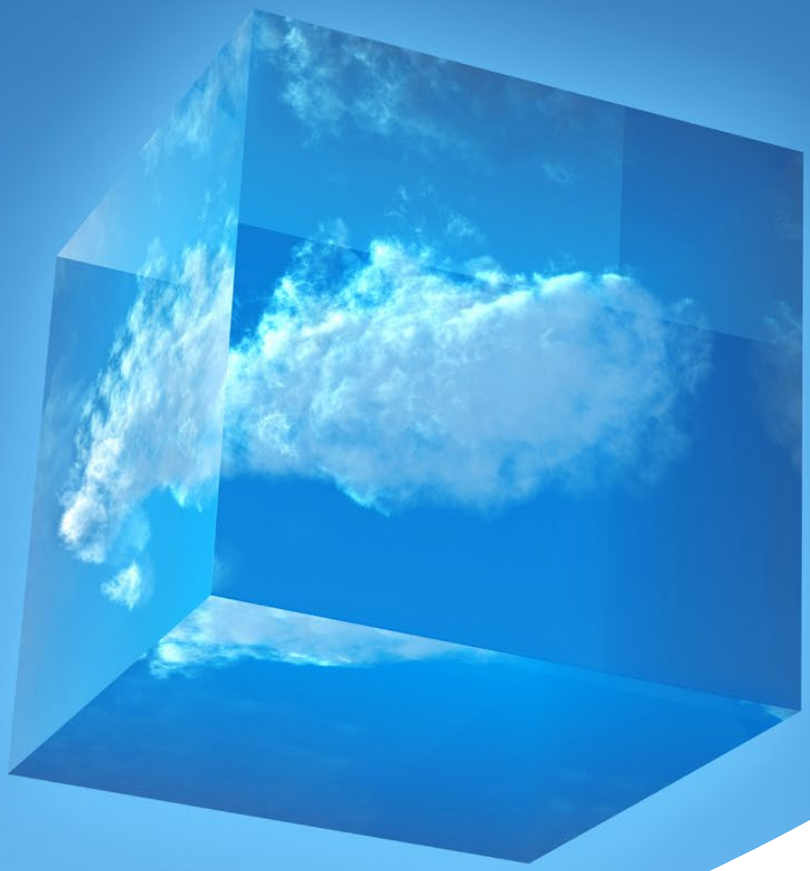

A cost-efficient energy transition solution delivering safe, sustainable and reliable solvent abatement and VOC recovery for pharmaceutical manufacturers

Whitepaper to learn about the merits of cryogenic condensation and its unique sustainability for today's pharmaceutical industry.

AIR PRODUCTS

Introducing Cryo-Condap®: A cost-efficient energy transition solution delivering safe, sustainable and reliable solvent abatement and VOC recovery for pharmaceutical manufacturers.

The pharmaceutical industry is currently making strenuous efforts to reduce its impact on the environment with leading companies such as Astra Zeneca and GSK publically announcing ambitious Net Zero targets for the relatively near term, 2025 and 2030 respectively [1,2]. Such efforts necessarily intensify the scrutiny of emissions from pharmaceutical manufacturing processes along with the impact of associated mitigation technology. Optimising solvent abatement and volatile organic compound (VOC) recovery processes is a small but important part of the overall challenge and calls for reliable, cost-effective solutions with a low environmental footprint.

Pharmaceutical manufacturers rely on a range of solvents that are classified as VOCs for API manufacturing, for chemical synthesis, extraction/purification and fermentation and for cleaning. Examples include acetone, ethyl acetate and isopropyl alcohol; chlorinated solvents, notably dichloromethane, are also still in regular use. VOCs are chemicals that volatilise at room temperature and that consequently have significant potential as air pollutants. Linked with the formation of smog and multiple adverse health affects their release is controlled by, for example, the Industrial Emissions Directive in the EU[3] and federal regulation 40 CFR 59 in the USA[4]. Legally imposed limits may be a starting point for VOC abatement, but the principle of 'Best Available Technology' (BAT) that applies in many jurisdictions sets more demanding standards. Within a Net Zero strategy, VOCs may be additionally significant because of their Global Warming Potential (GWP), as may abatement technologies such as thermal oxidation which often involve additional fuel consumption.

