounts of patient data to identify trends and patterns, which can then be used to improve patient engagement and outcomes

Another challenge is ensuring the accuracy and reliability of patient data. Pharma companies must ensure that the data entered into the CRM system is complete and accurate, as this information will be used to make important decisions about patient treatment and care. To address this challenge, companies can use data validation procedures, such as verifying the accuracy of data entered into the system, and implementing internal controls to ensure the reliability of data.

Despite these challenges, the utilisation of CRM in the pharma industry has the potential to greatly improve patient outcomes and enhance the overall success of the industry. By leveraging the power of CRM, pharma companies can create more effective strategies for engaging with their customers, resulting in better health outcomes and improved patient satisfaction. As the healthcare industry continues to evolve, it is likely that the use of CRM will become even more widespread, furthering its impact on patient outcomes and the overall success of the pharma industry.

Impact of AI, mobile technology and Big Data on the future

One of the most significant trends in the future of CRM in the pharma industry is the integration of artificial intelligence (AI) and machine learning. These technologies have the potential to revolutionise the way that companies engage with patients and healthcare providers by providing more personalised and relevant information. For example, AI can be used to analyse large amounts of patient data, including electronic health records, to identify patients at risk of adverse events, and provide targeted interventions to prevent them. AI can also be used to analyse patient data to develop targeted marketing campaigns, which can be more effective in engaging patients and improving outcomes.

Another trend in the future of CRM in the pharma industry is the increasing use of mobile technology. Mobile devices, such as smartphones and tablets, have become an essential part of the healthcare landscape, and pharma companies are starting to leverage these technologies to improve patient engagement. For example, companies can use mobile apps to provide patients with information about their treatments, track their progress, and communicate with their healthcare providers. These apps can also provide patients with reminders to take their medications and provide real-time feedback on their treatment plans.

The use of Big Data is also expected to play a significant role in the future of CRM in the pharma industry. Companies will be able to analyse large amounts of patient data to identify trends and patterns, which can then be used to improve patient engagement and outcomes.

For example, companies can use Big Data to analyse patient behaviors and preferences to develop targeted marketing campaigns and improve patient engagement. Big Data can also be used to identify patients who are at risk of adverse events, and provide targeted interventions to prevent them.

Conclusion

Finally, the future of CRM in the pharma industry will be shaped by the increasing emphasis on patient-centric care. Pharma companies are expected to focus on engaging patients and improving their experiences with their treatments. This will require companies to focus on developing patient-friendly technologies and tools, as well as providing patients with personalised information and support. The goal of these efforts is to improve patient outcomes and promote better engagement between companies, patients, and healthcare providers.

In conclusion, the future of CRM in the pharma industry is expected to be shaped by several trends and innovations, including the integration of AI and machine learning, the increasing use of mobile technology, the use of Big Data, and the emphasis on patient-centric care. These developments will continue to impact the way that companies engage with their patients and healthcare providers, and have the potential to improve patient outcomes and promote better engagement. Companies that are able to leverage these trends and innovations will be well-positioned to succeed in the future of the pharma industry.

Decentralised clinical trials software in 2023: What to expect

Rajesh Pothula, Product Marketing Manager, Clinion informs that decentralised clinical trials software market will witness trends like increased adoption of AI and ML, greater emphasis on patient-centred design, integration with wearable devices and IoT sensors

Lifescience technology is advancing at an unprecedented pace, and the clinical trials industry is no exception. The past few years have seen a steady rise in the adoption of decentralised clinical trials (DCTs) as an alternative to traditional clinical trials, and this trend is expected to continue in 2023 and beyond.

Decentralised clinical trials have gained popularity due to their ability to improve patient access, reduce costs, and accelerate study timelines. DCTs leverage digital technologies to enable patients to participate in clinical trials from the comfort of their own homes or nearby medical facilities, instead of having to travel to a centralised trial site. This has been particularly important during the COVID-19 pandemic, as traditional clinical trials were significantly impacted by lockdowns and social distancing measures.

However, as the adoption of DCTs increases, so do the challenges associated with implementing and managing them. One of the key challenges is the need for specialised software that can facilitate the remote collection, management, and analysis of clinical trial data.

In this article, we will explore the current state of decentralised clinical trial software and what we can expect to see in 2023.

Using AI and ML in clinical trials has the potential to significantly improve the efficiency and accuracy of clinical trials by automating tasks such as data cleaning and analysis, identifying patient cohorts, and predicting trial outcomes. We can expect to see more DCT software vendors incorporating AI and ML capabilities into their platforms in 2023

The current state of decentralised clinical trials software

The software landscape for decentralised clinical trials is still relatively new and fragmented, with a variety of different vendors and platforms available.

These platforms typically offer a range of features, such as patient recruitment and retention tools, remote data capture, telemedicine capabilities, and data analytics. Some platforms also integrate with electronic health records (EHRs) and other systems to streamline data exchange and improve interoperability.

However, there are still some challenges associated with the adoption of DCT software, including regulatory compliance, data security and privacy, and patient engagement and retention.

In 2023, we can expect to see continued growth in the DCT software market, with new entrants and innovations in the space. Here are some of the trends we expect to see:

◆ **Increased adoption of artificial intelligence (AI) and machine learning (ML):** Using AI and ML in clinical trials has the potential to significantly improve the efficiency and accuracy of clinical trials by automating tasks such as data cleaning and analysis, identifying patient cohorts, and predicting trial outcomes. We can expect to see more DCT software vendors incorporating AI and ML capabilities into their platforms in 2023.

◆ **Greater emphasis on patient-centred design:** Patient engagement and retention are critical factors in the success of DCTs, and software vendors are starting to recognise the importance of patient-centred design. In 2023, we can expect to see more DCT software platforms that prioritise patient experience and usability, with features such as patient portals, mobile apps, and real-time feedback mechanisms.

◆ **Integration with wearable devices and internet of things (IoT) sensors:** Wearable devices and IoT sensors have the potential to transform clinical trials by enabling remote monitoring of patient health and activity data. In 2023, we can expect to see more DCT software platforms that integrate with these devices and sensors to enable real-time data capture and analysis.

◆ **Improved interoperability and data sharing:** Interoperability and data sharing are critical components of DCTs, and we can expect to see more software vendors focusing on these areas in 2023. This may include the development of standardised data models and APIs, as well as partnerships with EHR and other systems to improve data exchange and reduce duplication.

Decentralised clinical trials are becoming increasingly important in the development of new drugs and medical treatments. These trials offer several advantages over traditional clinical trials, including increased flexibility, reduced costs, and improved patient access and engagement.

In recent years, the use of AI has emerged as a powerful tool for optimising decentralised clinical trials. AI algorithms can help improve patient recruitment and selection, automate remote monitoring and data collection, and build predictive models that can optimise trial design and dosing regimens.

Through the looking glass: Why innovative refractory solutions will be key to growing demand for pharma glass packaging

KS Kumar, Regional Sales Director Asia, SEFPRO, Saint-Gobain India, and **Patrice Fournier**, Market Manager, SEFPRO point out that glassmakers must explore new ways of making glass with low-carbon production processes such as adopting innovative refractory solutions to remain a relevant packaging option in a carbon-neutral world

KS Kumar, Regional Sales Director Asia, SEFPRO, Saint-Gobain India

Patrice Fournier, Market Manager, SEFPRO

To say the pharma glass packaging industry has experienced significant growth over the last few years would be an understatement. Thanks to properties such as superior durability and resistance to contamination, more and more drug manufacturers are packaging their products in glass bottles, containers, ampoules, pre-fillable syringes, tubes, and vials. This demand has buoyed the global pharma glass packaging market, which is estimated to have crossed $17 billion in 2021 and is projected to grow at a CAGR of 9.2 per cent until the end of the decade.

However, with the surging demand for glass for pharma-specific applications, glassmakers are facing a new challenge. Intensive energy use and related environmental concerns are some of the critical issues that the sector needs to address and overcome. With pressure building on pharma manufacturers to become more sustainable in light of the IPCC's Sixth Assessment Report, glassmakers catering to the industry are now wondering how they can fulfil the growing demand while reducing emissions.

The answer to this industry-defining question might lie in adopting innovative refractory solutions.

Handling the heat: How innovative refractory solutions will shape the industry's future

The glass business is undergoing a radical shift with a strong emphasis on environmental protection, just like many other sectors. More than ever, the focus is on furnace efficiency and the resulting CO2 and NOx emissions. Refractories and refractory solutions can complement these changes with cutting-edge technology and innovation. This is where advanced refractory solutions can play a significant role to help shape the future of the sector.

