



EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE

JANUARY 2022, ₹ 40

INTERVIEWS

V Krishnakumar
Executive Director and
Chief Operating Officer
Eris Lifesciences

Ravi Udaya Bhaskar
Director-General
Pharmexcil



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Interviews

Ravi Udaya Bhaskar
Director-General, Pharmexcil

V Krishnakumar
Executive Director and Chief
Operating Officer, Eris
Lifesciences

PREPARING FOR 2022 LESSONS AND STRATEGIES



The New Year issue explores strategies to implement the lessons learnt from the pandemic as India Pharma Inc embarks on the next phase of growth

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Executive Director and
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Eris Lifesciences



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Chattopadhyay**
Founder and CEO
Esperer Nutrition



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Ravi Udaya Bhaskar
Director-General
Pharmexcil



**23 | S.M.A.R.T
PHARMACEUTICALS
2021-2030**



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Why we need an Aatmanirbhar booster strategy

A year ago, I asked if intellectual property rights (IPRs) could be part of the COVID-19 solution, rather than the problem. (<https://www.expresspharma.in/can-iprs-be-part-of-the-covid-19-solution-rather-than-the-problem/>) I had assumed that a pandemic would change entrenched positions of various stakeholders on IPRs.

However, a year later, we still do not have consensus on a TRIPS waiver for COVID-19 essential medicines, vaccines and diagnostics test kits. With a highly infectious variant Omicron on the loose, some countries have organised booster shots while others are struggling to reach the first shot to all citizens. Thus, 2022 will continue to be a year of inequality on the healthcare access front.

As of December 23, India had 235 cases of the Omicron variant, of which 104 had recovered. While the severity of Omicron cases seems low, for now, we cannot afford to let down our guard.

India's health officials have emphasised coverage of as many citizens within the existing vaccination drive, rather than diverting resources to start a booster campaign. This stance was validated by the WHO's statement of December 22, that introducing booster doses should be 'firmly evidence-driven and targeted to the population groups at highest risk of serious disease and those necessary to protect the health system.' India's booster strategy is expected to follow these lines, prioritising booster shots for healthcare and frontline staff, the elderly, and those with comorbidities.

Policy decisions are like seeds; they need time to deliver a harvest. They need to be nurtured and it could be years before they bear fruit. Do we have the luxury of time to wait? Unfortunately, we don't have a choice.

Take the Production Linked Incentive (PLI) Scheme, where Rs150 billion will be distributed over six years (FY23-FY28) to incentivise the selected 55 pharma companies to invest in crucial manufacturing capabilities.

Schemes like the PLI Scheme are part of the government's Atmanirbharta campaign, to make India self-reliant in key medicines and their ingredients.

But what can be done to ensure that India has enough vaccines for our citizens today?

An October 2021 WTO report on COVID-19 vaccine production and tariffs on vaccine



An Aatmanirbhar booster strategy will save lives. As a bonus, it will also boost long term development programmes at local biopharma companies

inputs, showed that of the top 27 vaccine manufacturing economies, India was one of three nations, which have sensitive/critical "choke points" at varying levels in all 13 product groups of vaccine inputs. The report defined a choke point as a product group with at least a five per cent tariff.

This means that India's vaccine manufacturing supply chain is still very vulnerable to disruptions due to tariffs and logistics. Vaccine makers will need to plan procurement of vaccine inputs months in advance to meet the country's projected needs. Yet, with no fresh orders from the government, one major vaccine company warned that they were cutting production of their COVID-19 vaccine.

To be fair, the central government's analysis shows that states do have enough doses for now. Speedy deployment of these doses before their expiry date is now the focus.

The government also seems to be waiting for the next lot of vaccines under trial to submit data for approval, as most agree that boosters will have to be vaccines using a different platform technology from those used so far in the vaccination drive.

Given that other countries have already booked supplies for their booster dose campaigns, it is logical that India will turn to vaccines developed indigenously for its booster strategy, as time, cost and logistics are crucial factors. An Aatmanirbhar booster strategy will save lives. As a bonus, it will also boost long-term development programmes at local biopharma companies.

However, we will need more than vaccines to fight this virus. Many citizens have not come forward to take their second shots, including those in urban areas where there is no shortage of vaccines. Many more see the pandemic as a hyped-up health risk, an opportunity for companies to profit, disregarding the fact that as per WHO data, the global COVID-19 toll this year (of December 21) was 3.45 million people. This toll exceeded last year's deaths from HIV/AIDS, tuberculosis, and malaria combined. With these sobering numbers and predictions that India's third wave could peak in February 2022, it promises to be another year of learning to live with COVID-19.

VIVEKA ROYCHOWDHURY *Editor*
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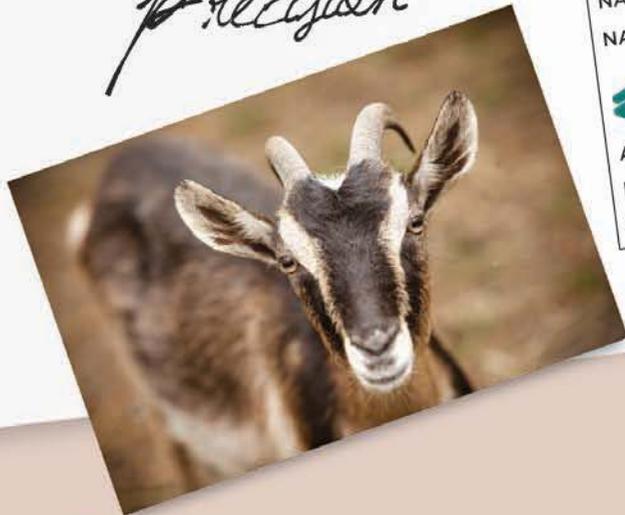
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INTERVIEW

Eris's revenue has grown six times since FY11

V Krishnakumar, Executive Director and Chief Operating Officer, Eris Lifesciences, informs **Akanki Sharma** about the company's differentiated business model that led to a growth in its journey since the inception, while also talking about the company's focus areas, acquisitions made, future business plans and more

Give us a brief about the journey of Eris Lifesciences in India.

We started our journey in 2007, and are the only publicly-listed Indian pharma company with a domestic branded formulation business model. We chose a differentiated business strategy at inception. While most new entrants tend to start off with regional business models in acute therapies focussed on local general physicians, Eris chose to build a pan-India cardio-metabolic business pivoted around super-specialists.

Eris's revenue has grown six times in the last 10 years (since FY11) to reach Rs 1,212 crores in FY 21 and net profit has grown approximately 17 times in the last 10 years to reach Rs 355 crores in FY 21.

We have an integrated business model with our WHO-GMP compliant manufacturing facility in Guwahati catering to 74 per cent of the revenue, and a pan-India sales and distribution presence. We are building our second manufacturing unit in Gujarat with a capital outlay of Rs 120-130 crores.

We acquired the Indian branded domestic formulations business of Strides in November 2017, and also acquired Zomelis, a Vildagliptin brand from Novartis AG in December 2019. Both these acquisitions have proven to be value accretive for our business. Recently, we announced our entry into the domestic insulin, analogues and GLP1



markets on the back of a joint venture with Mumbai-based M J Biopharma.

We are expanding our footprint in medical devices through our Circa range, currently comprising blood pressure monitors, IR thermometers and India's first blood glucose monitors with patented gold cartridge technologies. We are augmenting the range with Continuous Glucose Monitors (CGMs) and HbA1c monitors as well.

We also continue to pioneer

the generation of actionable medical evidence through initiatives such as the India Heart Study (IHS) and India Diabetes Study (IDS); these studies are helping create bodies of knowledge hitherto unknown and are paving the way for better management of health and treatment outcomes. The IHS is the only study of its kind on hypertension that is based on the Indian population and has been jointly accepted by the European Society of Hypertension and the

International Society of Hypertension.

Tell us about the major focus areas of the company and the contribution it has made specifically to the Indian pharmaceutical industry.

We are deriving 92 per cent of our revenue from chronic and sub-chronic therapies, primarily consisting of oral anti-diabetes, cardiac and vitamins-minerals-nutrients (VMN). We have outperformed the Indian pharma market by approximately 50 per cent since pre-COVID levels.

We have enough tailwind in our therapies which enable us to consolidate and grow this brand portfolio by driving better awareness, earlier detection and comprehensive management of diseases. We are also investing in expanding our coverage of specialists and consulting physicians. We will continue to focus on our core therapies of cardio-metabolic and VMN. We are also investing in CNS, women's health and dermatology.

In the past few years, you have made some large acquisitions. Tell us about their current status.

We acquired the Indian branded formulation business of Strides Shasun in 2017, and by discontinuing tail-end brands, we focussed our attention on Renerve, Raricap, Ginkocer, Serlift and Desval. Through optimisation of the field force, we were successful in ramping up the field force

productivity by approximately 2.5 times in a span of three years. The nutraceutical brand acquired from Strides – Renerve – has grown from Rs 77 crores (November 2017) to Rs 139 crores (September 2021), a CAGR of approximately 17 per cent since acquisition, after absorbing a seven per cent reduction on account of GST implementation. In addition, through in-sourcing manufacturing of key products in the portfolio to our Guwahati facility, we were successful in bringing about a significant reduction in the Cost of Goods Sold (COGS) from 35 per cent to 22 per cent.

Zomelis, a Vildagliptin brand we acquired in November 2019, has registered more than six times growth in monthly sales run-rate since acquisition. We have been able to reduce the COGS by over 500 bps since acquisition by insourcing manufacturing to our in-house Guwahati facility.

What impact did the COVID-19 pandemic have on Eris Lifesciences' business revenues?

During the pandemic period, the pharma industry saw a massive shift to digital in terms of MR-doctor interactions and doctor-patient interactions. We, at Eris, were able to seamlessly adapt to the new reality. We demonstrated strong resilience in the face of COVID with market-leading growth and robust financial performance. Excluding

COVID drugs which were a short-lived phenomenon, the core Indian pharma market has grown at 8.3 per cent p.a. since pre-COVID levels, whereas we have grown at 12.2 per cent p.a. – this represents an outperformance of nearly 50 per cent.

We had three product additions to our portfolio during this time:

◆ **Zomelis:** Market leader in the Gx Vildagliptin space with annual sales of over Rs 58 crores (MAT November 2021); monthly sales have grown by six times in less than 24 months

◆ **Gluxit:** Market leader in the Gx Dapagliflozin space with annual sales of over Rs 30 crores (MAT November 2021); monthly sales have ramped up eight times in over 12 months from the date of launch

◆ **ZAC D:** A convenient chewable combination of Zinc and Vitamin A, C and D launched in August 2020 with annual sales of over Rs 25 crores (MAT November 2021)

Any investment plans or tie-ups for future expansion of the company?

Our key growth drivers (and hence investment areas) are:

◆ We are taking the lead in the detection/management of post-COVID early-onset diabetes (“unmasking of diabetes”) through a significant ramp-up in our patient care initiatives involving CGM and HbA1C camps.

◆ We have a pipeline of patent expiration opportunities in the cardio-metabolic segment in the next three-four years. We are well-positioned in the cardio-metabolic space to gain significant leverage from these expirations.

◆ We expect to leverage the market opportunity in human insulin, insulin analogues and GLP1 agonists through our joint venture with MJ Biopharm.

◆ We are working on significantly expanding our coverage of specialists and consulting physicians.

◆ We are investing Rs 120-130 crores in building our second manufacturing unit.

◆ On the back of value-accretive deals (e.g. Strides, Zomelis), we continue to look for high-return inorganic opportunities to complement our organic growth initiatives.

Give us more details on the recent joint venture with MJ Biopharma. What is the

growth that you are expecting and what is the insulin market in India?

The market for insulins, analogues and GLP1 in India is currently valued at Rs 3,500-4,000 crores p.a. and we expect this market to double in the next five years as diabetes treatment protocols

in India get more aligned to western standards. This joint venture will enable us to tap the market opportunity in these lucrative segments. We are targeting a market share of 10 per cent over the next few years.

We will hold 70 per cent stake in this joint venture and

will take the lead in sales and marketing, distribution and pharmacovigilance. Our partner MJ Biopharm will be responsible for development, manufacturing and supply of products to the JV.

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INTERVIEW

“We aim to build a nutrition-literate planet with focus on oncological nutrition”

Raktim Chattopadhyay, Founder and CEO, Esperer Nutrition, talks to **Akanki Sharma** about the contribution his company is making towards cancer nutrition



What led to the origin of Esperer Nutrition? What is its aim and vision?

Nutrition imbalances, malnutrition, malabsorption, cachexia, anorexia and sarcopenia are the most common diseases during cancer treatment, leading to an increased BMR. All these impact the QoL of patients and subsequently impact mortality rates or even promote discontinuation of treatment leading to less survival. As per a WHO report, about 25 per cent of cancer patients die mainly because of malnourishment and lack of supplementation which are induced either by the disease or by the therapy itself.

With progress in cancer drug innovation which has shifted cancer as disease from preventive to curative therapy, the cytotoxicity level on patients has also increased. Hence, the supportive care treatment options are emerging worldwide. EON therapy addresses the QoL of cancer patients through nutrition as weapon establishes its value in cancer-supportive care space by complementing main therapy. The whole approach commits less chemo-cycle dropouts and hence adds value to the survival rate.

We aim to build a

nutrition-literate planet with a focus on oncological nutrition. We strive to maintain an ecosystem for cancer care and survivors through personalised and disease-specific nutrition therapy, disease management and expert guidance.

