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NITROSource NEWS 08

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JANUARY 2021

Hello and welcome to this 8th edition of NITROSource News

With the global focus and news being consumed by Covid-19 for the majority of 2020 along with the race for a vaccine, other medical research and accomplishments have somewhat taken a back seat.

Whilst coronavirus is extremely unpleasant and of serious concern, many thousands of other illnesses and diseases are addressed and treated on a daily basis by our dedicated health workers; through medicines and therapies developed by research and pharmaceutical professionals across the world.

Nitrogen gas produced by Parker NITROSource and NITROSource Compact generators plays a key role in protecting medical and pharmaceutical products and processes from spoilage by oxidation. In addition, centralised nitrogen systems used for numerous analytical techniques within laboratories, ensure the consistency and safety of medicines and treatments.

One country that has become synonymous with pharmaceutical production in recent years is India.

From humble beginnings in 1930 with the establishment of India's first pharmaceutical company in Kolkata - "Bengal Chemicals & Pharmaceutical Works", the industry has grown to encompass more than 250 large scale companies and 8000 small scale.

One area of expertise is the production of "generics". When a pharmaceutical company produces a new medicine, it is generally protected by patents for up to 25 years. This allows time to recoup the considerable development and trial costs while enabling profitability. Generally, this is the reason why new medicines are more expensive than those that have been around for a while.

When a drug becomes "off-patent", it can be produced by others and offered at reduced cost, whilst still maintaining the original efficacy.

Harish B Rao, Managing Director of Advanced Pneumatics Pvt Ltd, Parker's premier distributor based in Bangalore, India, shares details of some recent pharmaceutical installations for NITROSource based in the region.



Dr Reddy's Biologicals – Hyderabad, India



Harish explains - Dr Reddy's are constantly striving to bring the most advanced medicines within the reach of millions around the world. The efforts at their Biologics division, working on high quality global biosimilars for the last fifteen years, are a testament to that commitment.

Diseases like cancer or auto-immune disorders often require the long-term use of Biologics – large molecule protein therapies – for an effective treatment that may have fewer side effects. Effective as they are, biologics are very expensive and can place a significant cost burden on both, the patient as well as health authorities. Fortunately, Dr. Reddy's decades-long experience in generics manufacture, coupled with world-class capabilities allows them to create high quality, equally effective, but significantly more affordable generic biosimilars.

Harish and his Sales Director, Umesh Ichangi, fully understood some of the challenges faced by Dr Reddy's and the need for nitrogen gas in their production processes. During discussions with Mr. Sachin Goswami, Senior Director of Engineering & Projects, and his colleague Mr. Pramod Chadha, Director of Engineering, they discovered that there were several processes where ultra-high purity pharmaceutical grade nitrogen was specified. These required <5ppm maximum remaining oxygen content (European Pharmacopoeia monograph – 1685)

The existing cylinder supply was prohibitively expensive and the frequent delays in deliveries along with the manual handling problems, meant that it was no longer a sustainable method of purchasing nitrogen.



After a careful and thorough examination of Dr Reddy's applications and processes, requiring UHP nitrogen, Harish and Umesh proposed a system comprising of a NITROSource N2-80PXLN with Parker pre-treatment, to meet their UHP grade low oxygen nitrogen system demands.

Once installed by Advanced Pneumatics the system had to be fully validated by Dr. Reddy's QA & QC departments, analysing the output gas to ensure compliance with the relevant pharmaceutical monographs, before permitting the generated nitrogen to be used. This was a critical part of the acceptance process because Dr Reddy's is a United States of America FDA, European Pharmacopoeia and United Kingdom MHRA approved manufacturing plant.

The nitrogen produced by this installation is used in a multitude of applications including:

1. Fill Finish
2. Pre and post gasification
3. R&D
4. QC
5. Lyophilizer for spray drying

Harish advises – "Advanced Pneumatics, Pvt. Ltd., was successful in this case due to our knowledge and understanding of the relevant pharmaceutical standards. Along with the support of Sheilesh Sabnis, from Parker with the supply of the NITROSource, able to deliver a stable 5ppm MROC and our ability to provide a complete validated turn-key package with the correct documentation.

This takes all the risk away from the customer, allowing them to concentrate on their core business. Dr. Reddy's are extremely pleased with the result and the level of service we provide."

Biocon Ltd., Bangalore, India

In this application story, Harish replaced an aging and inefficient twin tower nitrogen generator with a dual bank NITROSource PSA.

Bangalore is primarily famous for being the "Silicon Valley" of India and is a well-known hub for some of the world's major IT corporations.

Amongst its other industrial inhabitants is a biopharmaceutical company named Biocon.

Biocon manufactures generic active pharmaceutical ingredients (APIs) that are sold in over 120 countries. A publicly listed research subsidiary of Biocon is Syngene. Between them they employ over 9200 personnel.

At the Biocon Campus in Bangalore, production of APIs for insulin takes place. Used to control blood

sugar levels for people with diabetes, synthetically produced insulin is a life-saving drug, administered to replace the naturally occurring insulin hormone secreted by the pancreas.

Biocon were using an old twin tower type nitrogen generator in this facility but were concerned about the amount of space it was occupying and also the high energy consumption because of the very inefficient air to nitrogen ratio.

Having previously installed MAXIGAS and NITROSource through Advanced Pneumatics at other manufacturing sites, Biocon began to explore upgrade options with Harish and his colleagues Mr. BS Ambarish & Mr. B V Sreekanth, supported by Sheilesh Sabnis from Parker India.