New melting technologies are driving the need for innovative solutions, co-designed by glassmakers and refractory experts. SEFPRO, a leading refractory supplier to the glass sector, is a pioneer in the production of fused cast and sintered refractories as well as associated service offerings. The company is one of the biggest manufacturers of refractories for glass-melting furnaces and the only one with a global footprint, with eleven manufacturing facilities across the world including two in India. Innovation is supported by four R&D centres in India, China, France and the US.

Carbon neutrality reduction should go beyond unrealistic claims. There is a stringent need to reduce the impact of manufacturing operations by decreasing energy consumption and switching to renewable power sources. Glassmakers should optimise regeneration to taper the fuel used in producing the same quantity of glass. Solutions like increased electrical boosting, and hydrogen firing can also effectively be utilised in furnaces with more sustainable melting technologies.

Identifying opportunities to foster sustainability in the refractories industry

The sustainability expectations of pharma companies for their packaging suppliers are growing as consumers are becoming more sensitive to these issues. The pharma packaging industry must improve its environmental impact and glass is a key material for its future. Endlessly recyclable, glass contributes to companies' circularity objectives. However, the glassmaking process is highly energy intensive and leads to high CO2 emissions. Glassmakers must investigate new ways of making glass with low-carbon production processes to remain a relevant packaging option in a carbon-neutral world. India has set itself a target to achieve net zero by 2070.

The use of state-of-the-art refractory materials helps glassmakers ensure uniformity in their products and avoid defects. Due to this, they are able to meet the demanding quality criteria, such as decarbonising the glassmaking process to manufacture glass suitable for the pharmaceutical industry. SEFPRO's latest innovation, XiROC, is designed to enhance pharmaceutical glass quality that lowers #zirconia solubility into the glass, XiROC improves upward drilling corrosion resistance and increases throat lifetime.

Refractory solutions are going to play important role in the future in the ever-evolving field of glass manufacturing. The demand for pharma glass packaging will only increase in the coming years, which is why glassmakers must adopt innovative refractory solutions to ensure their future readiness. In the coming years, these innovative solutions will only witness a growth in demand as this is one of the most effective and sustainable options in the pharma glass packaging space.

AI for better energy management in pharma

Rohit Kochar, Founder, Executive Chairman & CEO, Bert Labs details how AI can help energy-system stakeholders identify patterns and insights in data, learn from experience and improve system performance over time, and predict and model possible outcomes of complex, multivariate situations

Energy-intensive sectors like pharma are at the beginning of historic decarbonisation processes, driven by growing government and consumer demand for rapid reductions in CO2 emissions. The scale of these transitions is huge, Bloomberg NEF estimates that in the energy sector alone, achieving net-zero emissions will require between $92 trillion and $173 trillion of infrastructure investments by 2050.

The energy system is already in transition, but the scale and cost of decarbonising the global energy system remain gigantic. The new IPCC report says, more action is urgently needed to avert catastrophic long-term climate impacts. With fossil fuels still supplying more than 80 per cent of global energy, the energy sector needs to be at the heart of this action.

Navigating these trends presents huge strategic and operational challenges to the energy system and energy-intensive industries. This is where AI comes in: by creating an intelligent coordination layer across the generation, transmission and use of energy, AI can help energy-system stakeholders identify patterns and insights in data, learn from experience and improve system performance over time, and predict and model possible outcomes of complex, multivariate situations.

Considering, single-batch values for some drugs can exceed $3 million, it shouldn't be too surprising that the pharma industry can greatly benefit from AI. Yet, research indicates that this industry lags when comes to using analytics to improve production. Pharma companies are under pressure to use data to improve the time to market for their products and the executives confess their organisations have a poor digital flavour.

AI has innumerable prospects when it comes to the pharma industry and business transformation. AI-powered analytics has given the much-needed direction to Big Data and brought a profound shift in the innovation paradigm in the pharma sector. By leveraging and executing AI techniques in the core workflows, pharma companies can make all business operations efficient, cost-effective, and hassle-free

Asset management, predictive maintenance, and analytics are the areas of AI application focused on by pharma companies including asset performance management tools using advanced analytics to create manufacturing efficiencies and predictive maintenance systems to analyse failure patterns and provide anomaly alerts and advance warnings of pending equipment failures.

We are in the middle of a revolution - A digital transformation in the pharma world. The pharma sector in India is expected to grow at a Compound Annual Growth Rate (CAGR) of 12 per cent from $41.7 billion in 2020 to $130 billion by 2030.

In June 2021, Finance Minister Nirmala Sitharaman announced an additional outlay of Rs 197,000 crores ($26,578.3 million) that will be utilised over five years for the pharma PLI scheme in 13 key sectors such as active pharma ingredients, drug intermediaries and key starting materials. The FDI inflows in the Indian drugs and pharma sector reached $19.90 billion between April 2000-June 2022.

Pharma companies need to implement AI in the manufacturing process for improved efficiency, higher productivity, and more importantly faster production of life-saving drugs. AI can control, manage and improve all aspects of the manufacturing process, such as:

- ◆ Quality control
- ◆ Predictive maintenance
- ◆ Waste reduction
- ◆ Design and process optimisation
- ◆ Process automation
- ◆ Drug discovery and development

It is the booster technology to time-consuming conventional manufacturing techniques, assisting pharma companies to launch medicines in the market more rapidly and at competitive rates. And hence will also help in increasing the ROI, limiting human intervention, maintaining hygiene, in the process, and thereby eliminating human error.

AI has innumerable prospects when it comes to the pharma industry and business transformation. AI-powered analytics has given the much-needed direction to Big Data and brought a profound shift in the innovation paradigm in the pharma sector. By leveraging and executing AI techniques in the core workflows, pharma companies can make all business operations efficient, cost-effective, and hassle-free.

AI systems are a powerful tool in research and development to deliver better outcomes for drug discovery. Machine learning (ML) and deep learning (DL) process and evaluate massive amounts of data quickly. AI can help with this by analysing large amounts of biological and chemical data to identify promising targets for drug development, it also helps in the design of new drugs. By using machine learning algorithms to analyse the structure and properties of existing drugs, researchers can generate new drug candidates that are optimised for a specific target.

AI is also being used to improve the efficiency of the drug development process. For example, machine learning algorithms can be used to predict how a drug will interact with the body, which can help to identify potential side effects before the drug enters clinical trials.

Workflow of AI in pharma API and formulation clean room facility

If we take, for instance, a Pharma ISO 8 or Grade D clean room of HVAC and utility system at a pharma (API and formulation) manufacturing unit, let us check how an AI system will function for maximum benefit.

After collecting the design and operational data from the manufacturing unit, a digital replica of the HVAC and utility system is built using a hybrid model that is, physics-based 1D modelling using heat flow and mass flow rates as an approach, along with the data-based deep neural network modelling from the actual plant operational data. Once the digital replica of the HVAC and utility system of a pharma clean room is built, the design of experiment (DoE) is carried out with varied control parameters. Using Digital Twin, we can even generate those conditions which the actual plant many have not faced. The output of the DoE will produce a reduced order model (ROM), that contains the state space variables of the HVAC and utility system of the pharma clean room digital twin.

AI-based algorithms like reinforcement learning agent or RL agent, which is essentially powerful neural network-based algorithm and becomes expert in the domain by training is trained on the RoM and the plant's real-time operational data. The RL agent shall take random action on control variables and look at the observation or state space. If the action creates a positive impact on the rewards like chiller power consumption and chilled water demand, steam/hot water demand or energy (electricity) consumption of fan/blower, then it gets rewarded or else penalised. Thus, the RL agent shall continue taking action and keep getting rewarded or penalised and it shall try to maximise the rewards. This shall be done for a million plus episodes and an RL policy shall be created, that has the best combination of parameters which brings in the maximum savings for each state. The RL agent can be scaled up and deployed to other process sections rapidly as only the state space and action space shall change while the agent remains the same.

The result is savings on energy consumption thereby savings in electricity and fuel (also) coal consumption.

This will be connected to the blending room, with control parameters like AHU fan speed, chilled water valve, hot water valve and AHU On/Off/Sleep mode, which are combined with observation parameters like air flow rate, temperature, RH%, DP and other.

Deployment of RL agent at plant thus brings in the energy savings. In this case, reducing the mass flow rates of the chiller pump and boiler pumps has resulted in energy savings on the chiller pump by about 66 per cent and about 100 per cent on the boiler pump.