Tell us about the products that you have developed in the area of cancer nutrition. What is your business model?

Esperer Nutrition products address the cancer condition-specific nutritional intervention. Product formulation has been designed with pre-treatment needs of normal cells of cancer patients and with direct carbohydrates deprivation strategy to weaken cancer cell proliferation making the approach as the first nutritional preconditioning of cancer patients. During cancer treatment (chemo/radiation), the formulation is meant to address nutritional balance and facilitate physiological functions of the body, keeping drug nutrient interaction in check. Since post-cancer treatment recovery period is more vulnerable for patient, the EON formulation adds value specifically with its careful product design. In all these formulas, the whole

EON therapy maintains constant supply of basic nutritional need of cancer patients that is critical to arrest malnutrition-related death or cycle dropping during cancer journey.

EON therapy international patent has been accepted and published which gives the therapy a status of unique innovation in managing nutritional health in cancer disease management as world's first condition and stage-specific complementary therapy. Esperer's products like Es-Fortitude GH and Es-Fortitude HaemoCal target specific cancer like GI cancer and haematological disorders, respectively.

Esperer Nutrition cancer series products aim to add value in cancer co-morbid conditions, especially to protect kidney functions during cancer treatment. Since kidney function gets altered by diseases itself and also by drugs used in cancer treatment irrespective of CKD condition of patient, Esperer Nutrition product Ren Voitho HP/LP intervenes to make kidney output desirable during cancer treatment. Hence, the toxicity level remains below threat level.

Considering cancer wound is more complex post-surgery, special and fast



We strive to maintain an ecosystem for cancer care and survivors through personalised and disease-specific nutrition therapy, disease management and expert guidance

recovery is needed to accelerate the adjuvant chemotherapy. Esperer's nutritional supplement LISS WH is designed to speed up the process. All the cancer series products have been tested in Indian and various international markets, and made under strict US FDA plant using patented global sourced key ingredients, assuring the superiority of the whole range in quality.

The EON therapy maintains constant supply of basic nutritional need of cancer patients that is critical to arrest malnutrition-related death or cycle dropping during cancer journey

Give us a brief about the operations that you have recently started in the UK. We have chosen the UK as a business centre for Europe and other regulated countries. EN UK has started its operations with people under company's payroll in sales, marketing and distributions. EN products will also be exported from the UK to other European countries under strict regulatory norms.

How is technology accelerating the future of the nutrition market?
In India, new technology has always been accepted to improve the QoL of patients.

Nutra genomics and AI have already started impacting disease prevention and management. Since nutraceutical interventions is deeply embedded with disease prevention, such technologies can accelerate the

nutraceutical market growth. **Any new products in the pipeline? What are your business expansion plans?** EN research team Esperer Nutrition Development Centre (ENDC) is constantly engaged to create innovative

product pipeline in clinical nutrition segment. After successful introduction of seven products in cancer series and 10 products in NCDs segment, we have 44 new products in pipeline. Some of the innovative products like nutraceutical

interventions over cancer metastasis (spread of cancer), cervical cancer, childhood cancer, migraine, IBD etc. are under final stage of development.

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PREPARING FOR 2022 LESSONS AND STRATEGIES

As we enter into a new year, pharma industry's stakeholders talk about various strategies to implement the lessons learnt from the COVID-19 pandemic as India Pharma Inc embarks on the next phase of growth

COVID-19 has made serious dents on global economy

India is an exclusive generic exporter. As of FY21, India's exports of pharmaceuticals to North America and Europe are a little over 51 per cent. These regions being trend setters are all the more important. Hence, developments and thinking of these two regions would be of interest to India's pharma exporters. India has 18 per cent of the US FDA-registered facilities, the second largest source outside of the US.

COVID-19 has made serious dents on global economy, and has tested each country's preparedness to handle emergency and resilience to bounce back. India's pharma industry responded splendidly in managing its clientele. Most importantly, it could also contribute by crystallising its own version of COVID-19 vaccine which has covered many overseas brethren besides lot many countrymen.

Governments all over are exploring various possibilities, inclusive of extending financial concessions, for minimising import dependence of at least off-patented essential medicines. They are considering local pro-



“Governments all over are exploring various possibilities, inclusive of extending financial concessions, for minimising import dependence of at least off-patented essential medicines”

Ravi Udaya Bhaskar
Director-General, Pharmexcil

duction, or reshoring supply chains to regional peers. The Indonesian government is in talks over the possibility of offering the US-controlled pharma firms that wish to move factories out of China, a new production base, according to Coordinating Maritime

Affairs and Investment Minister Luhut Pandjaitan (as reported in Fitch solutions). Besides, in high-value markets like the US, pricing controls being discussed is likely to rollover by mid-2022.

The EU parliament recommendations suggest promoting

European-made pharmaceuticals by strengthening manufacturing and supply resilience throughout the EU; developing adequate capacity for sustainable production of active substances, raw materials and medicines to reduce dependence on external sources; and setting up a wider political high-level pharma forum.

Africa, yet another important region for India's pharma industry, is also gearing up for increased local production and some of the Multi-National Companies (MNCs) are loudly thinking of shifting some R&D facilities to these cost-effective locations.

Situation in LAC Region is getting tougher, and instances of companies pulling out of those countries are on the rise.

In this scenario, Indian pharma may have to adapt to the changing scenario of the industry which is moving towards biosimilars and newer dosage forms like drug delivery devices and injectables.

India's vaccine exports may bring in substantial revenue at least in three quarters of FY23 but it has to face intense competition from Africa besides

the existing, where more than six units are in the making.

While India's pharma exporters made fairly good inroads in device delivery doses of respiratory therapy and more to catch-up in other therapies, biopharma needs to be addressed more intensely.

Off-patent, highly-potent formulations offer major opportunities, especially in the segments of oncology and respiratory. Nearly half of the bio products are slated in this therapy. In the next five years, \$26 billion worth of products may go off-patent in some markets. Barrier to entry is high expenses, which requires specialised technologies and dedicated facilities, besides vast experience in regulations. India possesses workforce comparable to the best in the world. To meet the expenses of such infrastructure, working capital, top Indian pharma companies can pool their resources and, probably with adequate government contribution, can zero in on some select bio products to produce biosimilars and a way to share the gains could be modelled.

Pace of vaccine development holds great potential for future of drug development

For the clinical research industry, the pandemic brought to the fore the need for expedited approvals and how a combination of innovative and tech-enabled solutions could fast track the process without compromising on patient safety and confidentiality.

The pace of vaccine development across the globe is testimony to the possibilities of expedited trials and holds great potential for the future of drug development. For emerging

biopharma reliant on quick and nimble processes to progress their drug development aspirations, such developments hold much promise. The approach, however, requires the collaborative efforts of multiple stakeholders, amongst whom regulators play a vital role in creating an enabling environment.

India has been on the path of regulatory changes for the last few years. With the introduction of the New Drugs and Clinical Trial Rules in 2019, several regulatory concerns were

addressed, resulting in a more balanced and robust regulatory environment. However, despite the progress made to date, there is a need to take stock, review how much we have gained and what more needs to be done to further strengthen the regulatory environment, particularly as we incorporate learnings and the best practices from the pandemic that can become the norm in the future.

The key enablers that will encourage research and innovation from a regulatory

perspective are quicker approval and response time (regulatory approvals in some innovator countries like the US, EU and Israel take 20 to 40 per cent less time than India), simplification in the clinical trial submission and review process, inclusion of more technology/subject matter experts in the review and approval committees, and a more collaborative approach with sponsors. A key opportunity, and much needed by the industry is more digital enablement across various touch-

points in the clinical trial lifecycle and creating a robust technology backbone.

While the pandemic saw the introduction of digital approval processes for clinical trial protocol review by ethics committees, more needs to be done and the regulators need to incorporate more tech-enabled options, such as decentralised trials (DCTs), which are becoming more pervasive world over. These remote-based trials with patients participating from the comfort of

their homes would be a significant advantage in a country like India which has such a diverse and geographically spread-out population. Tech innovations in DCTs include telemedicine, electronic clinical outcome assessments, e-consent and integrated digital health platforms such as participant reminders and other engagement tools.



“While the pandemic saw the introduction of digital approval processes for clinical trial protocol review by ethics committees, more needs to be done and the regulators need to incorporate more tech-enabled options, such as decentralised trials (DCTs), which are becoming more pervasive world over”

Jinu Jose

Vice President, Head – Sales and Clinical Operations, R&D Solutions, IQVIA India

Strengthening India’s research and innovation ecosystem requires consistent and strong collaborative efforts of all stakeholder groups from big and emerging biopharma companies, startups and

entrepreneurs, academia and clinical researchers. These stakeholder groups’ efforts further need to be supported by growth enablers like infrastructure, financing, and supporting policies and regulations.

All of these developments hold promise for emerging biopharma companies that are flexible and eager to embrace new and innovative processes, be it for DCTs, remote monitoring, patient enrollment and

more. There is no doubt that India is a significant market with untapped potential in the biopharma industry. As we come out of the pandemic, we need to take lessons from the last couple of years and work closely

with regulators to build an ecosystem that is predictive and precise, and drives better patient outcomes in a country that has the second highest patient population and the world’s largest disease burden.



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Enhance resilience of industrial networks through longer-term emergency planning and strategic collaborations

Following the outbreak of the COVID-19 pandemic, the pharma industry and the global healthcare sector have been significantly affected in an unseen way, prompting pharma companies to shift their focus to prompt, flexible and transparent operations, as well as helping shape the workforce of the future.

In the path of COVID-19 recovery, focussing on key factors is critical for Indian pharma to emerge in the global pharma hierarchy. This involves creating a favourable climate for local production and exports, as well as fostering innovation through a greater focus on research and development.

While pharma sector companies had previously begun to consider methods to improve their value offer, the COVID-19 outbreak has hastened this process due to the challenges it has brought. Massive joint initiatives involving the government, industry and regulatory bodies are becoming increasingly prominent. Various stakeholders have banded together



“While pharma sector companies had previously begun to consider methods to improve their value offer, the COVID-19 outbreak has hastened this process due to the challenges it has brought”

Arvind Sharma
Partner, Shardul Amarchand Mangaldas & Co

to facilitate the cross-border delivery of critical medications, manage labour safety and deal with increasing regulatory limitations, all while preparing for new vaccines and therapies.

Several businesses have established crisis-response command centres to restore calm and effectively control a rather tense situation.

Companies may begin tak-

ing stock of what the future holds now that these efforts have been made. Corporations are also shifting their focus to recovery and the route to the new normal. This will very certainly result in significant changes in pharma operations. While several of these changes will be driven by individual enterprises, others will be industry-wide, along with external factors, such as government engagement, that will also influence the post-COVID-19 recovery.

Commonalities between well-studied diseases and the coronavirus are being assessed by researchers, who are sifting through massive databases and previous findings using AI, with the purpose of reusing drugs that have been already marketed or designing groundbreaking new drugs for coronavirus or other diseases. An important step to be taken is to enhance the resilience of industrial networks, for which longer-term emergency planning and strategic collaborations are required. Companies

must be able to rely on a large number of partners for this purpose. Following the pandemic, industry leaders are incorporating Artificial Intelligence (AI) in their processes and utilising AI's benefits. AI can also help pharma businesses manage the massive volumes of data and contracts they deal with on a regular basis. One of the key lessons learnt from the pandemic is that countries prioritising their own interests results in ramifications on the global supply chains which include bans or severe restrictions on the export of raw materials, medical products, personal protective equipment, human resources, as well as manufacturing supplies.

The progress gained in treating and preventing COVID-19 was enormous. When the world begins to recover, pharma should consider what remains to be done to better harness the industry's collective expertise garnered over this period, and to build on what worked while improving on what did not.

Technological trends are sure to transform pharma industry

In India, the pharma market is projected to reach \$65 billion by 2024 and grow to \$120-130 billion by 2030. Recent initiatives like the National Digital Health Mission (NDHM) and government attempts to unify the pharma sector are providing opportunities for innovation from within the pharma sector in different forms of technology. This includes AI and Machine Learning (ML)

capabilities being used more extensively now than ever before.

The use of AI and ML is propelling the drug discovery and development processes. Startups are employing these technologies to address the numerous challenges in the healthcare industry, including automation of manufacturing processes as well as designing effective post-launch strategies. Eligibility criteria

identification is an essential step in the drug discovery and development process, which makes it vital for conducting clinical trials. AI simplifies patients' identification by making it fast and affordable, thus saving time for this key step.

The large volume of data available throughout the drug discovery and development process requires high-performance systems to properly analyse data and derive value

from it. Therefore, pharma companies are looking to open up their data to third parties who can leverage those numbers for applications like modelling, thus making data management a crucial aspect of the innovation ecosystem. Moreover, the analytical techniques are used on almost all types of medical data from patient records, medical imaging, hospital data, etc.

Blockchain technology is

being explored to track the sale of counterfeit drugs and substandard medicine that enter into the pharma supply chain and kill thousands of patients every year. The ability to share transactions makes blockchain a promising solution for securing transactions in the pharma supply chain ecosystem.

Mixed reality, virtual reality and augmented reality are making the visualisation of



“Precision medicine is coming from new technology that has allowed researchers to better understand and apply the differences in the way people respond to drugs”

Vinay K Mayer
 Director – Market Research and Consulting,
 Asia Research Partners LLP

data a more meaningful reality than ever before, in several ways related to the biomedical sector. With tools like

HoloLens, enterprises can cost-effectively design holographic augmented-reality applications that facilitate better interactivity with live-data samples and construction blueprints for example. Because of this, there has been more exploration for potential human augmentation of pharma products in the manufacturing spheres.

