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Abstract

Pharmaceutical production and processing often involves drying operations. After sterilisation or cleaning, for example, the items manufactured must be completely dry within a specified period for further processing. Also, many items must not be overly heated while being dried to comply with process and/or material requirements. And the energy balance should be satisfactory, too. Meeting all these requirements at the same time often turns out to be a challenge. The drying operation is frequently a bottleneck in the production process. It hampers or even blocks the smooth sequence of operations. Present-day plants require highly-performing, gentle and energy efficient processes. As far as drying is concerned this goal may be achieved using an alternative approach. A heat pump based, closed system makes it possible to dry at low temperatures. This so-called condensation drying can be used wherever retained water needs to be removed.

Introduction

Heat pump based condensation drying is a process capable of drying any solid matter at low temperatures between 20 °C and 90 °C as appropriate for the specific application. This is done by passing extremely dry and, thus, unsaturated air over the items to be dried to absorb humidity. In a downstream dehumidification module, the air is stripped of the humidity it carries. The humidity is condensed and the condensate drained off. Subsequently, the cooled air is reheated using the energy recovered, and recirculated. The loop is closed. This makes the drying cycle almost emission free. The dehumidification module, which controls the environmental conditions inside the dryer, is at-

Authors

Reinhold Specht

looks back on more than 20 years' experience in drying plant engineering and construction. He played a leading role in developing the condensation drying process and was in charge of Manufacture, Development and Design for many years. Reinhold Specht is the brother-in-law of company founder Roland Harter who died in 1998. As active owner, he manages the company today in cooperation with manager Ursula Harter.

Jochen Schumacher

has worked for Harter since 2001. He was responsible for design and project management with a focus on advancing the drying technology for application in the pharmaceutical sector. Jochen Schumacher changed to Technical Sales at the beginning of this year to employ his expertise there.

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tached to the drying station. It does not matter if batch or continuous drying is used. This drying system may be adjusted to bulk, drum or rack dryers, and to belt or chamber dryers as well. Also, products to be dried may be made of any material. This heat pump based condensation dryer named Airgenex® was devised more than 20 years ago by the owner-managed company Harter Oberflächen- und Umwelttechnik GmbH in Stiefenhofen, Germany, and has since been used in various industrial applications.

Condensation drying as a problem solver

It was on company founder Roland Harter's initiative that heat pump based condensation drying was developed. He had identified hot air drying, which is still state-of-the-art in many sectors of the industry, to be problematic rather than particularly helpful for operators. In fact, hot air dried surfaces left the drying process incompletely dry and too hot for further processing. There should be a solution to this problem. So the company, established in 1991, developed the so-called heat pump based condensation drying for customised application in production processes. In a two-year development effort, the first production hot air dryers were replaced by the so-called Airgenex® dehumidification modules. They were initially used, for the most part, in surface finishing processes by suppliers to the automobile industry. Heat pump based condensation drying is superior to conventional hot air drying in that it

- reduces drying periods,
- improves drying quality,
- is gentle with the products because it uses low temperatures,
- saves energy because the system is closed,
- recovers heat.

Airgenex® condensation dryers have since been employed in a large variety of production processes of the automobile, plating/coating, electrical, toy and furniture, sports and textile industry. Enterprises of the optical and medical industry are also interested in this novel technology because they, too, are faced with the production bottleneck presented by drying. Applications in this field include the drying of optical glasses, coated frames, blister units for contact lenses, tubelet bundles to become hypodermic needles, medical carts and trolleys, diagnostic instruments, lozenges, implants and biomaterials. The low drying temperature is gentle with delicate products and is, thus, also beneficial in the production or processing of foodstuffs. The first system for drying organic fruit was recently put in operation.

Technological advancement for pharmaceutical application

Belimed Sauter AG, Sulgen, Switzerland, also got word of this type of drying. The Swiss company is one of the world's leading suppliers of innovative system solutions for medical, pharmaceutical and laboratory cleaning, disinfection and sterilisation. In the field of human medicine, when producing infusion bags or bottles, both drying and cooling after sterilisation is a delicate issue. It is essential to use a drying temperature perfectly meeting the requirements of the items to be dried, and to safely control the environmental conditions inside the drying/cooling compartment. Once Belimed had familiarized themselves with this novel technology, it was decided to launch a pilot project to use the Harter dryer for pharmaceutical applications. This required modification to the type and dimensions of the materials used, adjustments required to comply with the applicable GMP, FDA and other applicable regulations, and adequate qualification of all the staff involved in pharmaceutical activities.