In a similar way, RL agents have been created for other pharma clean rooms AHUs, viz., sifting, blending, granulation, tablet compression and tablet coating. The resulting energy savings on the chiller, boiler, chiller pump and boiler pump. For the pharma clean room AHU and utility system, the energy savings we get in the range of 15 per cent to 60 per cent.

AI is already proving its value to the energy transition in multiple domains, driving measurable improvements in renewable energy forecasting, grid operations and optimisation, coordination of distributed energy assets and demand-side management, and materials innovation and discovery. But while AI's application in the energy sector has proven promising so far, innovation and adoption remain limited. That presents a tremendous opportunity to accelerate the transition towards the zero-emission, highly efficient and interconnected energy system we need tomorrow.

With innumerable benefits like these, pharma companies simply need to start transforming into digital businesses to be competitive in the future. To align with this growth, pharma executives require ways to improve efficiency, uncover new business opportunities, and build better relationships with patients and prescribers. It will not be possible without a digital transformation. Hence, in my opinion, the sooner a digital transformation is adopted, the better it will be. The chances of catering to the future generations who will be used to everything being digital will also become better.

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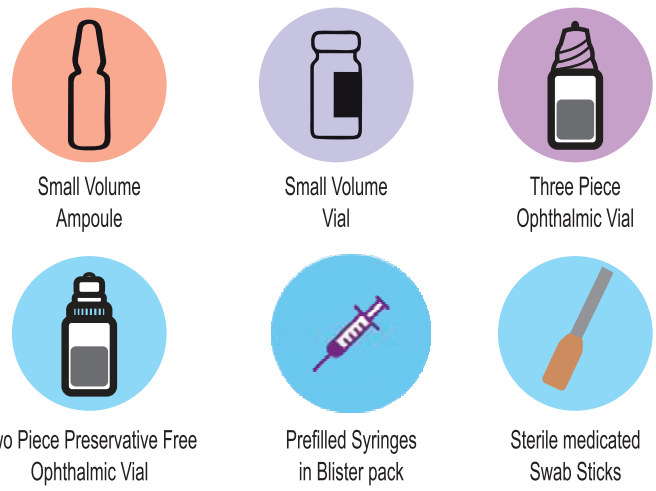

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L.B. Bohle: The full-system-supplier for your OSD production

L.B. Bohle, with its high level of process expertise and extensive product range, is the perfect partner for the productive, efficient, and high-quality production of solids

Tablets are the most used pharmaceutical form worldwide, accounting for nearly 50 per cent of all dosage forms. A key advantage of tablets is that a very large number of active ingredients can be tableted. Some active ingredients are processed by direct compression. However, most tablets are produced by a wet or dry granulation process. In addition to the raw material, other excipients are usually required during production.

L.B. Bohle (Ennigerloh, Germany), with its high level of process expertise and extensive product range, is the perfect partner for the productive, efficient, and high-quality production of solids.

Since its foundation in 1981, the technology company stands for quality, durability, and innovation.

With an export share of approximately 80 per cent, Bohle is internationally active and recognised as an established brand!

Focusing on the entire process

L.B. Bohle offers one of the world's largest product ranges to produce pharmaceutical solids. With machines and processes for weighing, wet and dry granulation, milling and sieving, blending, tablet coating, tablet checking and product handling, Bohle optimises production worldwide.

The core competence of the German company lies primarily in process technology. In the field of granulation, Bohle offers components and system solutions for wet and dry granulation.

Fluid bed granulation with tangential spray

L.B. Bohle developed the BFS fluid bed system with tangentially mounted spray nozzles and the patented Bohle Uni Cone BUC®, a specially slotted air distribution plate with a conical displacement cone, for batches of 1 - 500 kg. Granulation, coating and drying can be performed in one line without any modifications. The BFS is pressure shock resistant up to 12 bar, making it suitable for organic processes. Short product transfer times and effective cleaning provide additional savings in production time and costs. Scale-up is simplified by the geometrically similar design.

Dust-free suction and discharge of the product bowl is achieved by a multi-purpose valve. This provides ergonomic and cleaning advantages over alternative systems.

High shear granulation

The GMA is a granulation system optimised for pharmaceutical applications. The agitator blade with high shear and compaction effect guarantees effective granulation. Dense granules are formed. The chopper prevents excessive pellet growth and distributes the granulation fluid throughout the product.

L.B. Bohle's high shear granulation range includes laboratory and production scale systems.

Compact granulation module

The granulation module is the effective solution for optimising classical wet granulation and drying in an economical and ergonomic way. The individual components - high shear granulator, fluid bed dryer, wet screen, cyclone separator and drying screen - are optimally combined to form a single unit. Process, cleaning, control, explosion protection, zone concept and qualification are perfectly matched.

The benefits briefly:

- ◆ High-shear granulator and fluid bed dryer installed side by side in the wall; operation from a single control system
- ◆ Small footprint and minimal installation height
- ◆ Versatile use for different processes
- ◆ WIP cleaning ensures fast

cleaning cycles

Single pot granulation

Single-pot granulation has been used in the pharmaceutical industry for decades. The process steps of mixing, high-shear wet granulation and drying are performed in a single bowl.

The VMA series can handle batch sizes from 20 to 960 liters and can be installed in hazardous areas.

Dry granulation BRC

L.B. Bohle meets the increasing market demand for continuous processes with the BRC, an innovative dry granulator with gap control. The BRC enables high production capacity with minimal material loss.

This is achieved by fast and precise force control of the compacting rolls with a fully electro-mechanical roll drive. The BRC's innovative gap control produces uniform compaction of the material over a wide production range from <1 kg/h up to 400 kg/h.

Container blending

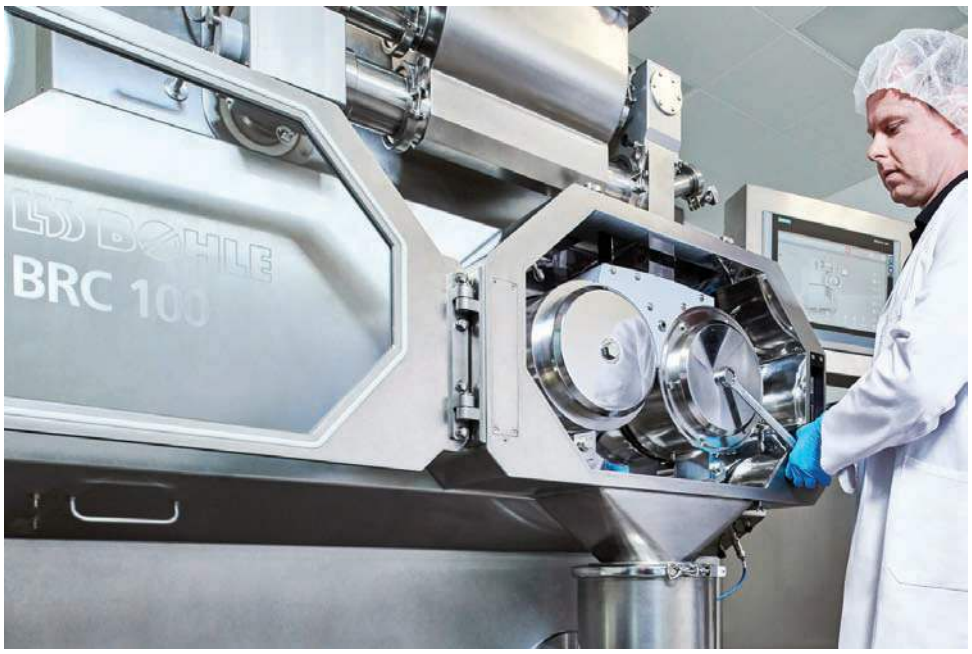
L.B. Bohle is a world leader in container blending. With mixing elements on the inside of the container lid, the blenders ensure a very homogeneous mixing of dry powder batches. The mixing process is scalable from four to 12,000 liters. Mixing containers with different capacities are available for optimum flexibility. Both round and square containers can be accommodated. The mixers are conveniently operated by a PLC of the latest generation.

Tablet coating

When it comes to fast, trouble-free, and efficient tablet coating, Bohle auto coaters have been setting the standard worldwide.

The interaction of mixing, spraying, and drying is elementary in tablet coating. All three processes must be performed simultaneously with the correct settings to achieve optimum coating uniformity.

