

A photograph of several glass vials with silver crimp caps, some containing white lyophilized powder. The vials are arranged in a cluster, with some in the foreground and others in the background, creating a sense of depth. The lighting is soft and even, highlighting the texture of the powder and the metallic sheen of the caps.

Inspection of vials with lyophilizates

As part of its quality strategy, a large pharmaceutical group worldwide relies on inspection solutions from WILCO AG. In the past, the focus was on leak testing of sterile pharmaceuticals. Now the pharmaceutical giant is expanding its machine park with another trend-setting inspection system from WILCO. An inspection system that combines 3 inspection technologies on one platform – the VARIO MTX.

The challenge

The central requirement of the system is the fully automatic inspection of various quality-relevant parameters of vials filled with lyophilized product. In addition to the non-destructive 100% CCI testing and Lyo inspection, defects in the packaging material, such as defects in the crimp cap, must also be inspected. The product itself has to be inspected at over 400 units per minute and in 17 different formats.

Our approach

Our broad technology portfolio was a good starting point for meeting these requirements, which also required some new developments. Our holistic concept convinced the customer. Our analysis of the initial situation and the objectives led to the conclusion that the requirements could not be met with one inspection technology alone. Our envisaged a combination of visual inspection, headspace analysis and NIR spectroscopy. The aim was to accommodate these three inspection technologies in the most space-saving way possible.

Our solution

Defects of the crimp cap are inspected with three camera systems. The special feature is that the optical system has no moving components and does not require any

manual adjustment in case of a format change. This significantly increases process reliability and is also very user-friendly.



This is followed by an analysis of the residual moisture in the lyophilizate. This may vary depending on the freeze-drying process. However, if a critical value is exceeded, this can have a negative impact on the durability and thus the effect of the drug. Accordingly, a 100% control should be performed. A high-performance NIR spectrometer is used for this purpose. At full speed, light reflections of the product in the near infrared range are detected and evaluated by a spectrometer. This information is used

to precisely determine water concentrations and thus enables the rejection of non-conforming products. Finally, the oxygen concentration in the vial is measured fully automatically. Headspace analysis is used for this. Since oxygen concentrations of less than 0.7% had to be measured at a rate of 400/min, multiple laser systems are used. One innovation which has been implemented here is the latest generation of laser, which sets new standards in terms of sensitivity and thus enables new applications.

The advantages

- Holistic view of the inspection tasks for lyophilizates
- Process specific technology selection & combination
- High process reliability due to integrated verification systems
- Optical system that does not require manual format adjustment
- 100% non-destructive inspection of various quality relevant attributes ensures product conformity
- Processing of various products on one inspection platform
- Support from method development to production start by our specialists
- Space savings owing to the combination of multiple technologies on one platform
- Low changeover times and high machine availability