The concept of precision

medicine relies on the idea that each patient is an individual. Precision medicine is coming from new technology that has allowed researchers to better understand and apply the differences in the way people respond to drugs. With advanced manufacturing methods like 3D printing and other innovations, precision medical manufacturing is helping shape how we, as a society, approach

healthcare by focussing on making drugs more effective and less dangerous for individual patients.

Pharma technology has advanced to the point where we can now predict patients' behaviour and outcomes. Predictive models like this certainly help match patients with the most effective treatment plans. The more we know about how each patient will respond to specific treatment plans, the better we are able to prevent adverse events and develop individualised plans for those who show signs of illness earlier in their healthcare experience. However, since their high costs prevent most businesses from adopting them, these technological trends are sure to transform the pharma industry.

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In the drug development process, the role of patients is fundamental

The pandemic has shown that an all-around patient-centric approach is the future of the pharma and healthcare industry. Pharma companies must be prepared to participate in an emerging health ecosystem where patient advocacy groups, disease foundations, healthcare systems and doctors, health plans, competitors, regulators, wellness and technology companies work in tandem, keeping the patient at the centre. With digitisation and technology pervading the healthcare industry at a rapid pace, this shift is expected to be much more immediate than imagined.

In the drug development process, the role of patients is fundamental. However, the



“Pharma companies are eager to understand how patients respond to therapies and identify sub-populations to ultimately improve health outcomes. AI platforms can help understand and predict the behaviour of the patients”

Nikkhil K Masurkar
Executive Director, Entod Pharmaceuticals

focus is now more on engaging patients as ‘individuals’ in clinical trials and not simply as ‘patients.’ To achieve the same, pharma companies are providing Plain Language Summaries, written keeping in mind the patient in mind, not the clinician. When patients are able to understand the re-

sults of the study, they feel better about the entire experience and are more willing to take active participation. This can improve the overall outcome of clinical trials.

A better understanding of the target population needs is also helpful in designing mechanisms that may affect the use

of certain drugs. For example, paediatric and geriatric patients often face difficulties in swallowing capsules or tablets. Another example is people with arthritis may not be able to use medication packages with child lock. Making oral dosages easier to swallow and better tasting can aid compliance, as would packaging that is easier to open.

The development of a drug starts with the discovery of an Active Pharma Ingredient (API) for potential use against an unmet or underserved medical need. At every stage of the development process, it is recommended to complete a detailed product profile ques-

Continued on Page 21

To job or not to job

In the wake of considerable success of vaccination drive in India, certain local administrators (e.g. district-level authorities at Bengaluru, Kerala, Pune and Chennai) imposed liability on the private employers to ensure that the employees attending offices physically are duly vaccinated and are compliant with COVID-appropriate behaviour. Some of these administrators have also gone ahead to state that the employers should bear the cost of vaccination and appoint an officer to ensure compliance. It may be pertinent to note that the orders issued by the local administrators are issued under the provisions of Disaster Management Act, 2005, Epidemic Diseases Act, 1897 or other similar state-level statutes. None of these orders are issued from the perspective of labour law-compliance and hence are silent on the vaccination being linked to terms of employment or actions to be taken against the employees for non-vaccination.



“Several high courts have taken the view that mandatory or forceful vaccination does not find any force in law, and continuity of employment linked to vaccination would unreasonably discriminate only against unvaccinated persons and deprive them of their livelihood”

Upendra Nath Sharma
Partner, J Sagar Associates

This raises the question of whether mandatory vaccination policy can be imposed by an employer upon its employees, and, if yes, whether any action can be taken against the employees refusing to take vaccination.

In this regard, the Central government in its FAQs has clearly stated that vaccination for COVID-19 is voluntary. Further, while the courts have emphasised on the importance of vaccination, several high courts have taken the view that manda-

tory or forceful vaccination does not find any force in law, and continuity of employment linked to vaccination would unreasonably discriminate only against unvaccinated persons and deprive them of their livelihood.

A few matters relating to legality of mandatory vaccination remain subjudice under different high courts. Currently, there is a lack of clarity as to the actions which can be taken by employers if the employees refuse to get vaccinated. Basis the

views taken by courts thus far and the clarity provided in FAQs, it can be inferred that termination of employment cannot be made a consequence of an employee’s refusal or inability to get vaccinated.

For implementing a mandatory vaccination policy, the employers may consider including requirement of vaccination as part of employee handbook, employment contract or pre-condition for appointment of a non-workman (white collar

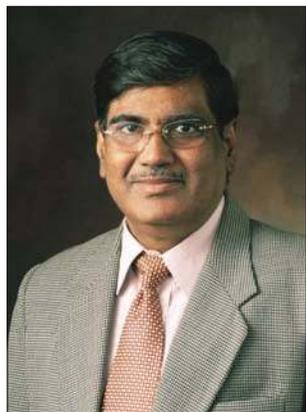
employees). However, in case of workmen (blue collar employees), vaccination cannot be made a ground for dismissal or retrenchment under the applicable statutes. As an alternative, employers can conduct vaccination camps, offer reimbursement of cost of vaccination or offer other positive incentives to employees who are vaccinated and can require attendance of such employees in the workplace.

Further, for implementation of vaccination policy, the employers must also ensure that they comply with all the guidelines of COVID-appropriate behaviours, applicable for their relevant jurisdictions, and obtain express consent of the employees before requesting proof of vaccination, as the medical records are considered as ‘sensitive personal information’ under Information Technology (reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

Innovations should be consumer-friendly

COVID-19 has been one of the strongest drivers leading to an increase in the concern of the patients towards their health. Moreover, the buying patterns of the consumers have also shown a tremendous change, wherein the consumption of products such as immunity boosters and vitamin supplements has shown a rapid increment. This change in attitude strongly indicates a dire need for the evolution from the traditional, disease-oriented methodology to a patient-centric outlook in the Indian pharma scenario.

Many changes and rising trends can be observed in the pharma domain owing to a lot of factors such as the pandemic and rapidly evolving technologies. Moreover, in order to achieve the ideal patient-centric pharma domain, improved drug delivery systems are available. For instance, formulations such as rapid Mouth Dissolving Tablets (MDTs) are developed that are geriatric- and paediatric-friendly and show better bioavailability than the conven-



tional tablet dosage form.

Additionally, with the rise in several genetic diseases, a one-solution-for-all model stands obsolete. Personalised healthcare can be the only solution and precision medicine is the key to it. Precision medicine is an emerging trend that is interdisciplinary in nature. Currently, what the pharma industry needs is appropriate technology and data analytics tools to manage patient data and provide necessary insights.

Engagement with the patients increases the quality of the treatment exponentially and also impacts the cost of

“Many changes and rising trends can be observed in the pharma domain owing to a lot of factors such as the pandemic and rapidly evolving technologies”

Dr RB Smarta

CMD – Interlink, and Vice President, HADSA

the treatment favourably. One such avenue is the patient engagement apps. These beyond the pill apps are essential as they regularly monitor the progress of a patient as well as supervise patient adherence towards the regimen. Various prominent pharma companies such as Abbott, Pfizer and Merck are adopting apps that help in monitoring their patient's health and providing doctor's assistance is evidence of the usefulness in going beyond the pill.

Furthermore, the Indian e-pharmacy sector is gaining rapid momentum as well. The market is estimated to reach

\$2.7 billion by 2030 and this figure was estimated even before the pandemic came into existence. The waves of COVID-19 resulted in a rise in demand for oximeters, PPE kits, sanitisers and other health equipment. Chronic diseases, the rise of the internet and the ease in ordering medications are some of the other growth drivers of the market. With various key market players such as NetMeds and PharmEasy aiming for patient satisfaction into the play, the growth looks promising. Telemedicine and teleconsultation are two such avenues because of which distance is no longer a barrier for

the patients to avail medical assistance.

As seen in the above examples, patient-centricity is the new norm and digitisation is inevitable. In order for companies to sustain themselves with the changing times, they have to adapt themselves keeping the patients or consumers in mind. Firstly, the organisation needs to adapt its goals and objectives in line with patients. Moreover, they also need to adopt various digital and data analytics opportunities to understand their strengths and weaknesses as well as engage and collect patient data.

The Indian pharma industry is highly driven by innovative technology. In such a situation, it is essential to note that the innovations should be consumer-friendly as well. The drug discovery, manufacturing and regulatory process are tedious and this would create a gap between the industry and the patients. It is of paramount importance that in order to create an ideal patient-centric model, such a 'patient-technology' gap must be met.

In the drug development process...

Continued from Page 20

tionnaire before the initiation of any formulation work, and this should be reviewed continually. This forms a crucial part of the risk assessment process at every stage of the project and makes sure that the programme is always aimed at improving the quality of life of patients. For instance, in the case of orphan drug products, it can be useful to engage with patient support groups to make sure that their particular needs are kept in consideration throughout the

programme and achieved upon conclusion.

The shift in focus to patient-centric care has given rise to the pharma Internet of Things (IoT). It mainly revolves around smart applications and connected devices, cloud services in creating patient medical record databases, drug development, clinical trials and patient care. Pharma companies are eager to understand how patients respond to therapies and identify sub-populations to ultimately improve health outcomes. AI platforms can help

This can help to understand the gaps in the lifecycle of the products and the findings can be used further for research and development

understand and predict the behaviour of the patients. This can help to understand the gaps in the lifecycle of the products and the findings can be used further for research and development.

Through the use of advanced technologies, pharma companies are now working on collecting multiple data points such as a patient's genomic, molecular, phenotypic and clinical data. The multiple

variables that are collected could be used to simulate clinical trials that can improve clinical trial outcomes and reduce the time taken to complete trials.

Moreover, with the increasing use of wearables, patients are now able to monitor their health and connect with their doctor, while the devices also act as alarms alerting doctors about an impending health outcome. This information can not only be used to help the patient concerned, but can also be used to develop better treatments that could help many more.

INTERVIEW

We are in a better shape to handle any untoward circumstances

Ravi Udaya Bhaskar, Director-General, Pharmexcil, shares the scenario of pharma imports and exports, and the role played by Pharmexcil to maintain the global supply chain during the COVID-19 pandemic, amidst more, with **Akanki Sharma** in an exclusive interaction

Since the outbreak of the pandemic, India Pharma Inc has dealt with unprecedented challenges. What were the top three challenges faced by the Indian pharma industry during the pandemic when it comes to exports? How did Pharmexcil help the industry in overcoming those?

India pharma industry imports most of the KSMs, intermediates and reasonable quantities of APIs. Majority of these are from one single source – China, which has been affected. While India had to, wherever possible, increase local capacities, it also had to find alternate sources across the globe to meet the high demand for finished dosage formulations and APIs from within as well as outside.

Further, transport to move the material was a big task. This was also the case in finding proper shipping lines to export the formulations as well as API. It was precise planning while liaising with the government and the industry, Pharmexcil could bring the issue to manageable levels.

Can you give us an overview on how Indian pharma exports have fared in the past three years? What are the targets for 2022? How is Pharmexcil helping the industry to work towards it? During the past three years, India's pharma exports did well, particularly during the



Pharmexcil has initiated virtual business meets with Oceania, Africa, LAC, GCC, NEA and other regions to facilitate our exporters for contacting more importers to enhance their exports

pandemic (2020-21) and the growth rate mentioned below is achieved after eight years.

Years	Turnover	Gr%
2018-19	19134.49	10.72
2019-20	20703.46	8.2
2020-21	24469.23	18.19

During the current year (2021-22), the commerce ministry set an ambitious export target of pharma that is around \$29 billion. Pharmexcil has initiated virtual business meets with Oceania, Africa, LAC, GCC, NEA and other regions to facilitate our exporters for contacting more importers to enhance their exports.

As new opportunities emerge in the global market for India Pharma Inc, what are the three most important steps that companies should consider to smoothen and de-risk their supply chain? The Government of India has already initiated Production Linked Incentive (PLI) schemes to improve bulk drug

production. Meanwhile, the industry would do well to always develop more sources for their needs. Newer opportunities in the form of vaccines, especially COVID vaccines and newer dosage forms for the existing products, are emerging. Our industry is aware of this development and we have most of our exporters taking strides in that direction.

Can you elaborate on the impact of the PLI scheme on pharma exports from India? Certainly, it will have a positive impact. However, it's too early to say how it synergises exports; but, for sure, it reduces our import dependence and enhances our export potential.

As newer variants of coronavirus emerge, how well-prepared is the Indian pharma industry to deal with the likely disruptions to its global supply chain? As of now, experts feel newer variants may be within manageable reach and companies engaged in vaccine manufacturing are capable of modifying their products accordingly at a rapid speed in India as well as in foreign countries. With the experience industry and other stake holders involved, including governments world over gained, we are in a better shape to handle any untoward circumstances.

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S.M.A.R.T Pharmaceuticals 2021-2030

Dr Ajaz Hussain, PhD and independent adviser, explains how to make common sense a SMART factory as the political and regulatory push for Industry 4.0 intensifies and take steps to understand options to align natural (i.e., within) and emerging artificial SMARTs - Self-Monitoring, Analysis and Reporting Technology in how we manage systems with Specific, Measurable, Achievable, Relevant, and Timely (or Time-bound) objectives

At the end of 2021, experiencing the surging uncertainty of Omicron as possibly a fifth coronavirus wave threatening a "Dark Winter" in the US and other countries, and anticipating advancing SMART factories making medicines called S.M.A.R.T Pharmaceuticals, this report spirals above the efforts on the ground supercharging the Industry 4.0 revolution to begin a professional journey to 2030.