Bohle coaters guarantee shortest process times, ensure best production results, and offer the best combination on the market.



The BFC auto coater is the high-end version of all tablet coaters and impresses with its high efficiency, optimum performance and lowest spray losses. With the BFC, process time can be reduced by approximately 30 percent while maintaining the best coating uniformity. The integrated high-pressure cleaning system guarantees cleaning-in-place (CIP) with first-class results. The coater can handle batch sizes from 50 to 980 liters.

The BTC coater stands for economic tablet coating. The main advantages of the BTC are its space-saving design and integrated control cabinet. With the BTC, Bohle offers a cost-saving system for more efficient and longer running processes in pharmaceutical production.

L.B. Bohle also has the optimal solution for research and development. The BFC 5 laboratory coater is designed as a stand-alone unit. The entire air technology as well as the electrical and control technology are integrated in the unit. Commissioning is quick and easy as only an electrical connection and a compressed air supply are required. The BFC 5 can handle batch sizes from 2 to 13 liters.

Containment - no problem!

For many years, L.B. Bohle has been known as a supplier of complete solutions. L.B. Bohle offers premium technology not only for standard machines, but especially for complex containment applications with a high degree of individuality - for handling systems and process machines for OEB classes 1-5.

Continuous manufacturing

In the field of continuous manufacturing, L.B. Bohle offers not only the QbCon® production system, but also stand-alone systems for twin-screw granulation, dry granulation, drying and tablet coating. The modular QbCon® production line realizes the continuous production of pharmaceutical solids from powder to coated tablets via direct compression, dry or wet granulation.

Continuous production for development

With QbCon® 1 Bohle offers the optimal entry into continuous production. The truly continuous wet granulator and dryer for R&D guarantees improved product quality while increasing flexibility and operator safety. It also reduces costs by using fewer resources and shortens development cycles using PAT. Unlike competing systems, QbCon® 1 enables a permanent, truly continuous process without the formation of sub-batches and blocked filters.

L.B. Bohle in India

L.B. Bohle has been active in India with its own subsidiary since 2009. Starting in Goa, the company moved via Mumbai and Ahmedabad to Hyderabad.

In Hyderabad, L.B. Bohle operates the Innovation Center together with Korsch AG (tablet presses).

The Innovation Center in Hyderabad offers a wide range of equipment and services, including product formulation and optimization, training, tablet production trials and factory acceptance testing.

The following equipment is available for trials and process optimization:

- PM 600 Container Blender
- LM 40 Laboratory Blender
- BTS 200 conical sieve with the option of a centrifugal sieve for breaking and sieving metformin lumps
- In addition, a **BFC5 Ex laboratory auto coater** for performing tablet coating operations for difficult formulations such as delayed release, sustained release and API coating will be available for testing and trials starting in April.

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PROSOLV® SMCC *HD 90* – A high-functional excipient from JRS Pharma

PROSOLV® SMCC HD 90 is a highly versatile pharma excipient that offers several benefits such as excellent flow, better compressibility and compatibility with a wide range of APIs, making it an ideal choice for solid oral formulations

In pharmaceuticals, the need for higher functionality excipients increased as APIs and manufacturing processes evolved. Over 25 years ago, JRS pharma developed a new high-functionality excipient PROSOLV® SMCC by co-processing of microcrystalline cellulose (MCC) and Colloidal silicon dioxide (CSD). This co-processing leads to homogenous distribution of CSD particles throughout the product and on the particle surface(s).

The components of PROSOLV® SMCC, MCC and CSD are in the ratio of 98:2 respectively. MCC is a highly purified form of cellulose that is derived from natural source such as purified wood pulp. CSD is originated from mineral source. Both the excipients maintain their chemical identities while synergistically providing increased physical and functional performances due to significantly increased surface area.

PROSOLV® SMCC provides solutions to the problems often encountered by formulation scientists while using conventional diluents like low bulk density (BD), poor flow, loss of compactability, sticking and sensitivity to lubricant(s). This article will focus on the physico-chemical properties, applications and advantages of PROSOLV® SMCC HD 90.

This grade offers several benefits to formulation development scientist(s) during development and production at a later stage. These benefits along with a few case studies will be elaborated in the next section of this article.

PROSOLV® SMCC HD 90 IS THE HIGH-DENSITY GRADE FROM THE PROSOLV® FAMILY OF EXCIPIENTS HAVING THE BELOW CHARACTERISTICS	
Particle size (d50)	Around 125 µm
Bulk density	Around 0.45 g/cc
Angle of Repose	Around 27

PROSOLV® SMCC IS AVAILABLE IN FOLLOWING GRADES	
Grade	**Functionality**
PROSOLV® SMCC 50 LD	Best in class binder (improves tabletability)
PROSOLV® SMCC 50	Formulas in which optimal compaction and decent flow are required
PROSOLV® SMCC 90	Formulas in which a balance of flow and compaction are required
PROSOLV® SMCC HD 90	Formulas in which optimal flow and consolidation are required
PROSOLV® SMCC 90 LM	Equivalent to PROSOLV® SMCC 90, with lower moisture content
PROSOLV® SMCC HD 90 LM	Equivalent to PROSOLV® SMCC HD 90, with lower moisture content

◆ **Excellent flow properties:** Because of coarse particle size, higher BD and reduced cohesiveness due to silicification, PROSOLV® SMCC HD 90 has improved surface characteristics, which imparts high intrinsic flow, as indicated by the angle of repose of around 27°. This helps to improve the flow of the blend significantly, providing uniformity in dosage weights, resulting in excellent CU along with higher production output.

◆ **Excellent compressibility:** PROSOLV® SMCC HD 90 is 30 – 50 % more compactible than similar MCC grade. Therefore, the tablets made with PROSOLV® SMCC HD 90 will have higher hardness as compared to those made of MCC, when the same compression force is applied.

◆ **Cushioning effect to MUPS in tablets:** Due to the excellent compressibility of PROSOLV® SMCC HD 90, the same tablet hardness achieved with MCC can be achieved with significantly less compaction force with PROSOLV® SMCC HD 90. This provides cushioning to pellets during compression and reduces/prevents breakage of functional coating. PROSOLV® SMCC HD 90 can be used alone or in combination with other PROSOLV® SMCC grade(s) depending on pellets size and concentration in the final blend.

◆ **Better suited to pressure-sensitive APIs, enzymes and probiotics:** Mechanically robust tablets with lower friability produced at comparatively lower compaction and ejection forces when formulated with PROSOLV® SMCC HD 90. This helps to get a better hardness for tablets with APIs exhibiting sensitivity towards hardness with respect to disintegration, dissolution and chemical stability. Similarly, viable cell counts were maintained for probiotic tablets. There is no significant reduction in enzyme activity when Enzyme tablets are compressed with PROSOLV® SMCC HD 90.