Pilot project using infusion bottles

One of Belimed Sauter's customers, a reputable pharmaceutical company, whose name may not be disclosed for secrecy, was also prepared to tread new paths. The post-sterilisation drying method used for their infusion bottles produced unsatisfactory results and needed to be improved. It was agreed to initially run a comprehensive series of tests on Harter's pilot plant station at their Stiefenhofen site to obtain proof of the performance of condensation drying. For the purpose of these tests, a drying station had a support system installed which consisted of seven supporting troughs on top of each other to hold a total of more than 1200 infusion bottles. The process parameters, such as air routeing and recirculation airflow, were determined at various testing stages. The correct airflow was obtained using a fan controlled by an airflow control. Optimum tightness of the support system, that is, ideal air routeing, was another important requirement to be met to ensure safe drying. The racks used by the pharmaceutical company were designed for sterilisation purposes and were not suited for drying, the manufacturer said. The operator was all the more pleased to learn of the positive outcome of the drying tests which implied that the infusion bottles could be left on their racks for drying and the process chain did not have to be interrupted. The test series also showed that Harter's condensation dryer is capable of meeting both the requirement for 99 % dryness without residues or drops and the requirement for the temperature to be achieved for further processing.

Exigent requirements

The pharmaceutical company did not only impose the requirement for complete drying of the racked bottles but also the following:

- complete drying of 100, 250, 500 or 1000 ml sized bottles,
- drying period not to vary for any given bottle size,
- drying and cooling to be effected in a single tunnel,
- automatic or controllable transition from drying to cooling.

The latter was a particular challenge to Harter engineering. Being a small business, Harter has both the size and organisational structure to build special equipment providing customized and functioning solutions. The task required fairly much development and design effort to bring the drying/cooling system in line with the process. Temperature differences in the process had to be reflected in the equipment design to cope with physical influences such as superficial condensation in cold ambient air, different temperature requirements for the drying and cooling processes and resulting variations in material volume. „A lot of know-how has gone into this equipment. So we cannot reveal any more details," says Reinhold Specht, managing owner of Harter.

Fig. 1: Drying/cooling tunnel being installed. The attached AIRGENEX®med dehumidification module is placed on top of the tunnel to save space.

Fig. 2: Specially adjusted air ducting system between drying/cooling tunnel and dehumidification module. Insulation of piping prevents unnecessary heat loss.

Post-sterilisation drying and cooling

The system finally introduced in the production process is as follows. Harter installed a drying/cooling tunnel 12,000 mm long x 2500 mm wide x 3400 mm high at the customer's premises. The tunnel includes 12 air recirculation fans – one for each rack position. These fans were designed for this special application. They generate a high, controlled total airflow. An exact figure cannot be given here for proprietary reasons. The tunnel has an AIRGENEX®med 40.000 dehumidification module attached which provides for the necessary environmental conditions for the various process stages inside the drying/cooling tunnel. The module was placed on top of the tunnel to save space (Fig. 1). The final system is, thus, very compact in design. Tunnel and dehumidification module are connected through a purpose-built air ducting system. Adequate insulation prevents unnecessary heat loss (Fig. 2). Batches of 12 support systems including seven support troughs each are loaded into the drying tunnel after sterilisation. A single load comprises, for example, as many as 15,000 plus of 500 ml infusion bottles. The sterilisation cycle time is 120 minutes. After sterilisation, the bottle temperature is approx. 55 °C. The whole process of drying and subsequent cooling was adjusted to the existing cycle time, upon request by the customer, so that the bottles also dwell in the tunnel for 120 minutes. Actual drying is completed after 20 minutes. The remaining 100 minutes are used for cooling the bottles to ensure smooth transition to continued processing. In this particular application, the energy released in the cooling process is removed through the existing cooling water system. The infusion bottles are uniformly and gently dried and cooled today. Downstream the drying/cooling station, the bottles are separated, inspected, labelled and packaged. Reliable drying and cooling now makes these downstream processes absolutely reliable.