Like some migratory birds navigate in the darkness using an internal "magnetic compass," this migration to the next stage of development utilises feelings (experience) to guide progress in uncertainty and complements vision 2020, naturally corrected SMARTly.

To prepare for this journey, let us recall some lessons in process understanding as defined in the "PAT Guidance" (2004) to make sense of anticipated chaos and pandemonium in this decade of the 21st century and know what it will take to be a "good practitioner." To be objective and evidence-based in our journey, let us select a predicated point of reference, the letter and spirit of the US Food, Drug, and Cosmetic Act of 1938, as amended in 1962.

Acknowledging that nothing is perfect, errors can occur but not repeat as mistakes. When necessary, course-correcting should be based on good and non-theory laden observations. Efforts to improve continually, based on continuing "scientific training and experience" is needed to "fairly and responsibly" deliver "substantial evidence of effectiveness." Let us begin to explore how to make common sense of SMART as Industry 4.0 advances and take steps to understand options to align our



natural and emerging artificial SMART - Self-Monitoring Analysis and Reporting Technology in how we manage systems with Specific, Measurable, Achievable, Relevant, and Timely (or Timebound) objectives.

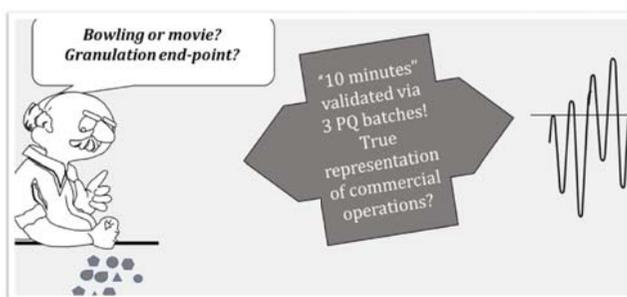


Figure 1 memorialises a point of initiation of the PAT initiative at FDA; it is included to invoke some thoughts and emphasise the importance of contemporaneous notes. In this case, a contemporary record; a presentation slide in 2000. It memorialises how the PAT/QbD journey began in 2000. Few presentation slides can still be found on the internet of the talk entitled "Advanced Quality Control of Pharmaceuticals: In-line Process Controls" at the FIP Millennium Conference, San Francisco (2000), by the author and his collaborator Dr Tom Layloff then at the USP. A related video message recorded in 2004 is available on YouTube; those interested can let their fingers go walking to locate it

"SMART Pharmaceuticals" invokes the notion of digital therapeutics and pills with embedded sensors that digitally track behaviours and medical surveillance and, broadly any pharmaceuticals made in a "SMART factory." Pharmaceuticals manufactured in standard and a "SMART factory" are the subjects of this report. Continued professional development is essential to remain "current" in pharmaceutical product development and manufacturing. The suitability and capability needed to do so in this decade will increasingly be gauged in the context of managing *fairly and responsibly*, locally and broadly, across sociotechnical systems we live and work.

The ensuing narrative intends to objectively empower individuals to progress in their efforts to develop to their next stage of maturity via attention to and proficiency in a valid experiential learning process.

What does it mean to learn from the experience? Do we do so with an SOP or broadly when allowed to experience different viewpoints and encouraged to innovate? What if such opportunities are not offered - how to self-empower are some questions explored implicitly in this report. The exploration itself is an experiential journey in practicing to take a migratory bird's-eye view to observe events in the real world from different viewpoints including insights. Within our worldview or scope is the experiential learning at the initiation and evolution of PAT initiative⁽¹⁾ at the US FDA, some twenty years ago and described in a journey from 2013 to 2020. How can this help to anticipate progress of the Industry 4.0 revolution in manifesting

SMART factories by 2030 is considered.

We experience unfairness in life and at work (in new drug development, manufacturing, and all functions) as negative emotions such as anger and hate. To consider the relevance of "*fairly and responsibly*" in the regulatory context, this report reminds of practices such as "*file [ANDA] first and figure it out later*," incentivised in the FD&C Act and habitually mandated in parts of the sector. Regulatory approval is often a reason to celebrate and grant bonuses to the development and regulatory departments. However, if or when the manufacturing and quality department struggle to reproducibly manufacture an "FDA approved" product with a process claimed to have been "validated," the finger is pointed at who?

The Subject of this Report is Experience

The word "*experience*, derived from Latin *experientia*," means a trial, experiment knowledge gained by repeated trials", and as a verb, it means having first-hand knowledge of states, situations, emotions and sensations.

In the regulated CGMP environment, processes are expected to be "validated," and validity provides a high level of assurance of repeatability and reproducibility of predicted results. Hence, to be considered good, personnel must follow "valid" procedures, no matter the outcome.

Experiments to ensure repeatability are for the development phase exhibit batches. When transferring technology from development to operations, reproducibility by representative operators is

verified as the process qualification, part of process validation as described, for instance, the FDA guidance. Adequacy of qualification, which is supposed to include the representative experience of the operators who will manufacture routinely. However, it is often difficult to assess the state of validation without continued process verification. Therefore, it is not uncommon to note lagging indicators of control and reactive events resulting in regulatory warning letters.

Such events can induce fear, and negative emotions are not conducive to learning. So, what does it mean to learn from experience in a CGMP facility and broadly when one must comply with Standard Operating Procedures (SOPs)?

As a good practitioner, responsibility, in part, is trustworthiness. With the "validation" of our professional development and maturity, *albeit* a subjective judgement, others should fairly and responsibly recognise individual "suitability" (for instance -to be fair) and "capability" to be responsible and, in the context of promotion, take on increasing responsibility. Can Artificial Intelligence (AI) as a SMART supervisor be more objective than a human supervisor?

What does 'exploration narrated is an experiential' noted above mean? It means an objective process is followed to account for feelings (experience). Such a process guides the ensuing discussion. It emphasises unbiased, non-theory laden observations, as illustrated in *Figure 2*.

Being wedded to our theories and plans can be comforting. Actively being aware of ex-

zones, egos and self-interest. When we do not acknowledge unexpected results, as often also observed with adverse reports and phase-IV commitment, it represents a conflict of interest. It takes away from our commitment to being *fair and responsible*.

In committing to being open to new data that may not be what we expected and practising to be a good observer, we test and challenge our plans, theories, and practices and go beyond our education and training to continuously experience and empower our development. So, then what is it that helps us to be SMART within, naturally?

Naturally, SMART within

In most corporations, it is a typical course of business for management to instruct how to set objectives for annual performance review. A SMART process of establishing and implementing performance objectives involves aspects of SMART as in self-monitoring progress, analysing deviations per plan, course corrections, remediation, and achievements, and providing periodic reports using accepted techniques such as reports, emails, etc.

In *Table 1*, the Specific, Measurable, Achievable, Relevant, and Timely (or Timebound) management objectives with Self-Monitoring Analysis and Reporting Technology in *Column 2* as an interaction or an interrelationship(↔) and *Column 1* a reminder to introspect on the previous performance (2021) and *Column 3* performance considerations for learning from experience going forward (2022-).

Table 1. Mind matters, naturally. SMARTs within to consider introspecting on 2021 performance, engage SMART interaction, and interrelationship(↔)between objectives and experience in 2022 and know-how to empower and enhance experiential learning in 2022

Performance 2021	Objective Experience 2022	Learning from Experience 2022
Objectives 2021	Specific (↔)Self	Self-authored and self-assured
Measure/monitor?	Measurable(↔)Monitor	Observe, feel, think and intend
Achived or not able?	Achievable(↔)Analysis	Recognize (patterns), reproduce, repeat
Reported relevant?	Relevant (↔) Reporting	Note insights contemporaneously
On-time or not?	Timely(↔)Technology	Texts, blog, report writing

What does it take to be SMART within, naturally in ways that ensure our commitment to the stated mission, vision, policies, and objectives we document? Sometimes or often as the case may be, it is hard to set SMART goals and be smart about these objectives and be committed? What "life experiences" are foundational to adult development and maturation? Some adults continue to mature, but at different rates; many do not. What are experiences relevant to professional development? How do these relate to experience as a mode of qualifying requirement for CGMP operations as in the US regulations at 21 CFR 211.25, education, training, and experience"? We can extend this question to other functions, for instance, experience as a qualifying criterion for new drug development in the context of the US Food, Drug and Cosmetic Act of 1938 as amended in 1962, the Kefauver Harris Amendment, or "Drug Efficacy Amendment." This amendment is considered to have revolutionised new drug development, and among other things, stipulates "*scientific training and experience*" to "*fairly and responsibly*" evaluate "*substantial evidence of effectiveness*."

Seeking experiential, not theoretical, insights to these and other questions, I embarked on a journey to 2020 (why 2020 is explained later) in 2013. As the core purpose, I sought answers on how experience interrelates and interacts with quality culture, management systems and good practices before the WHO declared the novel coronavirus (COVID-19) outbreak a global pandemic.

After providing an overview of this journey, the relevance of the insights collected is discussed in the context of SMART Pharmaceuticals 2021-2030.

The journey to 2020: "I can see clearly now."

Serendipitously in mid-2012, I returned to the pharma sector when the attention of the US FDA was sharpening on BAD-I, a topic familiar since when I had moved to the US FDA, leaving behind the comfort of a tenured academic career. I chose the word serendipitously because I had not expected return to the pharma sector, given that I had crossed its boundaries to venture into the tobacco sector. Venturing into the tobacco sector and working on tobacco harm reduction had expanded my awareness of human behaviour, development, and behavioural economics, which informed my journey to 2020.

After a year with Wockhardt, I launched my consulting practice 'Insight, Advice, and Solutions' in July 2013. Soon, two topics - 'Human Factors in GMPs' and 'Culture of Quality' - dominated my teaching and public speaking engagements as a growing cluster of GMP deviations specifically breaches in the assurance of data integrity or BAD-I dominated the sector. Given the opportunity to interact with pharma professionals up and down and across an organisational hierarchy of several companies, it was an opportunity to explore how experience interrelates and interacts with quality culture, management systems and good practices. The

commitment to do so until the 2020 calendar year is my journey to 2020 literally and metaphorically - "I Can See More Clearly Now," and it reconnected me to the launch of the Process Analytica Technology (PAT) Initiative at FDA, where in November 2001, I wrote a few statements to describe a vision of pharmaceutical quality in the context of the, and I titled it 'Vision 2020' - "I can see clearly now."

On this journey, I sought to take a development stance via adaptive and experiential learning focusing my attention on insight as a symbolic "internal magnetic compass" to notice patterns of interactions and inter-relationships between observations, feelings, thoughts and intention to make sense of experience, what it meant, an insight, which I recorded contemporaneously and my learning shared with my network on social media such as *LinkedIn* (e.g., blog posts and articles) and broadly with the community of pharmaceutical practice and knowledge via industry news and update media such as *Express Pharma* and *Biopharm Asia*, industry experts panels such as CPhI community, publication of professional associations such as Indian Pharmaceutical Association's (IPA) *Pharma Times*, and the American Association of Pharmaceutical Scientists Journal *AAPS PharmSciTech* and also a public-private partnership with US FDA - the National Institute for Pharmaceutical Technology and Education (NIPTe). *Table 2* lists the dates and titles of some of these reports to provide a glimpse of



Figure 2. The need to go beyond the theory and practice of industrial pharmacy to be vigilant has never been so acute as it is today. This report expands awareness of the need to validate a personal experiential learning process

ceptions to expected results can take us outside our comfort

The elements outlined in *Table 1* are deceptively simple.