◆ **Better disintegration:**

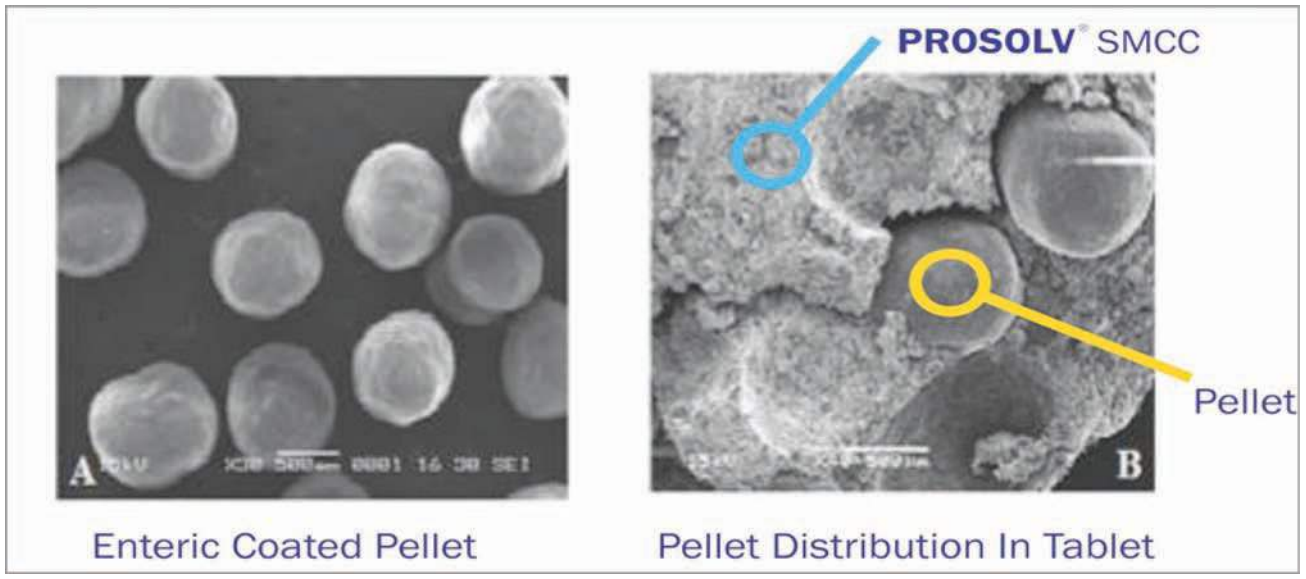

Image 1.0: Cushioning effect of PROSOLV® SMCC HD 90 to MUPS in tablets

PROSOLV® SMCC HD 90 imparts higher hardness to tablets at a relatively lower compaction force. Tablets compressed at lower compaction force exhibits higher porosity. This porous structure in combination with silicification leads to rapid water ingress which enables faster disintegration and more complete drug release. This is more relevant in the formulation of dispersible / oro-dispersible tablets where PROSOLV® SMCC HD 90 helps to balance between tablet hardness, disintegration time and friability.

◆ **Chemically inert:** PROSOLV® SMCC HD 90 consists of 98 per cent MCC and 2 per cent CSD. Individual entities (MCC and CSD) of this material are well known and two of the most extensively used in pharmaceutical dosage forms. This is important because some excipients may interact with certain APIs, leading to changes in the effectiveness or stability of the drug. PROSOLV® SMCC HD 90 has been widely formulated with a variety of APIs and has been shown to be highly compatible, making it a safe and reliable choice for pharmaceutical manufacturers.

◆ **Smaller tablet size:** Provides smaller tablet size(s) as fewer excipients are needed at lower usage levels including 30 – 50 per cent less diluents (MCC), 25 – 50 per cent less lubricants and 25 – 50 per cent less disintegrants. Even no additional glidant/CSD is needed. Smaller tablets formulated with PROSOLV® SMCC HD 90 may show better patient acceptability.

◆ **Simple processing:** With the help of PROSOLV® SMCC HD 90, conventional granulation processes can be converted to dry mixing. This leads to significantly lower processing time, cleaning and change-over gaps between batches. PROSOLV® SMCC HD 90 is an intricate and homogenous mixture of MCC and CSD made through co-processing and hence produces no dust when compared with a conventional physical blend of diluent(s) with CSD. This results in dust-free handling.

◆ **Accelerated product and process development:** PROSOLV® SMCC HD 90 is highly suitable for direct compression applications; hence, lesser process and formulation parameters needed to be optimised to finalise formulation and take it to market.

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

◆ **Less number of batches for the same output:** In the wet granulation process, RMG capacity/size limits the batch size; whereas in the dry mix process, the batch size is proportional to blender size, which normally has a higher capacity. When formulated using PROSOLV® SMCC HD 90 driven dry mix process, it leads to a relatively much higher batch size of the same formulation. Because of this, less number of batches is needed for the same production output, which means higher productivity in lesser time. As the number of batches is reduced, analytical testing cost also comes down significantly.

◆ **Higher outputs:** Simpler process as compared to wet and dry granulation results in shorter processing time and higher production yield. It also shows lower die-fill depths due to better flow and high-density properties. This makes PROSOLV® SMCC HD 90 a choice of excipient for high-speed tabletting for high-volume formulations.

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

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

◆ **Prolonged tooling and equipment life:** With PROSOLV® SMCC HD 90, sufficient tablet hardness can be achieved at lower compaction forces, which leads to prolonged life of tooling and equipment.

◆ **Complete regulatory support:** Like other PROSOLV® grades, qualitative and quantitative (QnQ) composition is disclosed for PROSOLV® SMCC HD 90 too. USDMF is available along with complete regulatory support.

Summary

PROSOLV® SMCC HD 90 is a flagship brand of JRS pharma. Similar to all JRS products, this excipient is also manufactured under strict quality control procedures to ensure that it meets the highest standards. Overall, PROSOLV® SMCC HD 90 is a highly versatile and effective pharma excipient that offers several benefits to formulator(s) and pharma manufacturers. Its excellent flow, better compressibility and compatibility with a wide range of APIs make it an ideal choice for solid oral formulations.

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PROSOLV®

www.jrspharma.com

Scan me to know me

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OPTEL inaugurates experience centre of end-to-end supply chain solutions in Goa

It is a place where one can have a live presentation of track and trace systems and a live demo of OPTEL's Optchain™ supply chain control tower

OPTEL opened an experience centre of end-to-end supply chain solutions at the Goa facility on February 16, 2023. It is a place where one can have a live presentation of track and trace systems and a live demo of OPTEL's Optchain™ supply chain control tower.

Optchain™ is an outcome-driven intelligent supply chain solution suite powered by OPTEL traceability technologies providing the right insight, at the right time.

The Optchain™ platform acts as a supply chain control tower. Granular data is captured and connected along the supply chain, providing visibility and transparency. It also boasts industry-leading traceability capabilities to help businesses have more performant and sustainable supply chains while complying with local regulations and international standards.

The inauguration of the centre was done by the chief guest, Nitin Kunkolienker, President Emeritus, MAIT. Many eminent personalities from the industry were also present during the event.

From OPTEL, Florent Bouguin, VP and Chief Technology Officer, gave a demo of the technologies displayed there. He said, "It is time to leverage the massive investments done in digital transformation to comply with international and local regulations. Deploying traceability upstream and downstream the supply chain will help businesses to get visibility on what is happening in the entire supply chain and take the best decision. It is urgent to take bold action to transform the industry to be better resilient and better responsible."

The inauguration of the centre was done by the chief guest, Nitin Kunkolienker, President Emeritus, MAIT. Many eminent personalities from the industry were also present during the event

On the occasion, Mangala Nagaraj, Executive VP, Global Software Professional Services expressed the need for the experience centre and said, "These technologies are very powerful and give many benefits to businesses in terms of efficient operation, better decision making, compliances and responsible sourcing. Now with this experience centre, our customers can experience these technologies in the real world, which will help them to understand OPTEL's intelligent supply chain solutions in the context of their needs."

Anirudha Katekar, VP-Sales - India said, "This demo centre will serve the ASIA's customers to experience the futuristic technologies which can help the business processes and sustainable goal of the organisation through an intelligent supply chain."

Guests from IIFCO, Cipla, Troika etc., were taken through the demo of OPTCHAIN's product during the inauguration. They appreciated OPTEL's efforts for being upfront about its technologies and encouraging the customers to gain experience before making investment choices.

OPTEL is a global company, with manufacturing sites on four continents, and 600 employees around the globe. The company has 30 years of proven expertise in developing and deploying track-and-trace, vision and traceability systems for the world's leading pharmaceutical, food and beverage, and agrochemical brands. OPTEL is a Certified B Corporation and co-founder of the Canadian AI supercluster for supply chains (Scale AI).

Learn more at OPTELGROUP.COM

High-Speed Doors from Gandhi Automations

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

Fast-moving functional and reliable doors are needed in industrial and commercial contexts. Designed and manufactured by Gandhi Automations, these 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 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.

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

- ◆ 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

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The growing importance of amino acids

Christoph Zahner, Senior Manager, Global Business Development, Biopharmaceuticals at DKSH elaborates on the need, value and applications of amino acids

Amino acids are the building blocks of life and serve as natural compounds in various industries and applications. They are widely produced and utilized commercially, including as food seasoning, animal nutrients, pharmaceuticals, and cosmetics.

The term amino acid is short for alpha-amino carboxylic acid. Commonly used as supplements in cell culture media and metabolism research, they act as building blocks of proteins and as intermediates in metabolism.

According to Grand View Research, the global amino acids market size was valued at $26.1 billion in 2021 and is expected to expand at a compound annual growth rate of 7.4 per cent over the next 10 years. The market is anticipated to be driven by the increasing demand for amino acids from the food, pharmaceutical, and nutraceutical industries.

The Asia Pacific market is expected to be the fastest growing market in terms of revenue-growth due to the increased consumer spending in the region. Other influencing factors include the growing adoption of a healthy lifestyle, and rapid expansion of industries, including nutraceuticals, pharmaceuticals, personal care, and cosmetics.

