

## DRYING IN JAPANESE QUALITY



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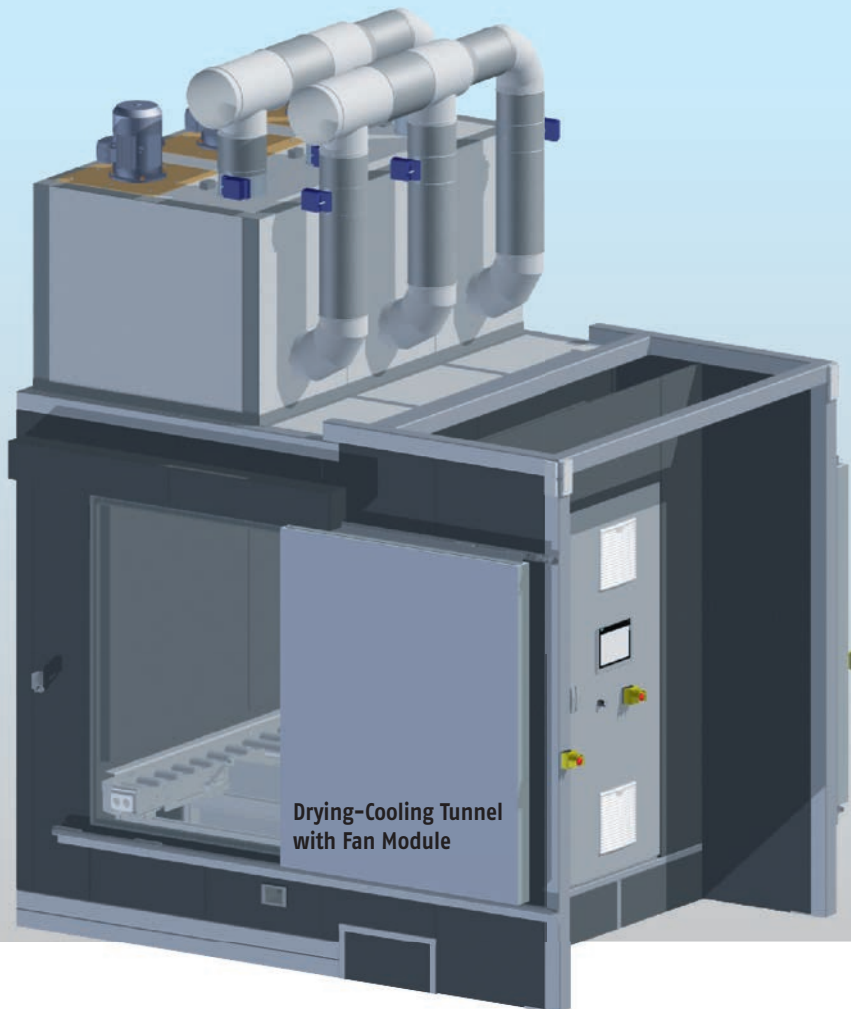
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# DRYING IN JAPANESE QUALITY

Producing pharmaceuticals requires such a multitude and complexity of aspects to be considered that the actual drying process stage is often overlooked. - This is despite the fact that high quality and reproducible drying can improve product quality while at the same time optimising the entire production process. This is what a major pharmaceutical company experienced when they implemented a condensation drying system.

By Jochen Schumacher\*

**T**akeda is a research-driven global enterprise mainly engaged in pharmaceuticals. Being Japan's biggest pharmaceuticals manufacturer and among the globally leading companies in the field Takeda is committed to improving the health-care of patients all over the world through innovation in medicine. The company is represented in some 70 countries with a focus on gastroenterology, oncology, cardiovascular and metabolic diseases, urology, gynaecology, immunological diseases, diseases of the central nervous system, general medicine and vaccines. The integration of Millennium Pharmaceuticals and Nycomed allowed Takeda to expand both geographically and in new therapeutic fields. Since 2012 Takeda have managed their activities on the German market from their base in Berlin complemented by additional administrative functions in Constance. As part of their global production network Takeda run production facilities at Oranienburg and Singen. The latter site is specialised in lyophilised pow-



picture: Harter

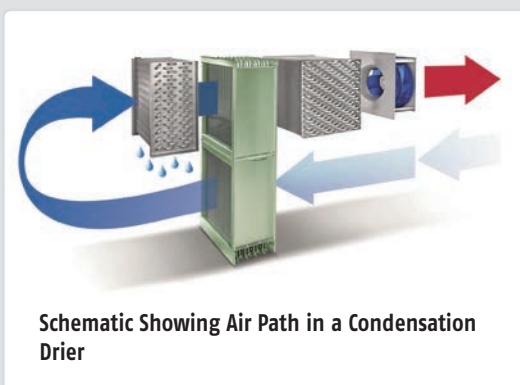
Alternative: Condensation Drying

## CUSTOMISED AIR ROUTEING MAKES THE DIFFERENCE

But how exactly does condensation drying work and what makes this technology so successful?