The dehumidification process

How exactly does dehumidification inside the AIRGENEX®med module work? Fig. 3 depicts the process: The filtered, moist air (3) flows through the first zone of a Harter designed heat pipe where it is precooled (4). It is then routed through the air cooler. In the air cooler, the precooled moist air is cooled to below the dew point. The moisture condenses on the air cooler fins. The water is then drained from the module through a condensate collector (5). The cooled dehumidified process air flows through the second zone of the heat pipe where the heat extracted in the first zone is reintroduced. The heat pipe is fully self-sufficient and does not require any energy. The air is heated to the desired temperature in the air heater (6). An air recirculation fan, which circulates the air through the whole system, routes the unsaturated, dry and warm air back into the drying chamber (1) (2). Air heater and air cooler are parts of the refrigeration circuit which Harter has adjusted and optimised for their drying technology.

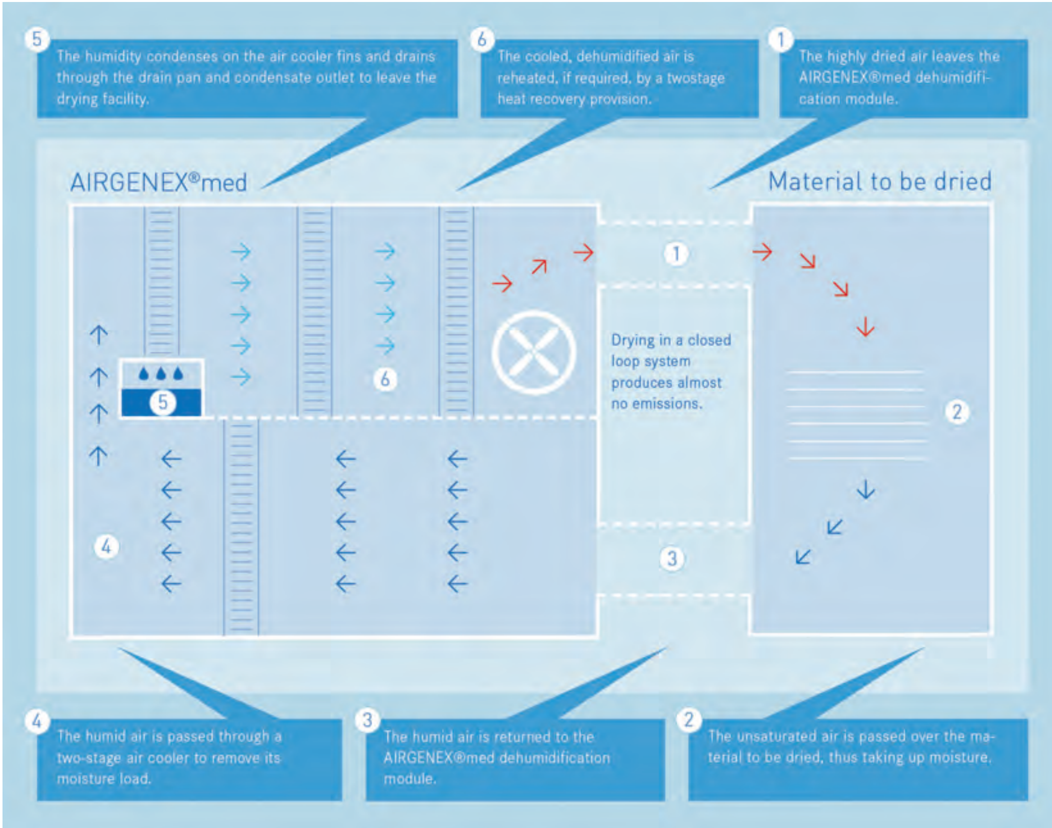

Fig. 3: AIRGENEX®med dehumidification module process diagram.