A closer look at amino acids

Today amino acids are used in several sectors, including the food industry as flavor enhancers. Glycine, cysteine, and D, L-alanine are also used as food additives, and mixtures of amino acids serve as flavor enhancers in the food industry.

Some products are often supplemented with certain amino acids to increase their nutritional value. Many plant-based products are deficient in certain amino acids, which can be introduced to provide consumers with extra nutrients to improve health. For example, bread can be enriched with lysine, and soy products can be enriched with methionine. Lysine, methionine, and glutamic acid are widely used in animal feeds.

Common uses of amino acids

Amino acids are used as precursors for chemicals used in various industries, such as pesticides and herbicides. For example, threonine can be used to produce the herbicide azthreonam and glycine can be used to produce glyphosate, another herbicide.

Amino acids are widely used in dietary supplements owing to their ability to treat muscle soreness, sprain, and mental fatigue. Several amino acids like leucine, valine, proline, alanine, cysteine, and isoleucine are used in supplements for muscle growth and bodybuilding. Amino acids are also commonly used as preservatives in food and drink. Fruit juices are often preserved with the use of cysteine as an antioxidant.

Amino acids are used therapeutically for nutritional and pharmaceutical purposes. For example, patients are often infused with amino acids to supply these nutrients before and after surgical procedures. Treatments with single amino acids are part of the medical approach to control certain disease states. Examples include L-dihydroxyphenylalanine for Parkinson's disease, glutamine and histidine to treat peptic ulcers, and arginine, citrulline, and ornithine to treat liver diseases.

Certain derivations of amino acids, especially glutamate, are used as surfactants in mild soaps and shampoos. D-Phensylglycine and D-hydroxyphenylglycine are intermediates used for the chemical synthesis of ß-lactam antibiotics such as synthetic versions of penicillin. Aspartame is a sweetener prepared from the individual component amino acids aspartic acid and phenylalanine.

DKSH offers a broad range of Amino acid solutions to cater to your pharmaceutical needs. Our international teams of technical specialists collaborate across borders to develop innovative solutions for companies looking to tap into the growing consumer needs. Contact us to learn more about our products and capabilities to support your business growth.

Waters introduces next-gen Alliance iS HPLC System

The Waters Alliance iS High Performance Liquid Chromatography (HPLC) System brings a new level of simplicity and instrument intelligence to QC analyses, helping laboratories eliminate up to 40 per cent of common errors

Waters Corporation introduced Alliance iS, the next-generation intelligent HPLC System, designed to reduce compliance risk by adding new levels of proactive error detection, troubleshooting and ease-of-use. When combined with Waters' compliance-ready Empower Chromatography Software and eConnect HPLC Columns, the Alliance iS High Performance Liquid Chromatography (HPLC) System streamlines the task of making accurate and precise measurements by detecting and eliminating common errors by up to 40 per cent. In doing so, the Alliance iS HPLC System helps QC laboratories consistently meet quality, safety, compliance, and on-time product delivery goals.

"Today's QC laboratories are very different than they were 50 years ago when Waters introduced its first commercial HPLC system helping ensure the tens of thousands of prescription drugs on the market are pure, safe, and will work as expected. Our conversations with hundreds of QC managers and bench analysts have yielded a deeper understanding of what they need today from a state-of-the-art HPLC system to help them perform at their best. The Waters Alliance iS HPLC System is ideally suited to address issues such as staff training, error-reduction, risk management, and compliance, helping bring significant productivity and quality improvements to high-volume QC laboratories," said Udit Batra, President & CEO, Waters Corporation.

Based on broad and in-depth customer insights, the Alliance iS HPLC System is thoughtfully designed for the unique needs of the QC laboratory, bringing intuitive simplicity to routine measurements. With visual prompts and alerts delivered via an intuitive touchscreen interface, the system notifies the operator if an improper method is chosen for an application, when a sample vial is missing, when it's time to refill a solvent bottle, or if it's time for system maintenance. These are common conditions that when caught early enough, can eliminate system errors that would otherwise degrade the ability of scientists to get needed drugs to patients and ultimately cost a laboratory time and money.

Next-generation HPLC System pairs with Waters Empower Chromatography Software and eConnect HPLC Columns to help laboratories manage operational risk, mitigate disruptions, and increase overall productivity

The system also integrates with the cloud-native waters_connect System Monitoring Software enabling real-time monitoring of the Alliance iS HPLC System and any other chromatography instruments controlled by Empower Software. Laboratory managers can view the live status of their HPLC instrument fleet from anywhere and at any time to further improve equipment utilisation and overall productivity.

Waters Alliance iS HPLC System feature highlights include:

◆ The very latest compliance-ready, industry-standard Empower Chromatography Software with full audit tracking capabilities.

◆ Advanced instrument touchscreen for guided system operation and maintenance.

◆ eConnect Column Tag Technology to link column information including injection counts via near-field communication (NFC) technology.

◆ Automated system diagnostic pre-checks to help meet error reduction key performance indicators (KPIs).

◆ Tool-free fittings to prevent leaks and provide better chromatography.

The Waters Alliance iS HPLC System will be available starting in May 2023.

Testo 400 – The intuitive air velocity & IAQ measuring instrument

The new testo 400 is the universal measuring instrument for all airflow and IAQ applications and impresses with smart technology, fast readiness and convenient application

The measurement technology expert, testo brings in the new generation of IAQ measurement technology: The new testo 400 is the universal measuring instrument for all airflow and IAQ applications and impresses with smart technology, fast readiness and convenient application. With the testo 400, Testo has cleverly extended its range of measurement technology for all volume flow and comfort measurements. The universal testo 400 is not just smarter, faster and better – it is also seamlessly integrated into Testo's comprehensive IAQ range. The range of probes for the new measuring instrument is among the broadest on the market. In addition to this, the Testo Smart Probes can also be connected to the universal measuring instrument. The testo 400 offers innovative functions which make the user's job easier in every way, and allow reliable, norm-compliant measurement including documentation.

Product overview

◆ **Intuitive with measurement assistant:** The testo 400 features clearly structured and unambiguously guided measurement menus which guide the user safely and easily through the whole application.

◆ The instrument is so smart that it guides the user during the measurement procedure by automatically highlighting the points of measurement, depth of probe insertion and grid area. This intuitive and innovative feature enables the user for a seamless experience.

❑ **Universally applicable:** Thanks to the broad selection of probes, all IAQ, ventilation and comfort parameters can be precisely and reliably measured.

❑ **Always ready to go:** If probes need to be calibrated, this is possible independently of the measuring instrument. The testo 400 can continue to be used with other probes while the affected probe heads are in service for calibration.

❑ **Saving time:** The new testo 400 allows all probes to be quickly and easily exchanged during the measurement eliminating the need for a bothersome instrument re-start, and the waiting times.

The documentation of the measurement job can be finished directly on-site with the customer and the measurement reports can be conveniently sent by e-mail and are also stored in the instrument.

Product features

◆ Can measure °C, %RH, CO, CO2, m/s, Lux, hPa

◆ Convenient smart touch operation with front and rear camera to capture live images.

◆ High-precision, location-independent and integrated differential pressure sensor

◆ Compatible with a wide selection of Bluetooth and wired probes, as well as testo SmartProbes and testo 440 probes

◆ 5.0" HD touch display with 1280 x 720 px resolution

◆ Zero-error display: Adjustment function at up to 6 measuring points

◆ Intelligent calibration concept with HD graphic display.

Smart and intuitive measurement programs

◆ HVAC grid measurement in accordance with EN ISO 12599 and ASHRAE 111

◆ PMV/PPD in accordance with EN ISO 7730 and ASHRAE 55

◆ Draught and degree of turbulence in accordance with EN ISO 7730 and ASHRAE 55

◆ WBGT measurement in line with DIN 33403 and EN ISO 7243

◆ NET measurement in accordance with DIN 33403

Multiple application areas

◆ Volume flow measurement in duct outlet with funnel and pitot tube

◆ Thermal comfort measurement (PMV/PPD), NET temperature and indoor air quality

◆ Volume flow via K factor and differential pressure measurement (ASHRAE 111)

◆ Thermal comfort measurement

◆ Energy efficiency of green building (SFP value), current, heating/ cooling load measurement

◆ Differential pressure measurement with mould risk measurement

◆ Radiant heat measurement

For more information, write to info@testo.in or visit: www.testo.com

Waters launches new battery cycler microcalorimeter solution

New battery cycler microcalorimeter solution collects up to six times more data than other commercially available calorimeters

Waters Corporation announced a new Battery Cycler Microcalorimeter Solution from its TA Instruments Division for high-resolution characterisation of battery cells. The instrument and software combination enables non-destructive testing under real-world operating conditions and significantly reduces experiment time from months to weeks, while providing decisive insights for greater battery efficiency, safety, and stability.

