

Consistent and precise climate control

Solutions for the pharmaceutical and
neutraceutical development
and production process

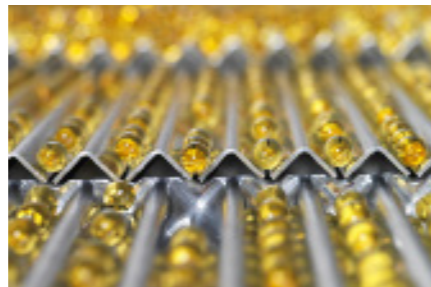
Munters provides optimal environmental conditions throughout the production process.



1. Dry Storage
Year-round stable humidity control in dry storage areas will prevent condensation, improve powder flow and reduce the need for frequent cleaning.



2. Cleanroom & R&D
Everything in a cleanroom needs to be accounted for and within specification, and that includes the air. Without proper humidity control, the exterior climate can affect the room conditions.



3. Drying
Optimal drying specifications for soft gel and hard capsule drying will be consistently delivered through desiccant dehumidification. Ideal air quality is provided year round to assure soft gels dry quickly and meet quality standards. Whether its gelatine, HPMC or other formulations, we can provide precise drying conditions. By carefully controlling the humidity, the moisture content of both filled and empty capsules is ensured.



4. Weighing/Mixing/Granulating
Optimal environmental conditions ensure that excipients and APIs can be continuously and reliably blended, while avoiding the influence of excess moisture that may affect mechanical and chemical properties. The right balance of moisture ensures that the granulating mixture remains in equilibrium with the air around it, maintaining the required moisture content for granules to form.



5. Milling & Compressing/Tableting
Maintaining the specified humidity set point will result in higher production throughput (prevent product sticking, reduce stoppages, and decrease waste), reduced energy consumption, and improved dosing accuracy.



6. Coating
Smooth, consistent thickness of coatings yields maximum visual appeal and proper dispersion characteristics. Avoid coating problems like roughness/orange peel, blistering, hazing, sticking and picking, and erosion by selecting and supplying the right drying conditions.



7. Biologics, vaccines, and parenteral products
Product quality relies on a clean, controlled manufacturing area. The presence of excessive humidity (>70% Relative Humidity (RH)) increases the potential for microbial growth. Humidity control also reduces drying time after cleaning operations.



8. Packaging
It's not just tablets or capsules that go into blister packing, the surrounding air also gets sealed in. With the right humidity level, you get packaged products that are longer lasting and durable. During blow fill seal packaging, condensation on cold surfaces can lead to surface imperfections that affect appearance and structural integrity. Controlling the dew point of the air around the packaging during the blow forming process can prevent this from happening.



9. Storage
Until the product leaves the plant, every effort needs to be taken to maintain quality and efficacy. Providing low humidity air to cold storage areas prevents ice, frost and fog, and improves worker safety. After production, dried capsule shells are vulnerable to the effects of humidity fluctuations, compromising mechanical strength and appearance. A stable climate during packing and storage avoids these risks.



Additional areas that benefit from climate control

Airlocks

Air within airlocks serves as a critical barrier between production zones. The optimal number of air changes coupled with humidity controlled air, reduces particle counts and reduces latent temperature loads on surrounding areas.



Pass Through Cabinets (PTCs)

Much like airlocks, PTCs need the right air treatment solution to maintain integrity of the adjoining zones. Using the same air handling specifications as neighboring airlocks reduces the moisture load within the cleanroom.



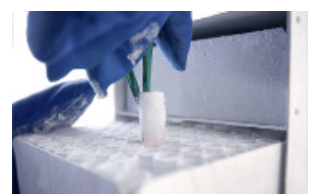
Corridors and anterooms

Controlling the air conditions in adjoining corridors and anterooms contributes to reducing the moisture load within the freezer. These areas will also benefit from correct humidity control.



Biological samples and products in freezers

When dealing with temperatures of $-25^{\circ}\text{C} / -13^{\circ}\text{F}$, $-70^{\circ}\text{C} / -94^{\circ}\text{F}$ or even lower, there is an ever-present threat of unwanted ice development. This reduces the efficiency of cooling coils, increases safety risks from slipping and poor grip, and can compromise packaging integrity. Control the humidity level, and the icing problem is eliminated.