A lot of know-how required

Many years of experience with and in-depth study of closed-system condensation drying have taught us that two factors govern the success of a given drying system. Firstly, high-tech dehumidification, as described above, is a must. Secondly, but not less important, the air recirculation system inside the drying pack housing must be adapted to exactly meet the requirements of the specific application. Failure to do so will reduce the performance of the dehumidification module. The air recirculation system installed in the drying chamber becomes a customised solution (Fig. 4). For high drying quality to be achieved within short drying time it is essential that the air volume inside the drying chamber be as large as possible. The extremely dry and unsaturated air is passed at high speed over the items to be dried. The air is supplied from the AIRGENEX®med dehumidification module through an air ducting system into the drying chamber. Upon entering the drier, the air supplied blends with the recirculating airflow inside the dryer to form a uniform mixture. The unsaturated air absorbs any existing humidity extremely quickly, which is a physical phenomenon. Some of the now saturated air is branched off to be returned to the dehumidification module. It is essential that air routeing be designed such that the air actually passes over or – if applicable – through rather than past the items to be dried. Of course, the air wants to take the path of least resistance. So it must be forced to take the adequate path, an engineering effort which is „one of Harter's specialties", reports Jochen Schumacher, the responsible project manager. The air speed always needs to be adjusted to the specific product to be dried. This is where the surface of the product comes in – complex geometries require higher speeds than smooth surfaces do (Fig. 5).

Basically, the system shall be closed as possible, that is, without air supply and exhaust provision unless required for explosion prevention and protection purposes. Of course, continuous applications, where items are dried on a belt or in a tunnel, require openings at the entrance and exit sides. Such openings must be considered in the attempt to meet a specific water absorption rate. The counterflow principle is most often used in such applications, that is, dry air is routed in the direction opposing the one in which the items to be dried are transported (Fig. 5).

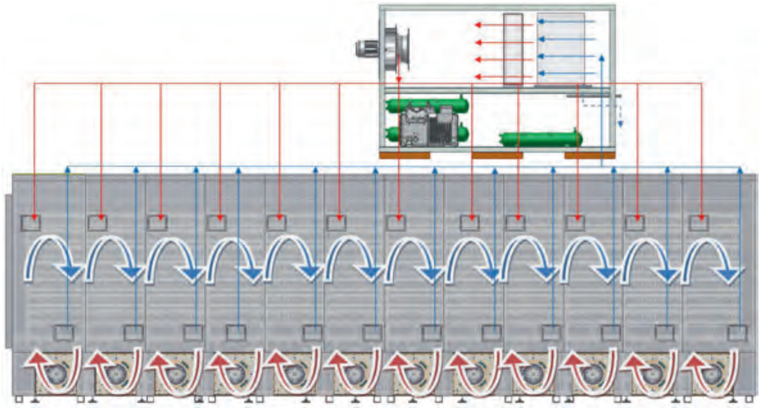

Fig. 4: Air routing in drying/cooling tunnel (infusion bottle project) driven by AIRGENEX®med dehumidification module.

Tube/pipe drying is a special application (Fig. 6). Tubes/pipes of various diameters are most often dried in bundles. Bundles sometimes include tubes/pipes of different lengths and/or diameters. This is why very long (16 m, for example) drying troughs are often used for drying. Exact air routing in such applications requires a special tightening system to ensure efficient drying of the inner and outer wall surfaces of the tubes/pipes and to eliminate energy loss. When drying hypodermic needles or filter tubelets, some of which have diameters of less than 1 mm, the tightening system automatically adjusts to the tube bundle geometry.

Drying of special surface coatings, such as lacquers or paints, is somewhat different. Air speeds required for such coatings are much lower than those required for retained water removal. The air speed must be adjusted to the coated surface such that the delicate coating is not impaired and cracking and rippling is precluded. Excessive air temperature will seal the coating surface so that any moisture enclosed may result in bubbling. Much the same applies when fluids are transferred on test sample cards. High drying temperatures will destroy the active ingredients. This can be prevented by gentle drying at below 42 °C.