After analysis of the processes and applications, it was determined that the existing twin tower nitrogen gas generator was significantly undersized as well as being inefficient.

Advanced Pneumatics proposed two NITROSource N2-80P units rated at a combined 135m³/h @ 0.5% purity be installed to replace the 25m³/h twin tower generator.

The Parker N₂ generators along with Parker compressed air pre-treatment packages were

installed in a very compact floor area, saving Biocon valuable space. After commissioning and hand over, feedback received by Harish and his team revealed that the system exceeds Biocon's quality and regulatory requirements, and they are extremely happy with the new equipments, and Biocon use nitrogen gas produced by the Parker generators in three main applications –

1. Blanketing of APIs to prevent material degradation and oxidation
2. Transfer of product through pipe-work
3. Breaking the vacuum in processing tanks



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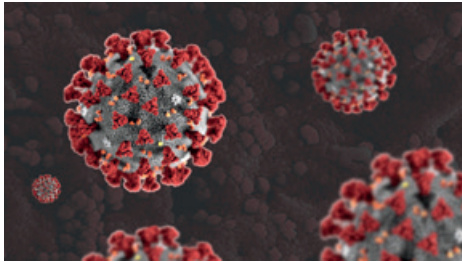
Liverpool – from Beatles to microbes!

This medical application located at Liverpool University, is presented by Tony Brown, UK sales manager for gas generation.

Liverpool is a major city in the North West of England; probably most famous as the birth place of the Beatles and home of Liverpool Football Club, current English Premier League Champions and FIFA World Club Champions.

Established in the 19th century, Liverpool University has recently secured multi-million-pound funding for the creation of the Centre of Excellence for Infectious Diseases and Research (CEIDR)

Leading pioneering research into coronaviruses and antimicrobial resistance to antibiotics, the importance of this work is paramount to the future wellbeing of humans and animals alike.



Before antibiotics were discovered by Sir Alexander Fleming in 1928, even small cuts, scratches and infections could be extremely serious. Staphylococcus aureus for example, was fatal in 80 percent of infected wounds.

Since penicillin was first prescribed in the late 1930's, we have enjoyed a very successful battle against microbes; but due to over-prescription and some bacteria developing resistance, the need to find new antibiotics and methods of treating microbial infections is crucial.

Tony explains "Liverpool University already had a NITROSource N2-20P on site, originally installed by our distributor in the region, Thorite, in collaboration with M&E contractor, TEKSOL.

When consulting engineers, White, Young & Green were commissioned to design an expansion encompassing the multi-million-pound investment, previous positive experience with Parker's NITROSource put us in good stead.

The new development involved the use of multiple nitrogen outlets in research laboratories and for the operation specifically of LC/MS, (Liquid Chromatography/Mass Spectrometry), analytical instruments.

Thorite subsequently proposed a NITROSource based system, using three N2-80PALY nitrogen generators in a two duty, one stand-by configuration. To output up to 100m³/h of nitrogen @ 100ppm, complete with three Parker OFAS pre-treatment packages.

The energy saving technology (EST), incorporated into NITROSource is predicted to reduce compressed air usage, and provide on average 25% energy savings for the department. With an eye on the future, the modular design can easily facilitate expansion when required, by simply adding further banks.

The system was commissioned in July 2020 and the University of Liverpool Project Manager stated -

'We are delighted with the performance of the Parker NITROSource which was installed on time and on budget by Thorite. It will prove to be a very valuable asset as the site extends its research capacity moving forward'



Penicillin



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Parker centralised laboratory gas generation systems – What makes sense?



When analytical laboratories operate just one or two instruments that require nitrogen gas, then a local laboratory gas generator is the obvious and most economical solution.

In situations where multiple instruments require gas, then the need to have a multitude of individual laboratory gas generators can be fulfilled by installing a Parker centralised nitrogen generation package.

Most analytical laboratories are climate controlled to ensure that the calibration standard for the equipment is constantly maintained at typically 20°C. Having many lab gas generators with inbuilt compressors can add to extra heat loading on the

air conditioning system, as well as contribute to additional noise, while taking up valuable floor or bench space.

The oil-free reciprocating piston compressors, found in most lab gas generators, also have a finite life span, simply because of the pressure they produce and lack of lubrication, typical of the design.

Using Parker's industrial NITROSource PSA or NITROSource Compact nitrogen generators, coupled with an oil lubricated rotary screw, or vane compressor, sited away from the laboratory in a plant or compressor room, ensures a very long, trouble free life span expected to be 10 years+.



Parker's OFAS compressed air pre-treatment package guarantees oil-free air and hence very clean and pure laboratory grade nitrogen.

Just recently, Parker in the UK and their distributor, Activaair, have won a contract to replace an old N2MAX110+MOD system based at the Drug Control Centre in Kings College, London, with NITROSource PSA. This facility uses a suite of LC/MS, (Liquid Chromatography / Mass Spectrometry), technology machines amongst its instruments to test sports people in line with anti-doping regulations, protecting the integrity of sport and the health of the athletes.

Situations where a centralised NS-PSA/NSC systems might be advantageous compared to individual laboratory gas generators –

- Multiple LC/MS suites – LC/MS instruments can use 30 to 40 litres/minute of nitrogen at up to 8 barg each.
- Multiple solvent evaporation machines
- Reaction blanketing in fume cupboards
- Glove boxes and incubators.



Solvent evaporation



Thanks for reading

and thanks to those that have contributed article details for this edition

If you have an application to share, please let me know and I will help develop an article. I just need the basic information and I can then work with you to expand upon the detail.

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