Humidity control for medical products and devices

Test strips

The sensitive chemicals used for test strips need protection from moisture during production and storage. Providing the optimal humidity conditions through these production stages allows the end product to work as expected, which increases patient satisfaction.



Medical devices

Implantable and external devices need a carefully controlled climate during assembly, as reliability is a major concern. A Relative Humidity level of 50% or lower eliminates corrosion caused by water as a vapor or liquid.



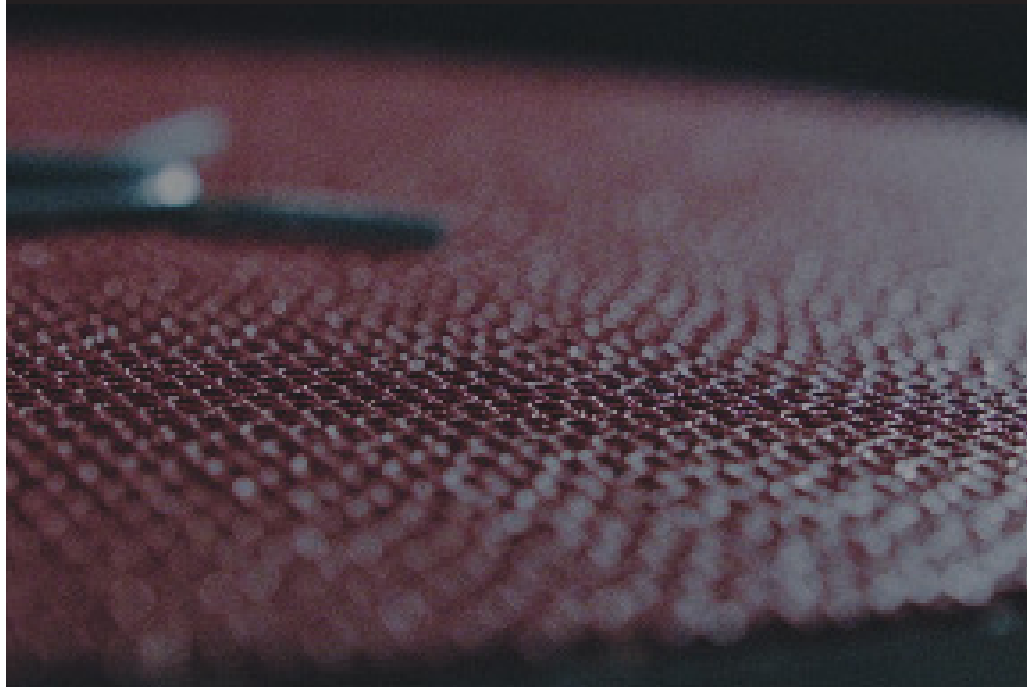
Your partner in production process improvements

All through the life cycle of Active Pharmaceutical Ingredient (API) development and production, Munters has a range of flexible solutions that deliver stable environmental conditions regardless of the weather or season and deliver your air quality requirements with fixed airflows and HEPA filtration.

Starting in R&D labs, our dehumidifiers for pharmaceutical and nutraceutical manufacturing can be used to control the relative humidity levels of isolators and glove boxes and allow fine tuning of the optimal humidity level for producing stable formulations making them the right choice when developing tablets, capsules, powders, and strips. This precise control allows Quality by Design (QbD) principles to be applied to Design of Experiments (DoE) centered on specific humidity levels in the early stages of product formulation. The findings of these experiments can then be transferred to pilot and main production later.

Munters can provide custom-designed humidity control solutions for every single area of pharmaceutical and nutraceutical production. Whether in silos, production facilities, warehouses or transport, humidity is consistently and precisely controlled. Munters systems provide considerable energy and cost savings, incorporating environmentally-friendly technology. Production capacity as well as hygiene conditions also improve considerably thanks to the effect of controlled humidity and GMP specified climate levels are continuously maintained.