"Innovations like our in-operando Battery Cycler Microcalorimeter Solution are revolutionary for the future of battery R&D. It significantly reduces testing time by up to 75 per cent, while helping researchers learn more about how batteries and their materials behave and change under both thermal and electrochemical conditions. The precise data it provides scientists is essential to help ensure battery performance and safety," says Jianqing Bennett, Waters Corporation Senior Vice President of the TA Instruments Division.

The solution combines the TA Instruments high-resolution TAM IV Isothermal Microcalorimeter and integrated TAM Assistant Software platform with a Bio-Logic VSP-300 potentiostat (battery research instrument) to deliver accurate, rapid detection of parasitic heat reactions, an early indicator of battery efficiency. The Battery Cycler Microcalorimeter supports testing of three common battery types – coin, pouch, and 18650 cylindrical – for charge/discharge and thermal testing in parallel. It can maximise researcher efficiency with support for testing and data collection of up to 12 coin-sized batteries simultaneously – six times more than competitive offerings.

> The Battery Cycler Microcalorimeter can maximise researcher efficiency with support for testing and data collection of up to 12 coin-sized batteries simultaneously – six times more than competitive offerings

The easy-to-read TAM Assistant Software reduces technical barriers to training while enabling researchers to define parameters and plotting options, as well as interpret aggregated data to make informed decisions for their experimental or process strategy. This novel solution enables researchers to better predict electrolyte calendar life, which aids in the development of new electrolytes and electrode materials.

Waters Corporation listed as No 5 on Barron's 100 Most Sustainable Companies 2023 list

Waters marked multiple environmental sustainability highlights in 2022, including the release of its sustainably designed Xevo TQ Absolute mass spectrometer

Waters Corporation's companywide commitment to "leaving the world better than we found it" has earned it the number five ranking on the Barron's 2023 100 Most Sustainable Companies U.S. list – its third consecutive year on the list, and its second time amongst the top ten.

Waters has a strong focus on making progress against a set of environmental, social, and governance (ESG) goals. At the highest level, these reflect Waters' efforts to reduce its environmental footprint, develop a workforce that is more representative of the society we live in, and to continue its strong governance practices. In 2022, Waters shared an update on its progress as well as a transparent framework that demonstrates how the company plans to build upon its strategy which is grounded in the company's guiding principle of "leaving the world better than we found it."

> Waters opened its new $215 million Precision Chemistry facility in Taunton, Massachusetts, the first and only LEED-certified chemical manufacturing facility in Massachusetts and one of a small number of such facilities in the US

"Success only comes if we all give more than we take from this world," says Dr Udit Batra, President & CEO, Waters Corporation. "We are thrilled to be recognised for our steadfast commitment to sustainability, which is enabled by focusing on solving problems that matter and empowering each Waters employee to make a unique and positive contribution."

Waters marked multiple environmental sustainability highlights in 2022, including the release of its sustainably designed Xevo TQ Absolute mass spectrometer. This essential instrument, used to test drinking water and environmental samples for contaminants such as PFAS, uses 50 per cent less electricity and nitrogen gas and produces 50 per cent less heat — lowering laboratory energy use, cost, and total environmental impact.

Waters also opened its new $215 million Precision Chemistry facility in Taunton, Massachusetts, the first and only LEED-certified chemical manufacturing facility in Massachusetts and one of a small number of such facilities in the US.

In its sixth year, the Barron's 100 Most Sustainable Companies list was built in collaboration with Calvert Research and Management by ranking 1,000 of the largest publicly traded companies by their performance in five key constituencies: shareholders, employees, customers, community, and the planet.

Peptide library synthesis: Using two different coupling reagents to improve overall crude purity

Elizabeth Denton, Senior Scientist, Biotage, explains how the use of two difference coupling reagents for synthesis of peptide libraries at particularly small scale improves the overall crude purity of the library with a case study

Synthesising libraries of peptides - potentially hundreds in a single synthesiser setup - has seen a resurgence of late. These synthetic libraries, often prepared on very small synthesis scales, are required most recently for secondary screening preliminary structure-activity relationship determinations, or neoantigen vaccine preparations. However, optimising the synthesis of hundreds of peptides to be made simultaneously is a very different beast when compared to optimising the synthesis of a single peptide.

We will describe a strategy that can increase the overall crude purity of an entire peptide library using two different coupling chemistries.

Given the expansion of peptides in therapeutics, and specifically the need for synthesis of libraries of peptides, it was time to start experimenting in this area. But peptide synthesis, when considering simultaneous synthesis of hundreds of compounds that may or may not be similar was pretty daunting the first time. After all, there is no longer one peptide to be concerned about (crude purity and yield predominantly), one now has to be worried about many many peptides. And ideally, the crude purity of the entire library would be sufficient that these could be take forward into validation experiments without further purification.

So we decided to start with something a little more "simple" - a scanning library centered around a peptide with which we already have some familiarity, *Figure 1*.

We like this peptide as a "parent" sequence for a couple of reasons:

1. the linear sequence is relatively straightforward to synthesise as an individual

2. the parent peptide sequence is of similar size to those currently being investigated for therapeutic applications.

3. the peptide has sufficient length to fill out a full 96-compound library using amino acid scanning

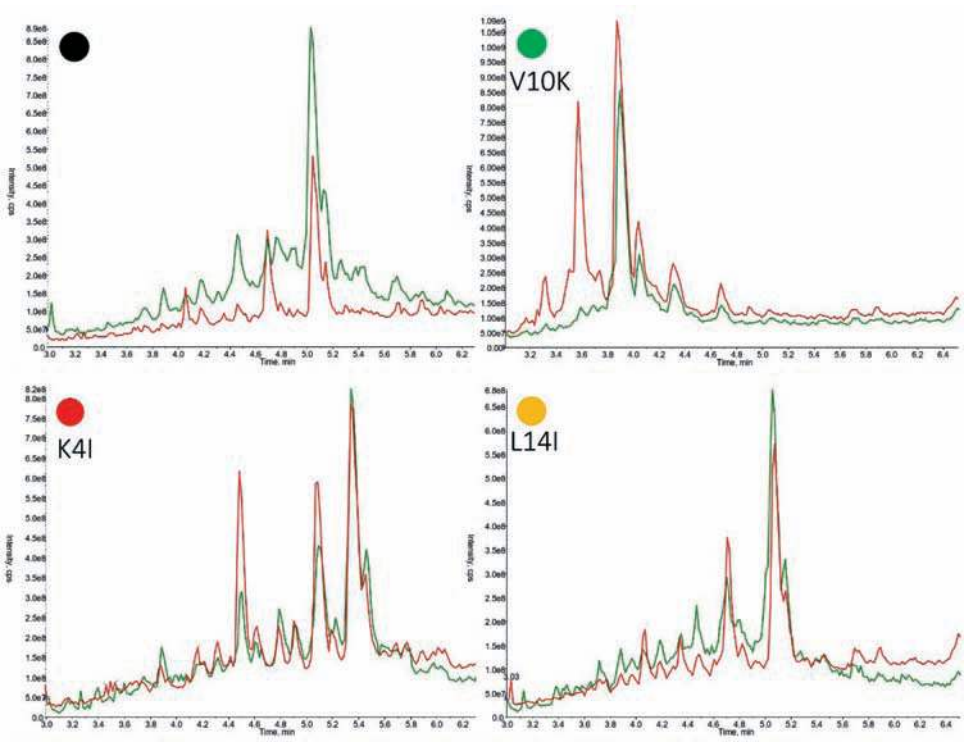


Figure 2. Representative crude chromatograms for members of the 18A peptide library synthesised using DIC/OxymaPure followed by HATU/DIPEA (red trace) or HATU/DIPEA followed by DIC/OxymaPure (green trace)

4. amino acid scanning will introduce a wide variety of sequence diversity, which it turn could correlate with synthesis difficulty