This whitepaper introduces the Cryo-Condap® system, a cryogenic solvent abatement and VOC recovery technology from Air Products with proven application in the pharmaceutical industry. Cryo-Condap® is a safe, inherently reliable and flexible, low environmental impact solution, delivered by a highly experienced company, making excellent progress towards greater sustainability. Here we examine its merits relative to alternative technologies within the context of 'Net Zero' solvent abatement and VOC recovery.

A case study illustrates the application of the Cryo-Condap® technology to reduce VOC emissions at a biopharmaceutical site to levels far below those specified by the EPA and at the same time eliminate the production of waste carbon.

Meeting requirements for solvent abatement within the context of Net Zero.

For pharmaceutical manufacturers, a key challenge with solvent abatement is to define requirements. With batch processing still dominating the industry, a common scenario is to have multiple unit operations linked to a common header delivering intermittent, fluctuating flows as process steps are implemented. VOCs levels in the combined, exiting gas stream must consistently meet licensed levels even as this occurs.

However, legal limits provide only a baseline standard for performance. The requirement to meet Net Zero means that the environmental impact of any solvent abatement technology must be considered carefully. The industry needs solutions that, for example, enable complete VOC recovery, while contributing minimally to environmental emissions. Other factors influencing system specification and technology choice include requirements to:

- Demonstrate the use of BAT – the technology identified by the regulators as being best for minimising or preventing emissions - notably in the EU where pharmaceutical manufacture is covered by the BAT reference document (BREF) for Organic Fine Chemicals[5].
- Futureproof, for example, to anticipate more stringent environment requirements, increased plant throughput or changing production schedules.

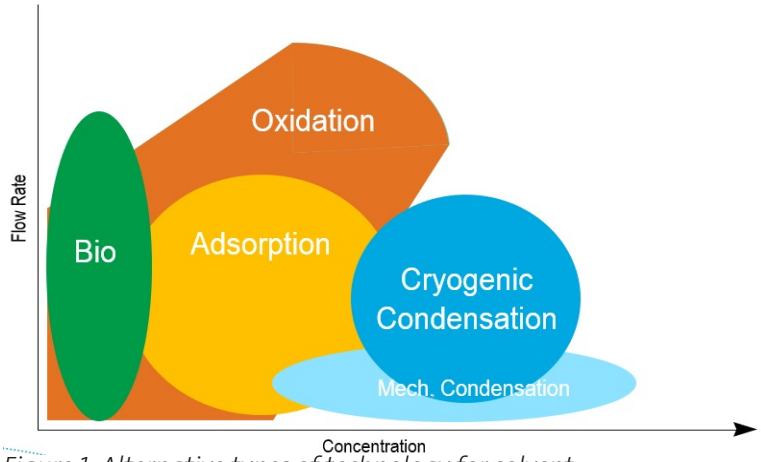

Figure 1: Alternative types of technology for solvent abatement and VOC recovery

Figure 1 shows the different types of technology used for solvent abatement and VOC recovery. A full discussion of the merits and limitations of each technique is beyond the scope of this paper but the

figure shows the flow rate/concentration ranges for which each is best suited. Thermal oxidation is the traditional approach but typically uses fossil fuels, offers no opportunity for VOC recovery and is ill-suited to chlorinated compounds. Adsorption, usually by activated carbon, is less energy intensive and highly effective, but dealing with the contaminated bed - by regeneration or disposal - can be environmentally problematic. Condensation by mechanical refrigeration eliminates all these problems but can be energy intensive. Cryogenic condensation is a highly attractive alternative.

