domnick hunter

MAXIGAS Nitrogen Supply

for the pharmaceutical industry

www.domnickhunter.com

Pharmaceutical manufacture

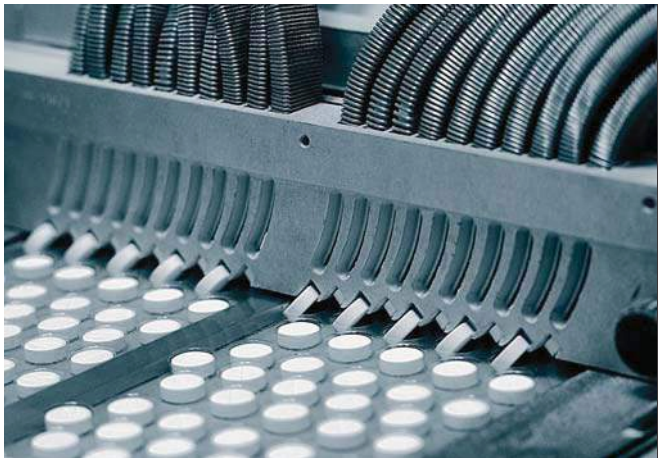
dependable solutions

domnick hunter's knowledge of pharmaceutical processes is reflected in our extensive **filtration, separation, purification** and **gas generation** product ranges that are used in pharmaceutical processes.

domnick hunter has extensive experience of installing **complete nitrogen solutions** that include pre and post filtration and drying treatments to ensure clean, dry nitrogen gas at the necessary purity level.

MAXIGAS convenient on-demand nitrogen gas at consistently reliable purity levels for blanketing, API production, final drug product manufacture and packaging saves time and money

Nitrogen Applications:



Transfer

High-pressure nitrogen gas can be used to assist safe transfer of substances from one vessel to another. This highly effective solution speeds up the process without causing any dissolution or build-up of substances.

Purging

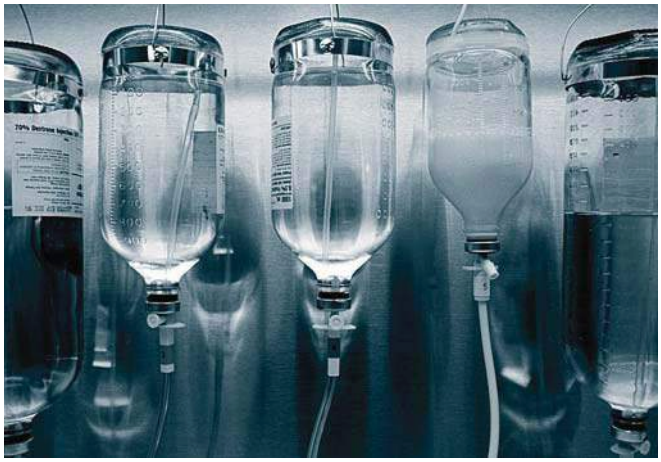
Manufacturing and analytical equipment can be purged with nitrogen gas to remove oxygen and water vapour from process lines, this can increase product quality and reduce the need for further conditioning treatments.

Blanketing

API's and final drug products must be stored in the appropriate way to ensure humidity and oxygen do not affect the product and powders do not agglomerate. Blanketing with nitrogen provides an inert atmosphere that suppresses airborne contamination such as moisture and bacteria. Nitrogen will also provide a blanket to protect potentially reactive materials from contact with oxygen, and so maintain quality.

Nitrogen Purity

Lower nitrogen purities are required for blanketing and other inerting processes than for drug manufacture. However where finished products are exposed to the gas as they enter an atmosphere created with nitrogen the final product must be carefully analysed to check for any adulteration.



Drug manufacture

Nitrogen with a purity of 10ppm oxygen content delivered at a pressure of around 6.5 bar can be used during the manufacture of API's and final drug products such as ophthalmics, LVP's and SVP's.

Nitrogen supplied by MAXIGAS meets the following requirements:

- nitrogen <10ppm oxygen content
- carbon dioxide <1ppm
- carbon monoxide <1ppm
- water vapour <5ppm (-66°C dewpoint)
- total hydrocarbons <5ppm

Aseptic packaging

Many pharmaceutical products cannot withstand any form of thermal sterilisation, in which case aseptic filtration followed by packaging in pre-sterilised containers in a cleanroom environment is the best solution.