The so-called Airgenexmed drying method uses an alternative physical approach. Extremely dry and, thus, unsaturated air is passed over the items to be dried to absorb any 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 and recirculated. The loop is closed. This makes the drying cycle almost emission free. The technology controlling dehumidification is integrated in the drying station. It does not matter if batch or continuous drying is used. The drying chamber includes a custom-designed air recirculation system with specific air routeing. „Adequate air routeing is essential for condensation drying to take full effect. Of course, the air wants to take the path of least resistance. So it must be forced to take the right path, an engineering effort

which is one of HARTER's specialties and requires a lot of know-how", say experts of Harter Technical Sales. Because it is the perfect combination of dehumidification, air routeing, air speed and airflow rate that ensures successful condensation drying for the applicable product.



Schematic Showing Air Path in a Condensation Drier

picture: Harter

ders and semisolid dosage forms such as creams and balms. These substances are mostly used in oncology and gastroenterology. „Takeda stand up for very high standards as regards quality“, says Thomas Griem, Takeda Engineering Project Manager. This quality mindedness was reflected at each single production stage, particularly when it came to optimising the drying process of the vials produced. Their previous drying technology no longer met Takeda's requirements. By recommendation, Takeda learned of the Allgaeu drying system manufacturer Harter GmbH. Upon a visit to the Harter site, Takeda was introduced to the Harter developed drying technology and agreed to have drying tests run in the Harter pilot plant station.

### Gentle and Reliable Drying

The Harter purpose developed drying method is the so-called „heat pump based condensation drying“. It combines seemingly conflicting features such as low temperatures and short drying times. The Airgenex condensation drying system and its variants „Airgenex med“ and „Airgenex food“ is capable of drying, in a gentle and stress-free way at temperatures between 20 °C and 90 °C, items made from plastic, glass or metal, or organic products such as food or feed. Quality drying results at very short times are obtained through the use of extremely dry air routed as required for the specific application. The integrated heat pump technology ensures highest efficiency of the drying process. Drying always takes place in a closed system, which makes it absolutely independent of the climate. Clean room environments are not affected. With minor modification, the condensation drying system may also be used for cooling if desired

or required by the specific process. Takeda's persons in charge found this technology basically appealing. Yet, drying tests had to furnish evidence of the capability of condensation drying to meet the demanding requirements of the pharmaceutical company.

### Drying Tests to be on the Safe Side

For 25 years, drying system manufacturer Harter has designed and manufactured condensation type drying systems including heat pump technology. More than 1,000 of these efficient and, at the same time, energy-saving drying systems have been implemented in various industrial applications. From the very start of the business Harter has run an in-house pilot plant station to test customer products for response to drying. This is both part of the services offered and a reasonable method for determining the parameters for successful drying such as temperature, drying time, humidity, airflow rate and air speed.

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In the case of Takeda, tests were run using a Takeda rack and cassettes holding vials of multiple sizes ranging from 5 to 100 ml. This setup was more challenging than actual production conditions where batches always include same-size vials. Takeda's rack was inserted in a lab drying cabinet and connected to the Airgenex dehumidification module. The customer required his assortment of vials to be dried and cooled within 60 min. The time available for drying in actual production was 45 minutes maximum. The final temperature requirement was 50 °C or lower. For the purpose of these tests, the vials were heated to 70 °C, immersed in hot water and subsequently dried and then cooled for 30 minutes. This process produced dry vials with a final temperature of 48 °C. Thus, Takeda's requirements were more than fulfilled. There was no more obstacle to realising this innovation project.

### Post-sterilisation Drying and Cooling

In Takeda's production facility the vials are filled, closed, crimped and subsequently subjected

to terminal sterilisation. The 100 ml maximum vials are contained in perforated sheet cassettes about 30 cm long, 20 cm wide. Eight cassettes each are placed at 13 levels of a rack. The steriliser is loaded with three racks at a time totalling 312 cassettes. After hot water rinsing, the racks are automatically moved, on a roller conveyor, into the drying-cooling tunnel. Inside the tunnel, they are dried at 55 °C for 45 minutes and subsequently cooled to 35 °C for 30 minutes. The 3,400 mm long, 2,800 mm wide, 4,580 mm high drying-cooling tunnel is designed to accommodate three racks. A total of three special fans inside the tunnel provide optimum air routing with each fan providing its own recirculating system to pass the dry air required for drying through the applicable rack / cassettes. The total airflow rate produced is about 30,000 m<sup>3</sup>/h. This way, the drying process will run smoothly with partial loads, too. The dehumidification hardware controlling the environmental conditions is housed in a separate module which is connected to the tunnel through insulated air ducts. Thus, the dried air is blown into the tunnel, passes over the vials and returns moisture-laden

to the drying module. Excess heat from the drying system is dissipated through a water cooled plate heat exchanger. The system is storage programmable controlled. Upon completion of the drying-cooling process, the vials immediately undergo further processing.

### High Process Reliability by Conformance with GMP Requirements

Today, Takeda's existing leakage test systems can produce valid results. „Now that the vials are truly fully dry, there are no more alleged leakage reports to the system. False rejects, which were really vials with residual external humidity, are a thing of the past.“, reports Griem. Downstream processes can be started much earlier and intermediate storage spaces can be greatly reduced. In summary, it can be said that this method of drying ensures best quality and highest process reliability. Airgenex condensation drying is a flexible system which may be integrated in any process. Air dehumidification by means of a heat pump may be implemented in any batch or continuous operation.



View into Drying-Cooling Chamber