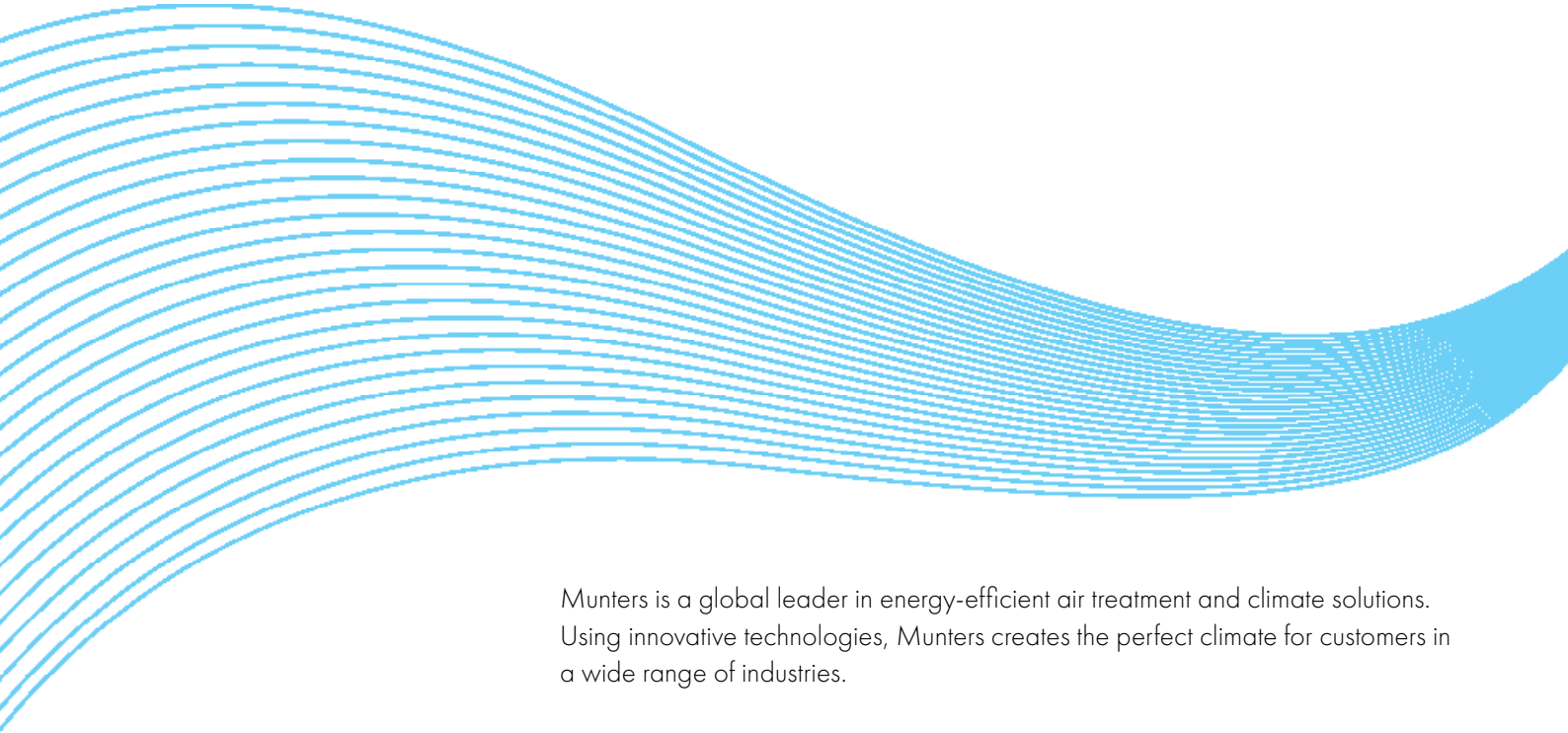
Munters Services With you all the way!

With Munters as your service partner, your air treatment equipment will receive the attention, care and maintenance needed to reach its maximum life expectancy. Throughout each phase of the equipment life cycle, the knowledge and expertise of Munters Services will ensure optimal operation, minimum energy consumption, and extension of the life of your investment.

Our range of services available through our global network of Munters Services engineers and technicians include:

- Comprehensive installation and start-up services
- PrimaCaire™ (extended warranty) agreement
- Flexible ServiceCaire™ maintenance agreements to fit your specific needs
- Performance checks and optimization
- Numerous upgrade options for substantial energy savings and improved performance

Regional availability may vary. Contact your local Services representative for further information.



Munters is a global leader in energy-efficient air treatment and climate solutions. Using innovative technologies, Munters creates the perfect climate for customers in a wide range of industries.

Munters has been defining the future of air treatment since 1955. Today, around 3,350 employees carry out manufacturing and sales in more than 30 countries.

For more information, please visit www.munters.com