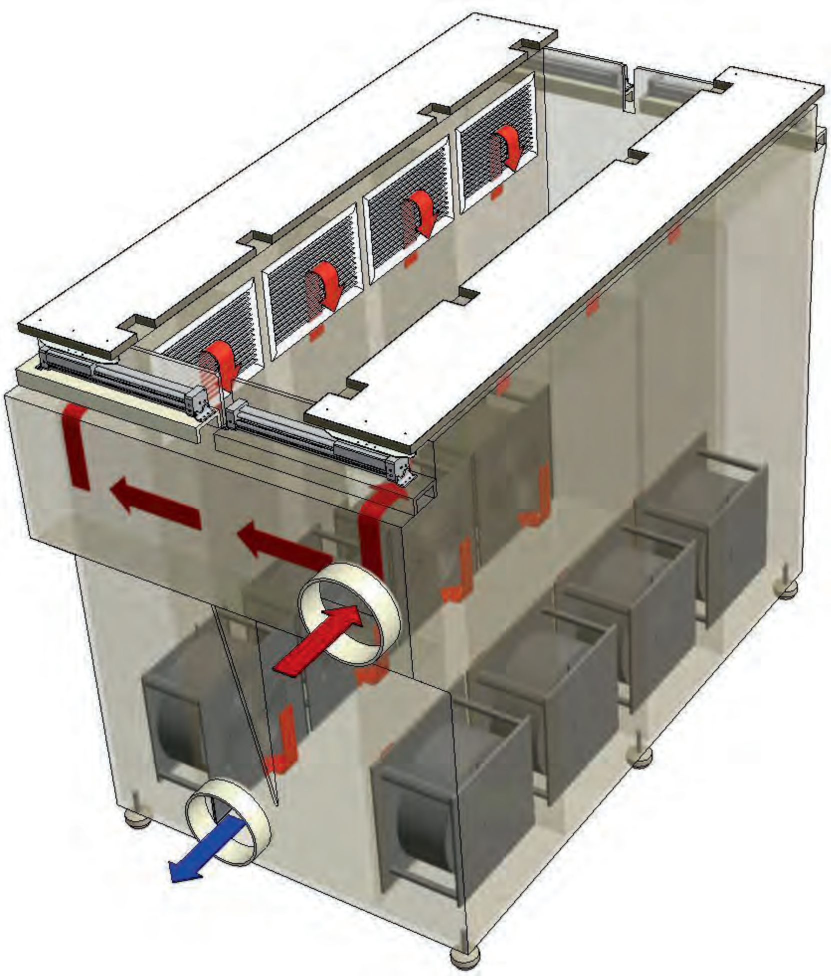

Fig. 5: Example of air paths in a drying chamber.

Fig. 6: Exact air routeing inside the drying trough is essential for drying bundles of tubelets.

Individual adjustments

Condensation drying is basically applicable to any process – using racks, drums, baskets, in batch or continuous operation, with items suspended, upright or flat. Each application has its particular requirements that must be met and requires a lot of experience. The pilot plant station (Fig. 7) at the Harter premises is used to run series of tests with items to be dried. Large items may also be tested in a scaled-down setting. The exact parameters for successful drying are determined, documented, and the hardware engineered accordingly. In this way, the specific air speed, air routeing and ideal drying temperature are realized for each application.

Process reliability and energy saving

It is safe to say that condensation drying in this way has many advantages for the plant operator. Time savings enhance plant economy. Heat recuperated in the closed system reduces cost of operation. The low input power of the AIRGENEX®med packs saves a lot of cost. The drying temperature is variable so that undesired heating of and resulting damage to the products is prevented which is particularly important for products made from plastic materials. Drying in the closed system makes processes independent from the seasons and resulting variations in the environmental conditions inside the workshops. Weather impact is thus essentially blocked off. The zero energy use of the heat pipe helps to further reduce the already low energy consumption of condensation drying. This Harter development provides highest drying efficiency. This heat pump technology closes an economically and ecologically reasonable loop. Quote by Reinhold Specht: *"As far as the future is concerned, it is obvious that the energy issue is gaining more and more importance throughout Europe. What used to be a nice-to-have when buying a dryer, namely energy saving, is rapidly becoming a top issue and, thus, a reason for investment. That suits us fine because our technology rides this wave."*

Fig. 7: Trial drying of infusion bottles in the Harter pilot plant station to determine parameters such as temperature, air speed and air paths.

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