Introducing Cryo-Condap® technology

The Cryo-Condap® system utilises cryogenic condensation technology, specifically liquid nitrogen, to condense and freeze VOC vapours in an exhaust gas stream. Condensed and frozen VOC particles are removed to leave a clean gas stream for discharge to atmosphere. This technology is particularly suited to low flow rate waste streams containing solvents with low boiling points/freezing points making it closely aligned to pharmaceutical requirements. Other key benefits include:

- **Close to 100% solvent recovery and re-use:** The ability to recover close to 100% of most solvents allows manufacturers to meet the toughest environmental standards. Equally importantly recovered solvents can be recycled back into the process, or sold, to minimise waste.
- **Production of a clean, gaseous nitrogen stream for inerting/blanketing:** the heat exchange process at the heart of the Cryo-Condap® system produces a clean, gaseous nitrogen stream that can be used for inert purging or blanketing, for example, to eliminate oxidation and prevent microbial contamination, as required. Since such activities are common place in the pharmaceutical industry this is a highly efficient re-use of what is essentially a vented byproduct.
- **A wide operating envelope:** Cryo-Condap® systems have a wide operating envelope, offering sufficient flexibility with respect to overall gas flow rate and VOC loading to maintain a consistent output in the face fluctuating inputs. This sets the technology apart from alternatives, which can be far less tolerant of exhaust gas variability.
- **Easy installation:** The equipment is skid-mounted, compact and requires minimal service connections.
- **High reliability:** An inherently robust design with no moving parts offering high uptime with minimal maintenance. Air Products Process Intelligence (APPI) provides remote monitoring to further minimise requirements for manual intervention at the site.
- **Minimum energy consumption:** With the Cryo-Condap® system solvent abatement is achieved by heat exchange with liquid nitrogen minimising requirements for additional energy inputs.

Working with you to achieve Net Zero

Cryo-Condap® technology uses liquid nitrogen for solvent abatement thereby eliminating the fuel consumption associated with thermal oxidation and the waste associated with adsorption. However, this brings the processes used to produce liquid nitrogen into focus. How sustainable and efficient are these?

At Air Products we have set ourselves comprehensive sustainability targets including our 'Third by 30' goal, a reduction in carbon dioxide emissions of a third (relative to 2015 levels) by 2030. Improving the efficiency of our operations, notably our air separation units, is key to this and by 2020 we were already saving > 1.3 million tonnes per year of CO_2 through efficiency gains. Around a quarter of the energy we purchase already comes from renewable sources, and we continue to drive this figure up; multiple carbon capture and low carbon projects are in progress. On the distribution front we have a commitment to construct facilities close to customer sites and ambitious plans to convert its global fleet of distribution vehicles to hydrogen cells.

Ultimately, there is no bar to producing all our liquid nitrogen using clean energy to drive the associated air separation processes. This makes Cryo-Condap® an inherently sustainable solution. We may not have reached that point yet but this technology undoubtedly has the potential to be a more suitable long-term fit for pharmaceutical manufacturers targeting Net Zero, rather than the alternatives currently available.

The following case study illustrates the application of Cryo-Condap® and shows in more detail what it can deliver.

Case Study: Transforming solvent abatement at a biopharmaceutical facility

A global biopharmaceutical manufacturer carried out a BAT study to identify technology for VOC emission control from the vent header at a site in Ireland. Cryogenic condensation was determined to be the most suitable option for treating the stream which is characterised by low and fluctuating volumetric flow rates, high VOC concentrations - chlorinated and non-chlorinated, and intermittently, appreciable levels of ammonia and carbon dioxide. The Cryo-Condap® system was selected in preference to commercial alternatives on the basis of its inherent robustness, quality and proven reliability.

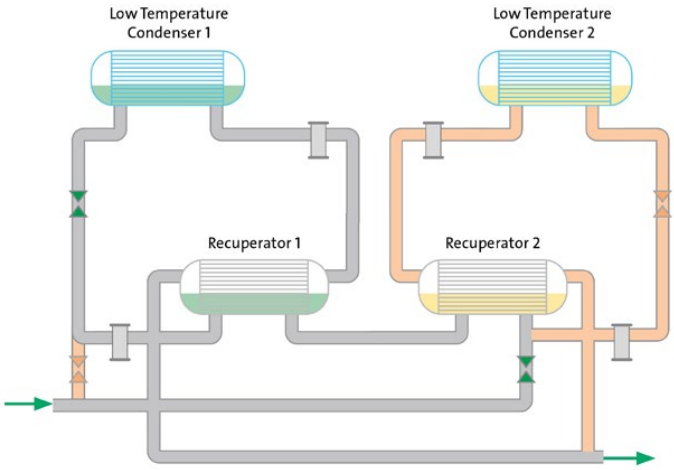

Figure 2: Schematic of a Cryo-Condap® installation at a biopharmaceutical manufacturing site with recuperators used to pre-cool the incoming waste gas stream.