Table 2. Timely, relevant insights reporting helped gauge and monitor progress and provided a means to take a development stance to leverage natural intelligence via SMART within to self-assess progress in self-authorship

Outlets	Date	Title
LinkedIn	23.12.2014	Schrödinger's Cat & My Journey From 2015 to 2020
	29.12.2015	Six Blind Men, Regulatory Science, "Bob's Big Idea" and Gandhi's "a way out of hell": Goodbye 2015
	30.12.2016	"New Prior Knowledge": Roadmap 2017
	30.12.2017	Will Remember 2017 As the Year of Confirming an Amazing Juxtaposition. Message for 2018 - Jump Frog Jump, While You Can!
	31.12.2018	Moving forward with 2020 Vision
	25.12.2019	Vision 2020+: End of a Journey
	22.12.2020	A journey without traveling
Express Pharma	16.11.2013	Strategies for making high pharmaceutical quality affordable
	15.05.2016	Pharma quality assurance in 21st Century: Sharper focus needed on education, training, and experience
	20.05.2017	Strategies for making high pharmaceutical quality affordable: Part II
Biopharm Asia	09/10. 2015	The culture of Pharmaceutical Quality: Connecting the Dots
	11/12. 2015	The culture of Pharmaceutical Quality Management System
	03/04. 2016	The culture of Pharmaceutical Quality: Personnel Development
CPhI Annual Industry Report	10. 2016 (Barcelona)	Adherence to the Current Good Manufacturing Practice (CGMP) Regulations in the 21st Century (also published as Compliance or Adherence? How To Approach cGMP Regulations In The 21st Century? Pharmaceutical Online. Guest Column 22 September 2016.)
	10. 2017 (Frankfurt)	Self-authorship of Performance Standards is Necessary to Break the Pharmaceutical 2-3 Sigma Barrier (also published as How to Break the Pharmaceutical 2-3 Sigma Barrier (Like Amgen). Pharmaceutical Online. 18 September 2017.
	11. 2019 (Frankfurt)	Chaos to Continual Improvement: Path to Harmonization
Pharma Times	06. 2014	Guest Editorial: Pharma Times Special issue on QbD in Pharma Development
	06. 2020	Pharmaceuticals Beyond 2020: Professionals and Artificial Intelligence. Indian Pharmaceutical Association
	12. 2020	Digitization in Pharma and Digital Therapeutics: A Migratory Birds Eye View for Charting a Path Forward
	Several	Mean Meaning Making and Manufacturing Maturity A Column
AAPS PharmSciTech	02.01.2019	Shah, H.S., Chaturvedi, K., Hamad, M. et al. New Insights on Solid-State Changes in the Levothyroxine Sodium Pentahydrate during Dehydration and its Relationship to Chemical Instability. AAPS PharmSciTech 20, 39 (2019). https://doi.org/10.1208/s12249-018-1264-0
	12.03.2019	Hussain, A.S., Gurvich, V.J. & Morris, K. Pharmaceutical "New Prior Knowledge": Twenty-First Century Assurance of Therapeutic Equivalence. AAPS PharmSciTech 20, 140 (2019). https://doi.org/10.1208/s12249-019-1347-6
	24.05.2020	Gurvich, V.J., Hussain, A.S. In, and Beyond COVID-19: US Academic Pharmaceutical Science and Engineering Community Must Engage to Meet Critical National Needs. AAPS PharmSciTech 21, 153 (2020). https://doi.org/10.1208/s12249-020-01718-9
	04.03.2021	Hussain, A.S., Morris, K. & Gurvich, V.J. Pharmaceutical Quality, Team Science, and Education Themes: Observations and Commentary on a Remarkable AAPS PharmSciTech Theme Issue. AAPS PharmSciTech 22, 88 (2021). https://doi.org/10.1208/s12249-021-01970-7
NIPTE related	18.12.2016	NIPTE 2016: from roadblocks to roadmap-2017, with a 2020 vision. President's report. 2016. https://nipte.org/wp-content/uploads/2018/10/Roadblocks-to-Roadmap-2017-with-A-2020-Vision-12182016-Final-Version.pdf .
	16.06.2016	The National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE) recommended topics for inclusion in the FY 2017 Regulatory Science Plan. 16 June 2016. Docket ID: FDA-2013-N-0402. Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives Part 15 Public Meeting, 2016.
	10.04.2017	How Trump and the FDA Can Create a Pharmaceutical Manufacturing Renaissance. Opinion Morning Consult. https://morningconsult.com/opinions/trump-fda-can-create-pharmaceutical-manufacturing-renaissance/
	24.06.2018	The National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE) recommends planning FY 2019 GDUFA regulatory science initiatives. Submitted 24 June 2018, to Federal Register Docket FDA-2017-N-6644.
	08.12.2020	Industrial Policy and NIPTE: Goodbye NIPTE. 2020 NIPTE Research Conference. https://www2.slideshare.net/a2zpharmsci/industrial-policy-and-nipte-goodbye-nipte

how the journey progressed. Beyond daily posts, over 45 articles are posted on *LinkedIn*; only the "end of the year" articles are listed. In December 2014, when insight into the value of social media posts to experiential learning was noted, the journey from 2015 to 2020 was named-'Schrödinger's Cat & My Journey From 2015 to 2020.' Further, not listed in *Table 2* are recordings and posted slides of conference presentations (if in-terested, see: YouTube <https://www.youtube.com/channel/UCRkXTgz4kZ7WQdYO1uf9RyQ> and SlideShare <https://www2.slideshare.net/a2zpharmsci/>).

It is beyond the scope of this report to summarise all insights collected. So, in this section, a few topics are elaborated.

What is a good quality culture? A sentiment (force) permeating the environment to help us expand our awareness and simultaneously empowers all to continue their development and maturity from their current capability and suitability. The commitment and message credibility of founders, promoters, corporate board and officers to generate quality culture is a social force, as is fairness and responsibility to pursue the stated mission and vision per formulated quality policies and incentives. These forces permeate horizontally and vertically with "peer involvement" and "employee empowerment" via formalised and informal interrelationships and interactions we call reporting and meetings. Intentionally becoming aware of and leveraging this force, horizontally and vertically, in any hierarchy is how the enablers interact and interrelate to share their source code openly so that others can assess and, when convinced, use it to build their executable continuous development programmes - stand-alone or aligned with an enterprise-wide system.

We sustain and build a quality culture in moments that can be gauged in the choices of words to report minutes of meetings. A pledge of commitment can be a

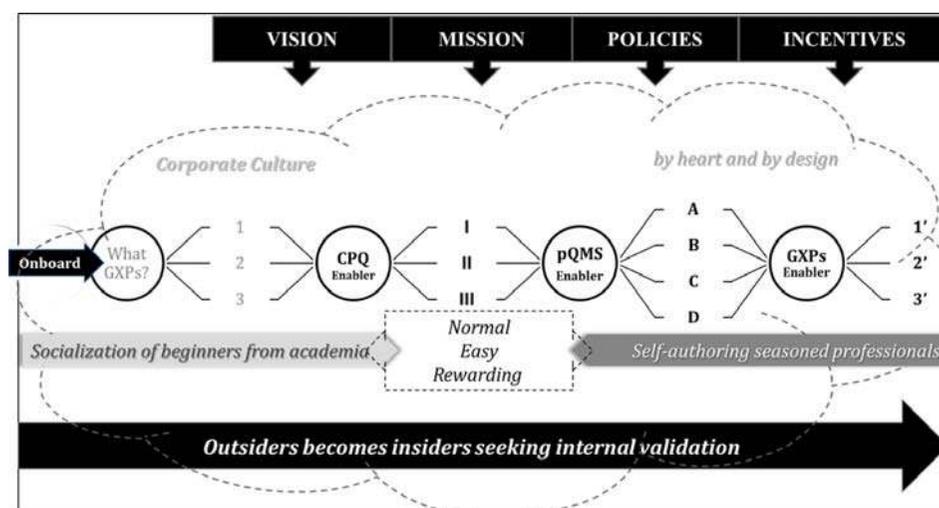


Figure 3. A simple "connect the dot" framework to visualise makes sense of cultures as a network of modulating interactions and interrelationships as in a neural network between people, systems and the sentiment (social force) in an environment that makes good practice normal, easy and rewarding

reinforcing interaction to understand a quality policy that typically hangs on a wall.

Recruitment and onboarding (- IQ) and orientation (-OQ) are socialisation processes that should carefully transform outsiders into insiders to build teams and prevent "group-think" by actively remove fear, expanding awareness and empowering mastery to be internally validated to self-author procedures and plans to be self-assured in their responsibilities and demonstrate suitability and capability of taking on increasing responsibility. To give others assurance with integrity, we first must be self-assured. The relevant interactions and interrelationships to achieve these objectives should formally be a part of the pQMS such that metaphorically anybody can dance - ABCD. We recognise knowledge and risk management as key enablers of pQMS; ABCD calls for a formal, systemic effort to acknowledge and manage uncertainty and expectations on deviations, OOS, CAPA, continual improvement and continuous professional development. In the letter and spirit of the FD&C Act, theory to practice takes us to commercial operations, commitment to being vigilant, good observers, and experience is essential to sustain credibility and develop professionally.

The PAT initiative, which opened the door to FDA's

Pharmaceutical CGMPs for the 21st Century: A Risk-based Approach and to Pharmaceutical Quality for the 21st Century at the International Conference for Harmonisation, ICH - which now is the International Council for Harmonisation, resulted in several "guidance documents" and this process continues to spiral with a draft ICH guidance on continuous manufacturing and a concept paper to spiral back to update ICH Q2 in the framework of analytical quality by design to facilitate real-time control and product release. In a highly heterogeneous sector spread across developed and emerging economies, converting this information to knowledge in practice remains a perpetual challenge. Efforts to educate and train need to be complemented with experiential learning to overcome this challenge. To facilitate experiential learning, we must change how we feel and think, and act synchronously. A quality culture needs to simplify interactions and interrelationships between management systems and practitioners to make it normal, easy, and rewarding.

The pharmaceutical sector is a heterogeneous collection of small and large corporations. Recruiting, onboarding and orientation programmes vary considerably - from "walk-in hiring" to elaborate orientation with programmes for continuous professional development.

At most, the notion of system and systems thinking and quality culture can be amorphous and "brand" identity at few corporations. The frequency at which the US FDA CGMP inspections are the only objective assessment of quality system effectiveness can be unacceptably high. Therefore, this journey aimed to collect insights to facilitate individual empowerment of continuous professional development and maturity. Facilitation means removing barriers, blind spots, sharing know-how and acknowledging that - "You have to do your own growing no matter how tall your grandfather was." -Abraham Lincoln. The opportunity to take a development stance while interacting and interrelating within (novice, seasoned professional, and at the board level) and across systems (multi-university collaboration, regulatory and political systems), i.e., taking a "system of systems" (review articles an reports in *Table 2*) perspective was indeed an experience worth writing and learning. The process of experiencing in practice remains similar; the challenge we confront varies, and what we experience, changes. For instance, we worry that we will look bad (to others), seek validation of our opinions, proposals, etc., or we seek to belong to a group, we feel self-assured (internally validated), or we can see the potential to do good in others

despite their failures. Although our development and maturity occur in many dimensions - the emotion in seeking to look good (to others) to be (considered) good by others point to a development stance in which we are seeking external validation, whereas "do good" and "see good" in others point to internal validation.

The following observations on human experience in interaction with smartphones are worth mentioning here. SMART's addictive, enslaving power is troubling in trend and scope. "Aiyo! my SMART phone is developing more efficiently than I, a phrase I wrote in 2020 in an article entitled "Pharmaceuticals Beyond 2020: Professionals and Artificial Intelligence."

Given that artificial SMART is a human invention, it should be obvious that it is manifested from within; obviously. Far from it, it seems to be hidden in plain sight, and for a large segment of the population, far from being obvious. Our dependence on SMARTs can retard our ability to feel in ways to empathise.

The feeling (experience) can be an inner compass, and learning using it objectively is essential to development and maturity. Like a migratory bird, the ability to simultaneously attend to details and panorama during planned introspection and integrate feelings helps to make good sense in uncertainty; this is "Vision 2020+" elaborated in the article (see *Table 2*) "Digitization in Pharma and Digital Therapeutics: A Migratory Birds Eye View for Charting a Path Forward." Such a journey can be transformative, expanded awareness and appreciation of the need to emphasise professional development, which we will discuss further in the current (2021) context and look forward to 2030.

Journey for 2021 to 2030: S.M.A.R.T Pharmaceuticals

A key lesson learned is that vision 2020 was necessary, but not sufficient; Vision 2020+, analogous to the bird's eye view with left-right lateralisation and a built-in magnetic com-

pass to migrate in darkness, is needed to be suitable and capable in chaos - an unpredictable system showing extreme sensitivity to initial or starting conditions.

Amidst the chaos and pandemonium in multiple systems, which are disrupting our supply chains, we must become aware of the S.W.O.T (strength, weakness, opportunities, and threat) of [our] development and maturity in today's realities to prepare to plan and keep these current in being ready to modify the our plans smartly. Concerted effort to "reset" the financial and economic systems and political "build back better" mandates intending to accelerate the revolution we refer to as Industry 4.0 can pose threats and present opportunities which we miss out with lingering weakness and leverage in our maturity, which is now a key strength. To begin such an analysis, we need to know our current state, the leading edge of competition, and the time it takes to be competitive per corporate mission and vision.

The stages in the adult development and maturity model for a SMART factory are illustrated in Figure 4. The leading edge of a digital plant is stage III- the Connected Plant. It is anticipated that several plants will be at maturity stage V - end-to-end automation, machine-to-machine communication and

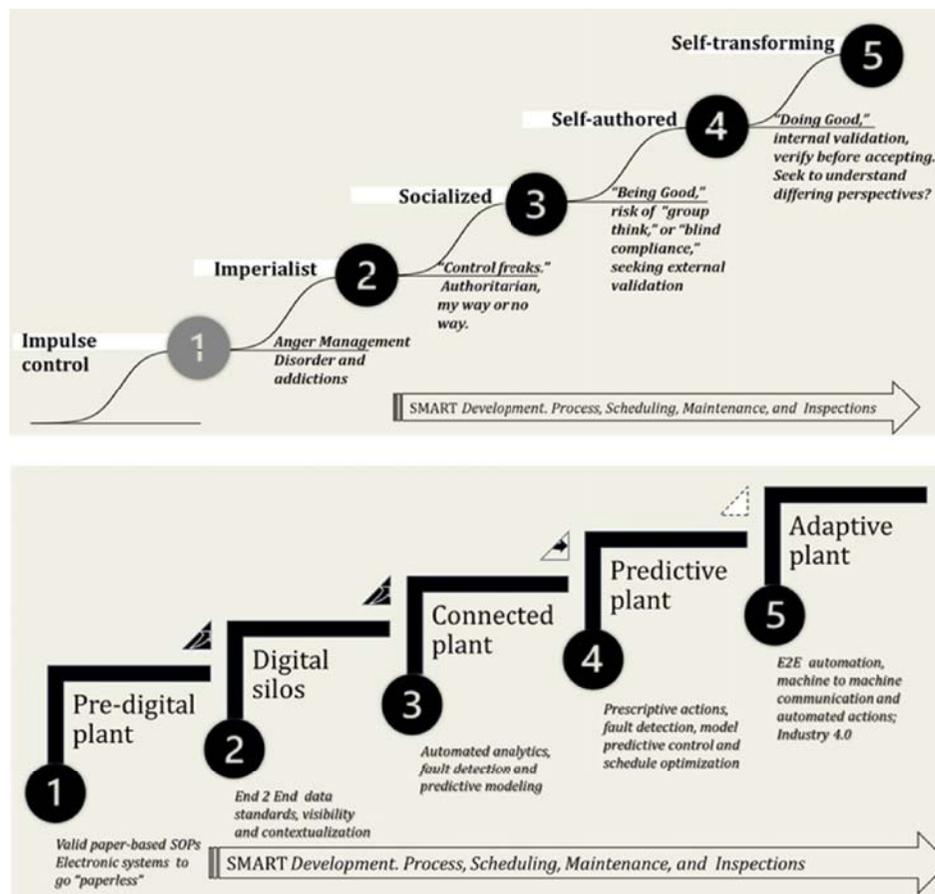


Figure 4. Staged adult development based on Robert Kegan's In Over Our Heads: The Mental Demands of Modern Life, Harvard University Press (Publication Date: 21/07/1998) and BioPhorum Digital Plant Maturity Model (<https://www.biophorum.com/resource/digital-plant-maturity-model/>)

automated actions; i.e., "humanfree" and "carbon-neutral," etc. Regulators in the US, EU and others are politically charged to promote and accelerate the Industry 4.0 revolution; perhaps at disadvantage to traditional manufacturing, it seems that chal-

lenges to regulatory inspections, given the lockdowns, social distancing and travel restrictions, are here to stay in to the future.