Because aseptic filtration/fill operations are complex, environmental controls are required to maintain standards. Nitrogen gas can be used to provide a suitable atmosphere and for filter integrity testing.

Analytical testing

domnick hunter's laboratory gas generators produce ultra high purity nitrogen, hydrogen and zero air specifically for use in analytical testing such as LC/MS, GC and nuclear magnetic resonance.
For more information please request brochure 770.

Laboratory gas generator range

Filtration Separation Purification

domnick hunter has an extensive range of air, gas and liquid filters designed to maximise process efficiency. All filters incorporate high flow membranes to minimise filtration system size whilst meeting full validation and integrity test requirements.

domnick hunter can offer scalable solutions for all stages of drug development from filter discs and disposables for early phases of development through to multi-cartridge systems for full-scale production.

Full validation support for domnick hunter products is provided by our dedicated Technical Services Group to the latest regulatory requirements, including bacterial challenge validation facilities, coupled with training in the use of domnick hunter integrity test instrumentation.

Sterile grade filters

Why MAXIGAS?

MAXIGAS is a cost effective alternative to other gas sources with no on-going costs such as refills, order processing or delivery charges.

It is also a safer alternative as manhandling of high-pressure cylinders is eliminated.

Production downtime is minimised due to the permanent availability of an on-demand nitrogen supply.

Maxigas gives manufacturers increased control over flow rates and requires minimal maintenance. It can also bring valuable space saving advantages.

MAXIGAS deliverables

- nitrogen purity of up to 10ppm oxygen content
- on-demand safe nitrogen supply
- increased control
- no reliance on gas deliveries in remote or congested areas
- modular space saving design
- ability to add extra banks of generators
- simplicity
- innovative regeneration feature requires minimal maintenance
- domnick hunter global service and support
- industry experience of designing and building bespoke stainless-steel units
- easily retrofitted

MAXIGAS
model N2MAX116

How it works

MAXIGAS is constructed from pairs of extruded aluminium columns filled with carbon molecular sieve (CMS) and operates on the pressure swing adsorption (PSA) principle to produce a continuous stream of nitrogen gas from compressed air. Oxygen and other trace gases are preferentially adsorbed by the CMS, allowing nitrogen to pass through.

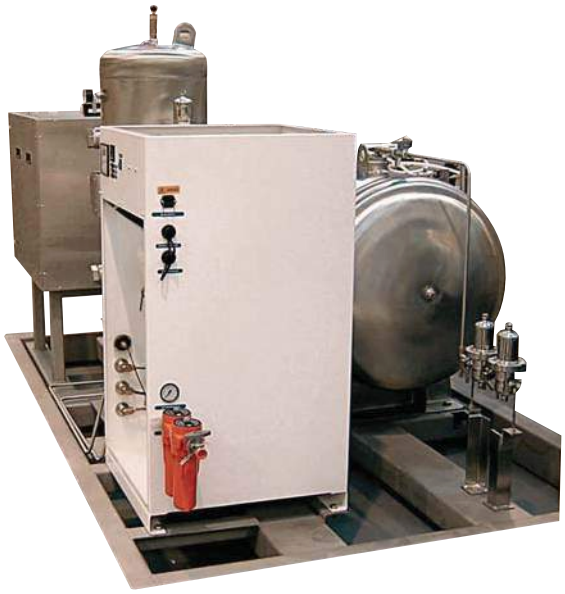
Carbon molecular sieve differs from ordinary activated carbons in that it has a much narrower range of pore openings. This allows small molecules such as oxygen to penetrate the pores and be separated from the air stream. The larger molecules of nitrogen by-pass the CMS and emerge as the product gas.

After a pre-set time when the online bed is almost saturated with adsorbed gases, the system automatically switches to regenerative mode, venting the contaminants from the CMS. The second CMS bed then comes online and takes over the separation process. The pair of CMS beds switch between separation and regeneration modes to ensure continuous and uninterrupted nitrogen production.

Pre and post filtration is recommended to ensure absolute nitrogen quality.

A buffer vessel gives a smooth flow of nitrogen gas. The bespoke stainless steel system pictured on the right shows a complete skid mounted nitrogen solution.

Carbon molecular sieve



MAXIGAS MIDI with bespoke stainless-steel buffer vessel