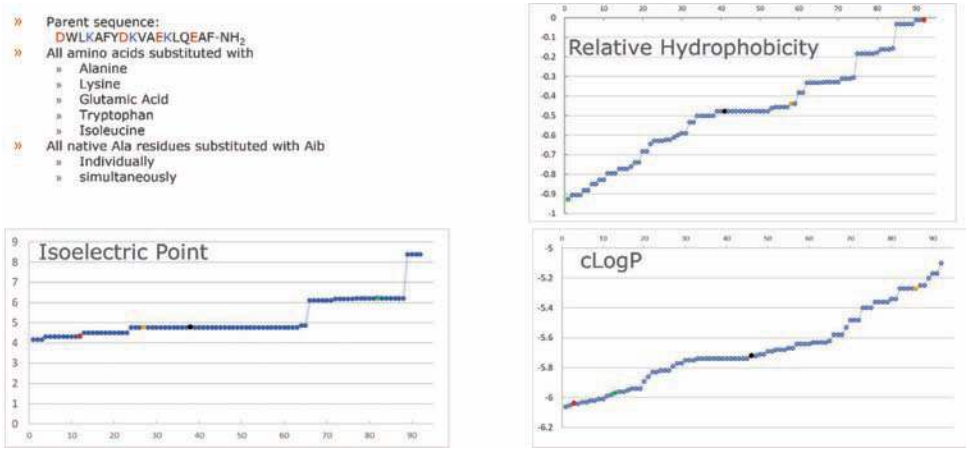


Figure 1. Description of synthetic peptide library under investigation and properties of resulting library members. Red circle represents the most hydrophobic peptide (K4I), yellow circle represents a median hydrophobicity (L14I), green represents the most hydrophilic sequence (V10K) and black circle represents the parent peptide sequence on the charts for various physiochemical properties

To synthesise this library, we decided to use Biotage Syro II in the Tip Synthesis configuration. Tip synthesis allows for synthesis of peptides on 1-5 ❁mol scale using a 0.4 mL fritted pipette tip for reactor vials. Given the small liquid volumes used in these reactor vials, the vials are stationary. To ensure synthesis success then, double coupling and amino acid preactivation are employed.

We knew that we would use five equivalents and 0.5 M amino acid solutions, but at this point I decided to think a bit harder about the specific coupling reagents used for this library. It simplifies programming of the synthesiser and reduces time spent preparing reagents. But we recalled a publication in which two different coupling reagents were used with greater success for synthesis of aggregation prone sequences. Using this information as a starting point, we decided to synthesise the library using first DIC/OxymaPure then HATU/DIPEA for the second coupling. In a second synthesis, we then switched the order of coupling reagents and looked to see if there were any significant differences in crude purity.

We would like to focus on the sequences highlighted previously, Figure 2.

For the peptides shown here, the protocol using HATU/DIPEA followed by DIC/Oxyma Pure generally produced peptides with higher

crude purity. What we find most interesting though is just how different the two chromatograms are in some cases (V10K variant for example). Simply switching the order that the two different coupling reagents are used eliminates completely the presence of a significant impurity. On the other hand, some crude purity profiles are strikingly similar (K4I variant).

The differences are less surprising, given just how different the activated amino acid species are when compared to each other. Not only are they significantly different structurally, *Figure 3*, but they also have different reaction kinetics of formation, condensation, and lifetime, which all impact overall coupling efficiency.

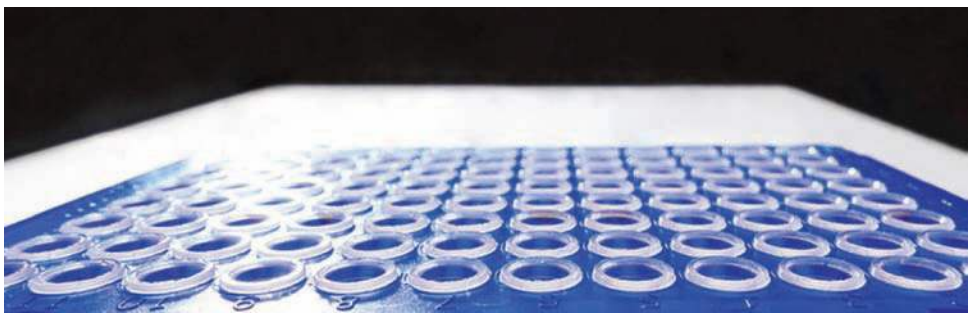
As with any peptide library, there were a couple sequences that stood out as particularly terrible from a synthetic perspective, *Figure 4*.

These results indicate that there probably won't be a tried and true, use this protocol for all libraries rule. This isn't unexpected, given the synthetic diversity that could be present in a single library. What I would like to highlight though is that the mixed coupling reagent protocol, specifically using HATU/DIPEA for the first coupling reaction and DIC/OxymaPure for the second coupling reaction gave the best results for the A17E library variant, adding further evidence my hypothesis that two different coupling reagents can in fact improve the crude purity of the library as a whole.

What is clearly evident in these data, and others not shown, is that the use of two difference coupling reagents for synthesis of peptide libraries at particularly small scale improves the overall crude purity of the library. Also, the order in which two different coupling reagents are used during peptide synthesis will, unsurprisingly, impact the synthesis outcome.

Have you ever used two different coupling reagents for a single amino acid?

If you would like to learn about more strategies for synthesis of peptide libraries, click the link below and achieve even greater crude purities, **contact india@biotage.com; www.biotage.com**



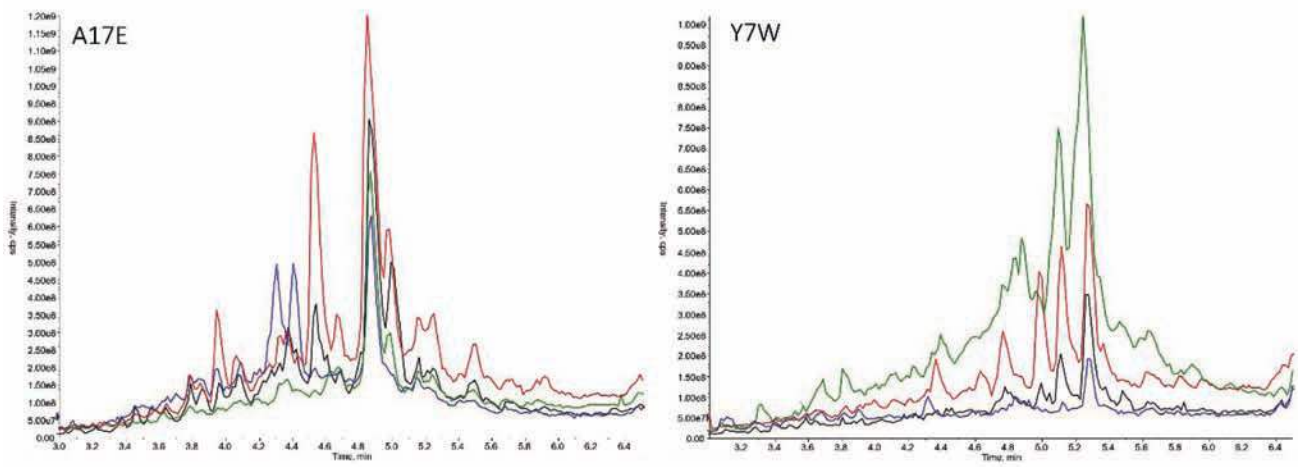


Figure 4. Library members prepared using DIC/OxymaPure then DIC/OxymaPure (black), HATU/DIPEA then HATU/DIPEA (blue), DIC/OxymaPure then HATU/DIPEA (red) or HATU/DIPEA or DIC/OxymaPure (green).

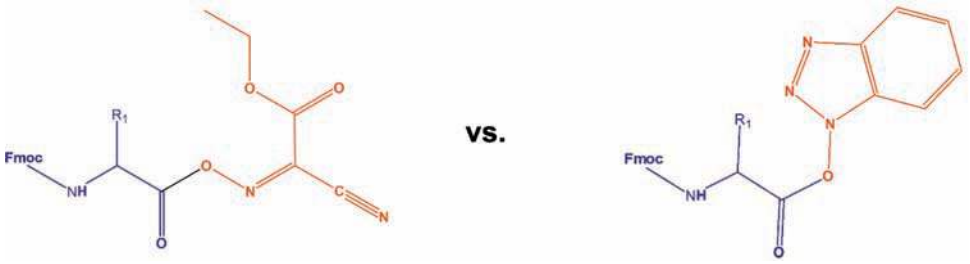


Figure 3. Structure of a generic amino acid activated using either DIC/OxymaPure (left) or HATU/DIPEA (right).

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