Do not underestimate the exponential growth of AI technology; beyond machine learning, natural language

processing, a third-generation emotion chip can understand 64 trillion possible emotional states every 1/10th of a second at any moment. We are in an epoch of unprecedented changes in working and living. In the emerging new world, technologies will dominate

more the markets and business; many (humans) engaged today in manufacturing will need to mature quickly or risk becoming victims to the "mean meaning-making" by profiteers and AI.

We need to smartly go beyond our education a training to continuously learn from experience and empower our development in moments. Note that we sustain and build a quality culture in moments and feelings and intentions are in the words we choos to think and report as in meeting minutes. Learn what you can do to be SMART within, naturally. Prepare for an unprecedented journey to 2030; this is your journey. I wish my journey to 2020 makes a contribution to expanding your awareness to articulate your Vision 2030. Remember - "You have to do your own growing no matter how tall your grandfather was." -Abraham Lincoln.

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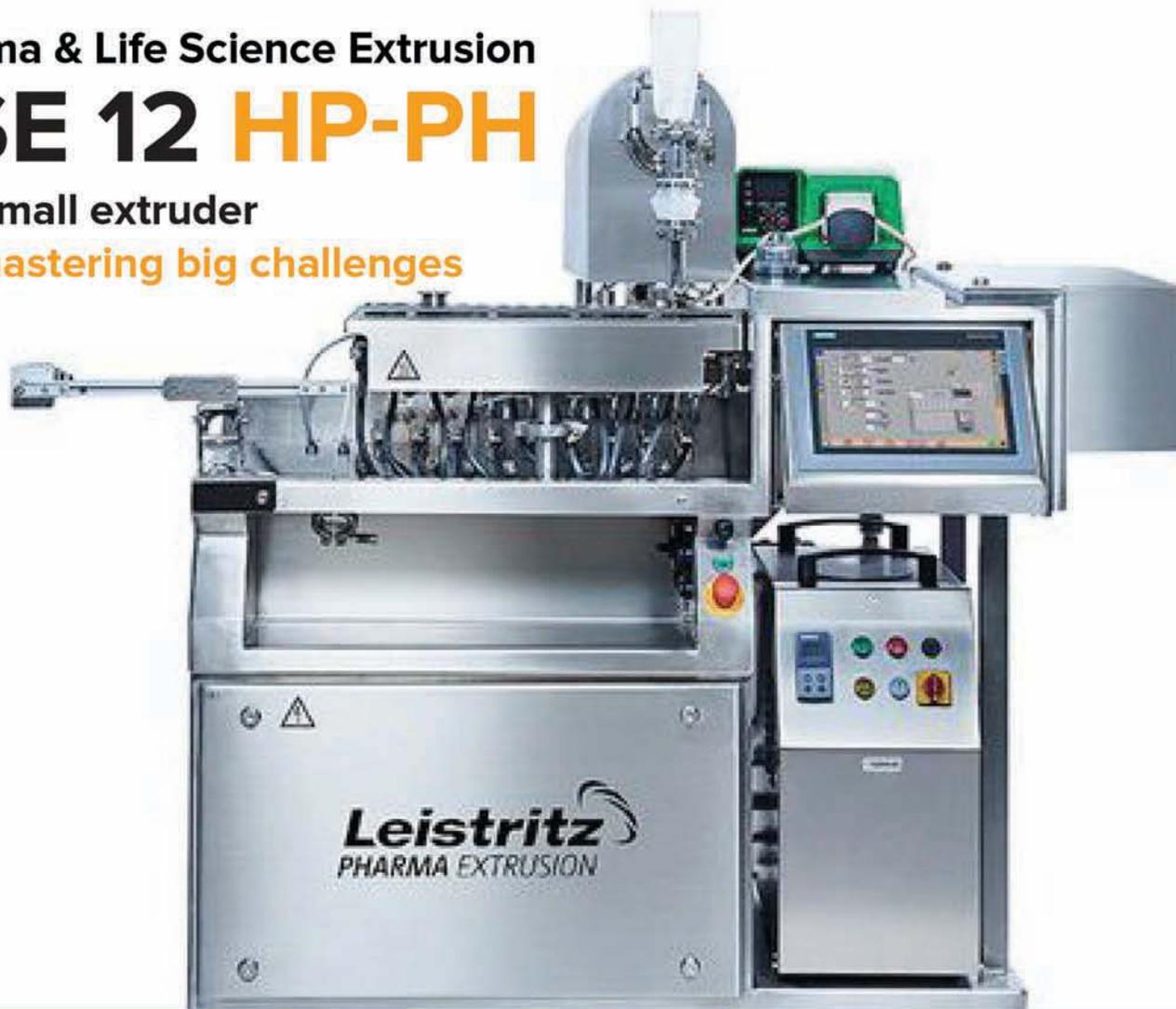
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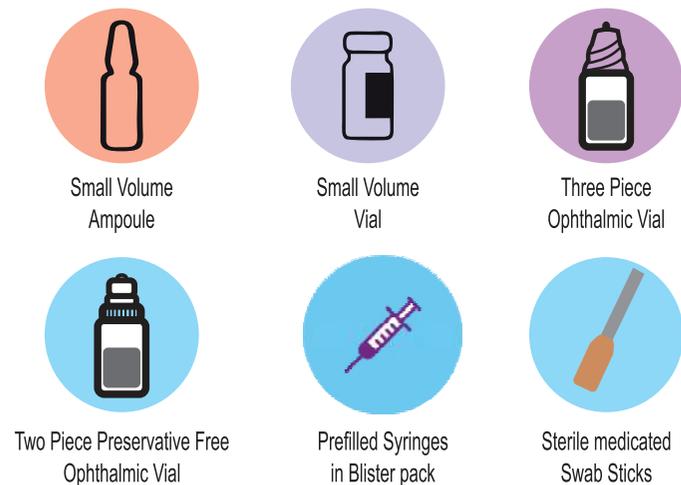
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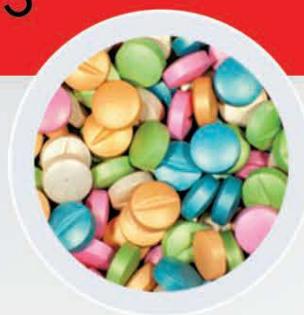
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CPU:	720M/1GHZ ARM Cortex A8	Mechanical Specifications	Material : SS304 with matte finish
Power Supply:	DC 24V, 0.6A		Installation : Floor-mount with stand
Communication:	Ethernet, MODBUS RS 485		Weight : Enclosure + Stand = 24.15 kg
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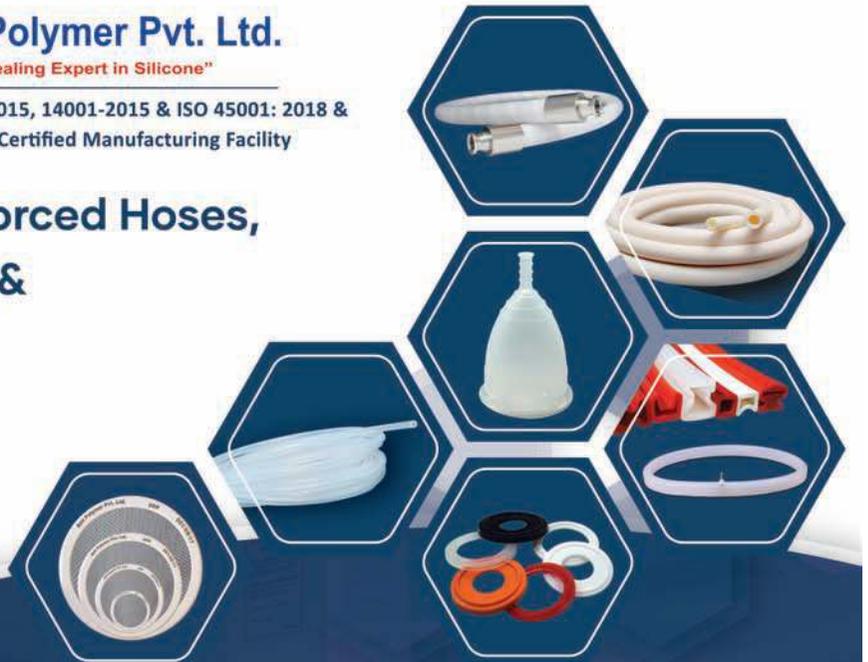
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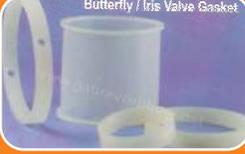


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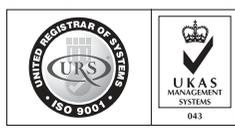
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Serialisation is the key to digital supply chain

The first column of this series looked at the role of product inspection in fill level and product completeness control in the liquid pharmaceutical market. In this article, **Jürgen Kress**, General Manager, Checkweighing and Vision Inspection, Mettler-Toledo Product Inspection, examines the importance of serialisation and aggregation, and how product inspection helps drive transparency in the digital supply chain

The pharma supply chain is a digital one, driven by the electronic exchange of data. It cannot operate without serialisation – giving each product its own unique and verifiable code – and aggregation of batches of products under a similarly verifiable code.

The context is especially important here. A worrying trend in the pharma market is that of counterfeit medicines, with unscrupulous suppliers seeking to make money from copycat medicines, where the standards of product quality and safety are dubious.

Serialisation

The digitalisation of the pharmaceutical supply chain has helped to tackle this problem, and serialisation of products is required in marking out the legitimate products from the fakes. Far more than this though, serialisation also paves the way for digital transparency and traceability throughout the supply chain of individual packs, and manufacturers can benefit from that in many different ways.

For example, it is a fact of life in the pharma business that occasionally there are problems with a product, e.g. a single vial, and it needs to be recalled. With serialisation in place, the manufacturer can utilise the serial code and access an audit trail of events and stages in an individual product's progression through manufacturing and packaging to distribution. If a recall must be made, the manufacturer can therefore be much more targeted in the scope of its recall, calling back just the specific products that it knows have been affected, rather than entire batches, many of which



It is important for liquid pharma manufacturers to make an analysis of their applications, bearing in mind the type of packaging they want to use at the final point of sale

might be perfectly good products.

Aggregation

Serialisation is followed by aggregation, where large batches are grouped together in a box, case or pallet for global or regional distribution of products. Aggregation can also serve as an anti-counterfeit measure offering additional assurance by

checking these secondary boxes at key distribution points. Aggregation is becoming a mandatory requirement for compliance in many countries.

Whether we are talking about the unique serial code on an individual product or that on aggregated batch, the existence of a verifiable code immediately suggests quality and le-

gitimacy. It reflects positively on the pharma manufacturer. However, an important word here is “verifiable”: the application of the code itself needs to be carried out with high quality, so that it is readable, with no smearing or skewing.

Partly, this is an issue of labelling and printing, in that printing onto labels or directly onto the side or top of a package, must be approached with a view to producing a code that is both clear and legible. That is only half of the story, though – inspection of the code is the second part.

Vision inspection

Vision inspection systems are responsible for reading and quickly identifying packs with incorrect or poor-quality codes. This can save a great deal of time, money and resources in allowing line stops so that any faults can be quickly rectified, and good-quality coding can begin again.

In liquid pharma, the shapes and sizes of the primary packaging – bottles, vials, ampules – present their own problems for serialisation and aggregation. For a start, since these kinds of vessels are typically round, they will rotate on the conveyer without a clear orientation of the package label visible at any time. Good product handling is going to be required in printing or applying serial codes directly onto pharmaceutical bottles, if that is the application. In vision inspection, it may be necessary to have technology that provides a full 360-degree view of the product surface, so that serialisation codes can be verified. Such a system would be able to view the product from all sides, regardless of the orientation, and, thus, verify the serialised codes on the package.

A common practice with aggregated products is to use “helper codes,” printed on top of the products, so that the code can be read even when the product is packed into a container with other products. This still requires some forethought and co-ordination, since not every vision inspection system is able to read codes on the top of products.