Figure 2 shows a schematic of the installed system which consists of two parallel condenser/recuperator loops. The cold gas exiting the condenser is used to precool the process waste gas stream in the recuperator to improve process efficiency. As part of the project Herco also installed aqueous scrubbers for ammonia and carbon dioxide removal and polishing molecular sieves to efficiently remove residual traces of solvent. This integrated system is now the site's primary abatement solution; in the event of failure the vent header is routed to a backup carbon bed system. The technology was supplied as a turn key project with support continuing throughout commissioning and including a number a test scenarios to fully optimise the process. These efforts brought the uptime of the unit to 99% and ensured that the criteria of the EPA test program were successfully met.

The installed technology reduces emissions in the exhaust gas streams to around 0.1% of EPA license limits for the process which are 150 mg/m³ for Total VOCs, 30 mg/m³ for ammonia and 20 mg/m³ for dichloromethane. This provides considerable scope for higher throughput, an appreciable level of future proofing should operations at the plant change in the future. Nitrogen is recovered in gaseous form, post VOC condensation, and supplied to the plant's gas distribution network for use in manufacturing processes; recovered VOCs are also reused, after further processing.

Prior to the installation of the Cryo-Condap® unit the site relied primarily on an activated carbon bed system for VOC removal, generating ~48 tonnes of hazardous waste for disposal. This waste is no longer generated. Furthermore, sizing of a thermal oxidiser unit for this application/process indicated that it would be associated with annual natural gas consumption in the region of 2 – 3 million kWh and generate between 350 and 550 tonnes of CO_2. This environmental impact has been avoided. The cryogenic technology offers a superior solution to either of these alternatives.

In conclusion

Cryogenic condensation is an inherently reliable, low environmental impact technology for solvent abatement and VOC recovery that is well-suited to pharmaceutical processing. With the flexibility to deal with fluctuating VOC loadings of varying composition it has the added benefit of delivering a clean, high purity gaseous nitrogen stream as a by-product, which can be used for inert purging or blanketing. Cryo Condap® makes cryogenic condensation readily accessible to pharmaceutical manufacturers in the form of compact, versatile, skid-mounted technology that is easily adapted to specific requirements and backed by expert engineering input. Case study data illustrate what can be achieved and how leading pharmaceutical manufacturers are already benefiting from this cost-efficient, high performance, environmentally-benign solution for VOC control.

Herco Kühltechnik and Air Products: a successful partnership for solvent abatement and VOC recovery.

Air Products and Herco Kühltechnik developed the Cryo-Condap® technology together over four decades ago, and continue to work in partnership today. Customers across the globe rely on Air Products for the industrial gases that drive their processes and the company is a pioneer in gas separation, notably the cryogenic processing used to produce high purity liquefied gases. Herco Kühltechnik bring plant design and construction expertise to the partnership, offering a range of technology for solvent recovery that extends beyond cryogenic condensation. For many, choosing Air Products means working with a trusted onsite partner, already supplying gases. Herco Kühltechnik has the expertise to ensure a truly optimal solution for every customer, incorporating complementary technologies to Cryo-Condap® where needed. Together the companies provide a compelling offering for solvent abatement and VOC recovery projects.

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Jon has been working in the Industrial Gas Business for over 30 years focused on low temperature cryogenic applications.

He leads an Advanced Technology Team with a focus on developing new and sustainable innovative cryogenic applications. Cryogenic solvent recovery technology (Cryo-Condap®) has been a key application area for Jon and his team.

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