It is important for liquid pharma manufacturers to make an analysis of their applications, bearing in mind the type of packaging they want to use at the final point of sale. Understanding this will aid in the setup of serialisation and aggregation processes so they can assess what their vision inspection requirements will be. For instance, in liquid pharma, equipment should be able to handle different types of round containers, can read top or helper codes, and can verify small detail datamatrix codes or codes of various sizes.

Sharing data

The analysis must stretch beyond the factory walls too. Serial and aggregation data needs to be shared with the supply chain. So, it is also critical that the technology deployed to read and verify codes can also communicate this information to the next links in the chain.

That communication comes about through digital connectivity, requiring software systems that can talk to each other, and that's what the third and final column in this series will look at: the role of software connectivity in quality assurance for packaged liquid pharmaceutical products.

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Cyclodextrin – a super molecule, beyond drug vector: When the administration matters

Cyclodextrins are able to form water-soluble inclusion complexes with many lipophilic poorly-soluble compounds

Cyclodextrin (CD) are classically known to be an excellent drug carrier, although applications as active drug have been studied (orphan drug, antiviral, etc). However, there is no clear explanation about the increase of activity of drugs when they are administered by cyclodextrin. The team of Dr Francesco Trotta (Turin, Italy) tried to obtain the possible explanation of this issue in his recent review “Cyclodextrin Monomers and Polymers for Drug Activity Enhancement” on polymers. Based on numerous studies reviewed, the drug appeared more active in a complex form because of increasing the stability and the establishment of a pure drug reservoir preventing its degradation by different physicochemical agents (pH, temperature, ROS). The increase of bioavailability seems to be justified by the increase of apparent solubility of the molecule. On the other hand, the intrinsic activity of CDs against some agents could generate an apparent increase of drug activity.

Remarkably, this review indicates that not only the concentration, but also different bioactivities can be improved if the inclusion complex is formed opening up a new realm of other advanced applications expected to arise soon.

Aqueous solubility is one of the key determinants in development of new chemical entities as successful drugs. However, new drug development technologies, such as combinatorial chemistry and high throughput screening, are based on the basic principles of medicinal chemistry, teaching that the most reliable method to increase in-vitro potency is to add lipophilic moiety at appropriate position of the lead structure. This has led to an increase in the number of lipophilic and poorly-soluble molecules being investigated for their therapeutic activity (Lipinski, 2000). Var-



Dr Tamas Sohajda, CEO,
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ious formulation techniques are applied to compensate for their insolubility and consequent slow dissolution rate. These include formulation of the amorphous solid form, nanoparticles, microemulsions, solid dispersions, melt extrusion, salt formation and formation of water-soluble complexes.

By such techniques, pharmaceutical formulators try to increase the apparent solubility of lipophilic compounds without decreasing their optimised potency. Cyclodextrins are cyclic oligosaccharides, with hy-



drophilic outer surface and a somewhat lipophilic central cavity. They are able to form water soluble inclusion complexes with many lipophilic poorly-soluble compounds (Loftsson and Brewster, 1996; Rajewski and Stella, 1996; Loftsson et al., 2004a). However, cyclodextrins (the hosts) are also known to form non-inclusion complexes (Loftsson et al., 2002, 2004b). Most lipophilic compounds (the guests) form apparent 1:1 guest/host complex although apparent higher order complexes are not uncommon. Cyclodextrins and cyclodextrin complexes have been studied intensively for the past couple of decades and these studies have generated a wealth of informa-



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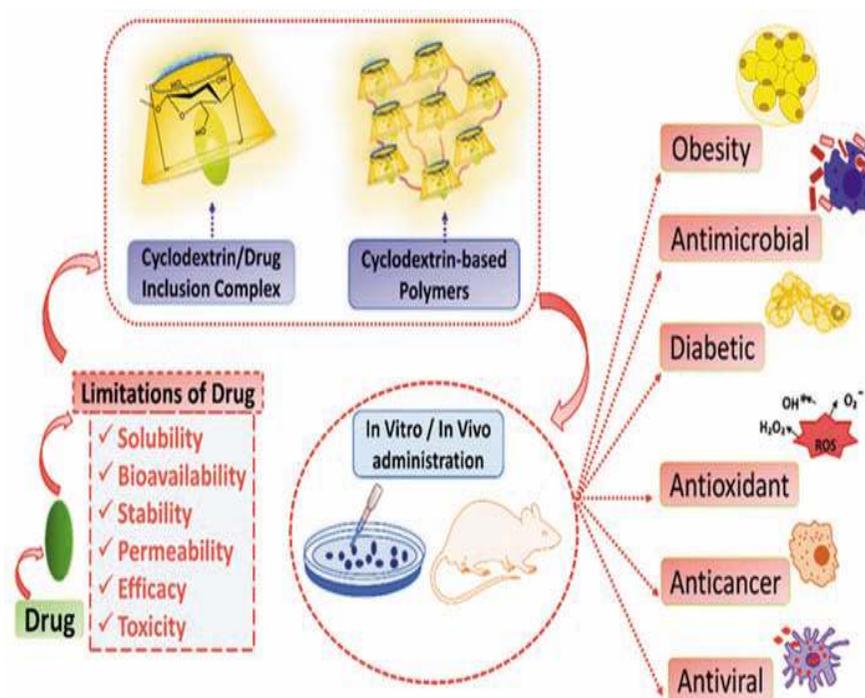
tion on the structural requirements for complex formation and the forces involved (Bodor and Buchwald, 2002; Katritzky et al., 2004).

However, most of these studies have been performed in dilute aqueous solutions under close to ideal conditions, or conditions that can almost never be found in pharmaceutical formulations. Lipophilic drug molecules, as well as drug/cyclodextrin complexes, are known to form aggregates in aqueous so-

lutions, and common pharmaceutical excipients, such as water-soluble polymers and surface-active preservatives, are known to solubilise drugs in aqueous solutions (Loftsson and Masson, 2004; Loftsson et al., 2004b). Still, current stoichiometric models treat aqueous formulations as ideal solutions in which dissolved drug and cyclodextrin molecules, and individual complexes, are independent of each other as well as of other excipients. In the present paper, we will investigate some of the discrepancies caused by this over simplification and how they affect the determination of stability constants of drug/cyclodextrin complexes. We will also suggest an alternative constant, the complexation efficiency, for evaluation of drug/cyclodextrin complexes under different conditions.

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PURIFY'22, all set to usher in vibrant 2022

The one-of-its-kind event in the country will be held on 24th February, 2022 at ITC Kohenur

With PURIFY'19, the industry was all agog with the quality of content, quality of delegates, choice of speakers and their topics, expansive venue, lucky draws, etc. The upcoming edition, PURIFY'22 Chromatography Purification Conclave, promises even more to the discerning community of 'purification chromatographers'!

This one-of-its-kind event in the country will be held on 24th February, 2022 at ITC Kohenur, Hyderabad; the entire ballroom at ITC Kohenur has been booked to ensure comfort and space for a growing number of attendees as well as the galaxy of speakers from India and overseas, along with an opulent display zone which provides an elaborate exhibit of global advances.

PURIFY'19 witnessed fine content being shared with over 113 fellow chromatographers across 19 cities representing 51 companies. 14 industry experts addressed the gathering to share their experience in chromatography purification. Now, Custage Marketing Solutions LLP, Mumbai is confident that PURIFY'22 is set to be on a much grander scale. This event will help purification chromatographers find answers on how to improve productivity, know about newer technologies, better comprehend the market and regulatory requirements, get updated on the latest technologies, understand the best global practices, and gain lots of practical tips to get that additional gram of pure product at the lowest possible price!

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Alliance Management, AbbVie, New Jersey and Manish Chawla, Managing Partner, Custage Marketing Solutions LLP, Mumbai. They come together to bring an unparalleled experience to PURIFY'22 and create a knowledge platform that will provide significant business opportunities to stakeholders in chromatography purification.

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Sigachi and NIPER Hyderabad sign MoU

By signing this MoU, both the parties have mutually agreed to extend assistance and support in the field of innovation and research

Sigachi Industries and the National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad have recently signed a Memorandum of Understanding (MoU) at NIPER campus. By signing this MoU, both the parties have mutually agreed to extend assistance and support in the field of innovation and research.

Signing the MoU, Amit Raj Sinha, MD and CEO, Sigachi,

said, "We are delighted to sign the MoU with NIPER. In the recent past, Sigachi's IPO on the day of listing broke 13-year-old Bombay Stock Exchange record with a whopping 270 per cent return. This shows the confidence investors have in us and we believe in reciprocating the same by excelling at what we do. One of them is by having a closer interaction with academia, learning more about the subject and expanding our cur-



rent core capabilities. The collaboration with NIPER will help us master new skills and the latest technologies, while benefitting from the expertise of faculty members. I am confident that by working hand-in-hand with NIPER, Sigachi can achieve better results in product development."

Adding to it, Dr Shashi Bala Singh, Director, NIPER-Hyderabad said, "There is a crucial need for building the academia

and industry relations, as only through continuous collaboration, both can achieve great results with synergy. NIPER-Hyderabad gives the highest priority to industry requirements and fulfills the same by providing quality workforce, experienced guidance from faculty members and research collaborations. The current MoU would lay path towards greater achievements such as product development, technology transfer and workforce that would be committed to Sigachi from day one. We would like to thank Amit Raj Sinha for the collaboration and I believe that if the industry and academia go hand-in-hand, India can truly achieve the potential of *Aatmanirbhar Bharat*."



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Gandhi Automations offers Porto and Max Vista - Automatic Sectional Overhead Doors

The overhead doors are the ideal solution for all industrial and commercial needs

Porto: Porto Sectional Overhead Doors are ideal for all industrial and logistics needs. The design and different solutions offered ensure the door to be aesthetically pleasing and perfectly suited to any architectural environment - from modern and traditional industrial buildings to fine commercial buildings. As these doors slide vertically, stopping in the proximity of the ceiling, they blend in with the architectural features of the building. Porto doors are built to ensure the highest ease and flexibility of use, which, in turn, ensures a quick, hassle-free and accurate replacement of old doors. Their compact size ensures more available space both inside and outside the premises. Depending on the structure of the building and the requirement, a choice can be made from a standard lift, vertical lift, horizontal lift, low head-room or inclined lift. Porto range comprises a wide series of track systems, panel options and safety features. Special glazed doors provide excellent lighting and vision into the building where required.

Max Vista: Max Vista Sectional Overhead Doors are ideal for industrial and commercial buildings. The doors are made with a combination of aluminium panels and transparent acrylic, grilled or meshed windows giving it a distinctive look and enhancing the look of a building. Max Vista Doors make the environment bright and pleasant to work in as it allows natural light to pass through the large clear areas.

Gandhi Sectional Overhead Doors provide heat insulation and sound proofing, thus improving the working conditions on the premises and saving energy. The products are



Gandhi Sectional Overhead Doors provide heat insulation and sound proofing, thus improving the working conditions on the premises and saving energy

affixed with a CE mark making them reliable and safe.

Key features:

- ◆ Reliable and low-noise operation
- ◆ Extreme robustness
- ◆ Safe operation in compliance with safety requirements
- ◆ Design-oriented surfaces and optimum light solutions
- ◆ Minimal bulk for more space indoors and outdoors
- ◆ Easy and practical to open and operate
- ◆ Energy savings and more comfort
- ◆ Bright indoor environment and attractive design
- ◆ Pre-painted, galvanised steel, sandwich panel, thickness 40 mm
- ◆ The gaskets, made of a special non-ageing rubber, seal the perimeter of the door opening
- ◆ They produce a perfect seal, preventing water, air and

dust infiltration

- ◆ Minimal bulk for more space indoors and outdoors
- ◆ Easy and practical to open and operate
- ◆ Energy savings and more comfort
- ◆ Bright indoor environment and attractive design
- ◆ Sectional Overhead Doors can be customised as Gas Tight Ripening Room Doors
- ◆ Opening - Closing speed = 0.2 - 0.4 m/s.
- ◆ Sizes available: Width (max) = 15000 mm
- ◆ Height (max) = 10000 mm

For more information:

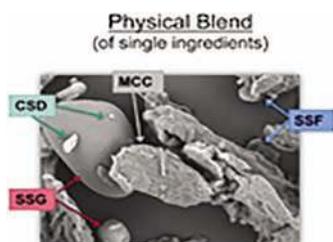
Gandhi Automations Pvt Ltd
 Chawda Commercial Centre,
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 Mumbai - 400064, India.
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PROSOLV® EASYtab – All-in-one excipient

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

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

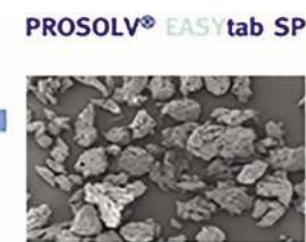
- ◆ Microcrystalline cellulose (filler/binder)
- ◆ Colloidal silicon dioxide (glidant)
- ◆ Superdisintegrant
- ◆ Lubricant



cleaning and change over gaps between batches.

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

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



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

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

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

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

Benefits of PROSOLV® EASYtab:

Process benefits

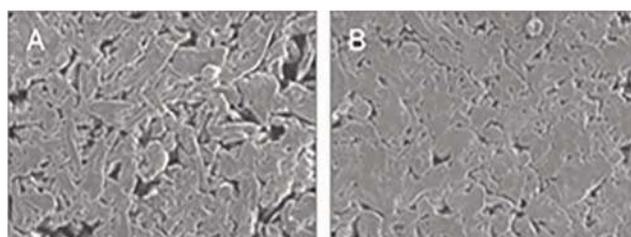
◆ **Simple process steps:** Processing with PROSOLV® EASYtab requires only blending as compared to conventional granulation techniques. This leads to less dust generation and significantly lower

Formulation benefits

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

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

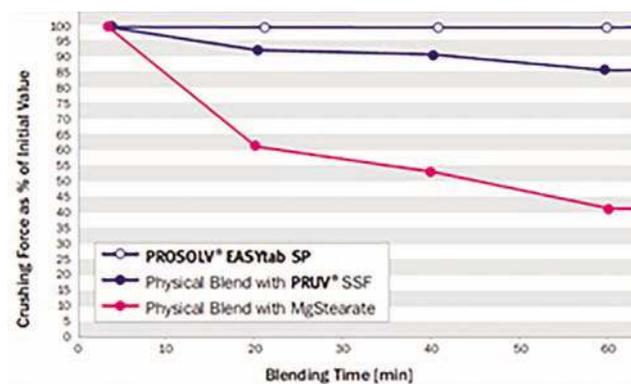
Sampling point	% API amount
Initial	105.1
Middle	101.4
End	100.5



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

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

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



Effect of blending times on tablet hardness

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

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

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

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

Cost benefits

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

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

◆ **Accelerated product and process development:** PROSOLV® EASYtab is most suitable for direct compression applications; Hence, lesser

process and formulation parameters needed to be optimized to finalize formulation and take it to market.

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

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

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

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

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

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

Other benefits

◆ **Patient compliance:** Smaller tablets formulated with PROSOLV® EASYtab

Continued on Page 52

How to choose the best fit for peristaltic pump

Peristaltic pump is the type of positive displacement pump used for pumping variety of fluids/media and every need of fluid-handling operations

A lot of equipment around us uses the mechanisms of pump, from the smallest pump used in household to the large scale of the industries.

Peristaltic pump is the type of positive displacement pump used for pumping variety of fluids/media and every need of fluid-handling operations. The suction and discharge principles of pump mechanism results in a powerful self-priming positive displacement action. Peristaltic pumps explain why you should consider specifying one of your next fluid transfer application.

In every peristaltic pump, a tubing is the only component which is exposed to fluid, play and make it happen an ultimate goal of “media/drug/sterile transfer processing.” They can also pump “IV fluids or slurries with a high degree of fluid content.” It ensures that a pump doesn’t contaminate the fluid and the fluid can’t contaminate the pump or its surroundings. It avoids direct metal contact, is reliable, seamless and easy to maintain.



Now a days, variety of pumps are available. In accordance to their special needs, media transfer medium has to be chosen such as for high pressure “hose pumps,” long tubing lifetime “360 design pumps” – which contain more flow per revolution, and for low-pressure deviation “tube pumps.”

Increasing in popularity of peristaltic pump is just because of its safe and contamination-free fluid transfer. As stated earlier, each application demands a spe-

cialised tube material. So far, it’s been accepted that a tube material selection is an important factor.

At a glance, let’s go through the factors which play a vital role to match the perfect fit for peristaltic pump.

◆ **Chemical compatibility:** It defines a polymeric tubing behaviour against fluid or media, it is

◆ **Transparency:** If visual inspection is required during the operation, then it’s important to have a transparent tubing.

◆ **Gas permeability:** For application where the media must be isolated from gases in the environment, the tubing material must have acceptably low gas permeability rating.

◆ **Regulatory approval:** For certain sectors like biopharmaceuticals and pharmaceuticals, the tubing material must meet certain “regulatory compliances and norms.”

◆ **Dimension stability and tolerance:** Size of the tubing is directly proportional to flow rate of material. For better pump operation and effective flow, a correct size tubing is important. It’s a variance in the dimensions, where close tolerance gives better performance.

◆ **Cost:** The cost of the tubing material must be acceptable in conjunction with its intended life expectancy. As selecting a low-cost material is not economical as its life span intends to low and

material with great life can be costly. Hence, selecting the right material with the least loss is essential.

◆ **Safety:** Tubing choice plays a major role as it will decide better performance or great loss in terms of rupture/damage to a process, equipment and human being.

Why Ami tubing?

Ami tubing offers below bunch of particulars, which make it the first choice of pharma and biopharma giants.

- ◆ Precise/ideal flow rate
- ◆ Excellent tubing pump life (high durability)
- ◆ Outstanding compression property
- ◆ Dimension stability (precise wall thickness)
- ◆ Smooth bore surface leads to less contamination
- ◆ Tear and kink resistance
- ◆ Excellent biocompatibility
- ◆ Highly chemical inert
- ◆ Manufactured and packaged in ISO class 7 clean room
- ◆ World-class certificate and compliances

Applications

- ◆ Pharmaceutical production
- ◆ Dialysis machine
- ◆ Open – heart bypass machine
- ◆ Sewage sludge
- ◆ Analytical chemistry experiments
- ◆ Food manufacturing industries
- ◆ Construction and pumping cements
- ◆ Aquarium, etc.

Tubing validation packs available upon request: www.amipolymer.in/ www.amipolymer.com

COMPLIANCE & CERTIFICATIONS					
 FDA 21 CFR 177.2600	 USP CLASS VI	 TOXIKON ENHANCING YOUR INVESTMENT	 European Pharmacopoeia E.R. 3.1.9	 USP USP CLASS 87 (IN VITRO)	 FDA DMF# 26201
 BfR Risiken erkennen – Gesundheit schützen GERMAN BFR XV	 ISO 10993-3 GENOTOXICITY	 ISO ISO 10993-10 SENSITIZATION	 BPA free	 French Pharmacopoeia FRANCE ARRETE DU 25	 ISO 10993- 4 HEMOLYSIS
 ISO ISO 10993-11 SYSTEMIC TOXICITY	 RoHS Compliant	 NSF NSF-51 (AESOP 6516; ISSUE 14) CERTIFIED SILICONE RESIN SLE-(PT)-30 to SLE-(PT)-80	 ISO 10993- 5 CYTOTOXICITY	 TSE FREE BSE	 PHTHALATE FREE

The versatility and ease of use will help to meet multitude of fluid-handling challenges.

The fluid flow is generated in equipment by periodically pressing a tube segment to the pump housing. Now, here, a question arises! Why tubing?

Why tubing and how to choose the perfect one?

cialised tube material. So far, it’s been accepted that a tube material selection is an important factor.

At a glance, let’s go through the factors which play a vital role to match the perfect fit for peristaltic pump.

◆ **Chemical compatibility:** It defines a polymeric tubing behaviour against fluid or media, it is

able rated life expectancy to “reduce downtime and costs” associated with replacement.

◆ **Temperature:** The tubing material must be able to operate within the temperature range of the system. Users should identify the span of temperature achieved in the system and select a material with an appropriate corresponding temperature range.



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testo Saveris Pharma: A complete pharma solution

Testo provides the best-in-class solution for comprehensive data monitoring and management of equipment as well as environmental parameters in the pharma industry

A sector like pharmaceuticals that is governed by strict norms and regulations must operate with utmost efficiency. Testo provides the best-in-class solution for comprehensive data monitoring and management of equipment as well as environmental parameters in the pharma industry called the testo Saveris Pharma. It is an automated system that is integrated into the facility and constitutes wireless or ethernet probes installed at different locations that are connected to one base station to document and monitor all measurement data of its own. The monitoring process is uninterrupted, and the system provides a number of alarm options in case the measurement values violate the defined limit values. Some advantages of testo Saveris Pharma for environment and equipment monitoring system includes:

- ◆ Holistic system comprising sensors, software, and services
- ◆ In accordance with 21 CFR Part 11 and GAMP compliance
- ◆ Provides seamless recording, automated tamper-proof documentation
- ◆ Secure triple layer storage of the measurement data of all audit-relevant parameters
- ◆ The data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in
- ◆ Real-time alarm facility to



highlight unexpected results
 Testo Saveris Pharma system consists of testo Saveris base V 3.0 which is the core component of the system. It manages and evaluates data from all over the facility from 3000 channels. The four testo 150 data logger modules can be flexibly combined with the three communication modules (WLAN, LAN, testo Ultra-

Range) making it a very convenient and user-friendly system along with the web-based, intuitive cockpit to detect alarms, initiate corrective measures, and acknowledge them whenever necessary.

Application areas

- ◆ Manufacturing/Production area
- ◆ Research and QC labs

- ◆ Cleanrooms and data centers
- ◆ Warehouses and packaging
- ◆ Deep freezers, refrigerators, cold rooms
- ◆ Incubators, stability test and walk-in chambers
- ◆ Blood and tissue banks
- ◆ Autoclaves and nitrogen tanks
- ◆ Sterilisers and many more

The company's specially trained service team supports you throughout the process in a very systematic

way – from planning, documentation, system qualification, and software validation through to service and support. Testo also has a NABL accredited service and calibration LAB that takes care of the after-sales support locally from Pune.

For more details, log in to the company's website www.testo.com or write back to info@testo.in

PROSOLV® EASYtab...

Continued from Page 50

may show better patient acceptability.

◆ **Complete regulatory support:** QnQ composition revealed for all PROSOLV®

EASYtab grades. USDMF is available along with complete regulatory support.

Conclusion

Excipients have come a long way since powdered

cellulose, particularly with the introduction of all-in-one excipients such as PROSOLV® EASYtab. Designed for direct compression, this excipient can achieve excellent functional

tablet properties that cannot be achieved when adding the same components individually to a formulation. PROSOLV® EASYtab has some special benefits when used in

continuous manufacturing applications too.

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

Virosil Pharma: A revolutionary, eco-friendly fumigant

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

ABSTRACT

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

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

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

ABOUT US

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

strict regulations imposed by European Health bodies.

PRODUCT DESCRIPTION

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

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

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

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



ADVANTAGES

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

PROPERTIES

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

USFDA DRAFT GUIDELINES

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

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

WHO 2002 MICROBIAL LIMITS

Grade	Max. no. of microorganisms permitted / m ³
A	Less than 1
B	5
C	100
D	500

EU GMP 2002

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

time can be guaranteed. As the product remains stable at high water/air temperatures, and as its effectiveness is even increased at high temperatures. ◆ Due to its long-term effectiveness and pronounced characteristics to prevent recontamination, this product is perfectly suited for disinfection of drinking water and wells.

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

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

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

Fumigation with Virosil Pharma, the perfect SAlternative to Formalin

Fumigation is one of the most

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

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

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

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

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

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

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

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

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

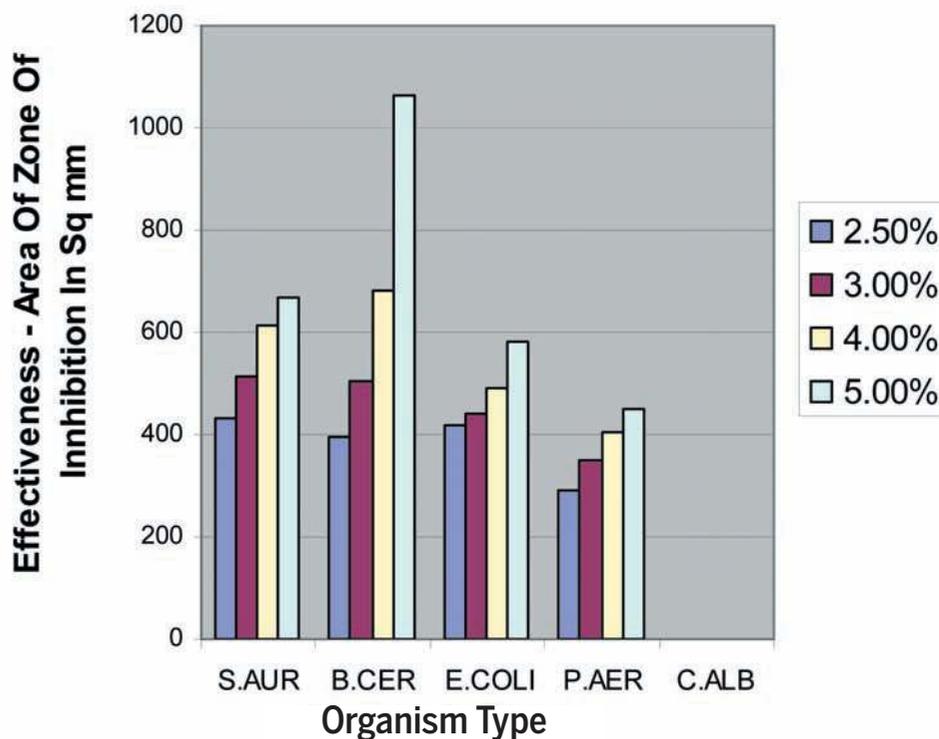
Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to re-wash equipment and surfaces disinfected with Virosil Pharma since it is H₂O₂ based and decomposes into water and oxygen.

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

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

A GRAPHICAL VIEW ON DISINFECTANT EVALUATION DATA - VIROSIL PHARMA

Disinfectant Effectiveness Evaluation Data
Virosil Pharma



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

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

Targets

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

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

DMF
Available



ACRYCOAT[®]
Methacrylic Acid Copolymer

COLORCOAT[™]
Ready-to-use Coating System

ACRYPOL[®]
Carbomer

KYRON[™]
Taste Masking Polymer

ACRYSOL[™]
Castor Oil Derivative

ACRYFLOW[™]
Stearate Derivatives

NUTRACOAT[™]
Natural Coating System

KYRON T-314[™]
Polacrillin Potassium



COREL PHARMA CHEM

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Website: www.corelpharmachem.com

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