

HOF Massanalyser

Quality monitoring of pharmaceutical freeze drying plants –
meets all criteria of the EU GMP Guide Annex I



premium pharma solutions

Safe handling and high accuracy



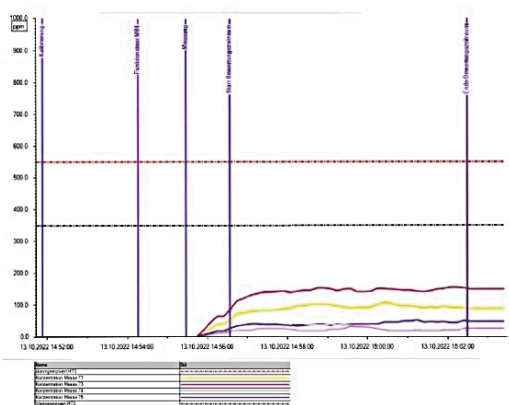
■ State-of-the-art technology for process monitoring

Mass spectrometers are being used more and more frequently in the pharmaceutical industry because they increase production reliability and enable continuous monitoring of the production environment.

The HOF Massanalyser is an integrated measuring solution based on a mass spectrometer for determining specific mass spectra in the processing chamber of a freeze drying plant. It is particularly suitable for analysing traces of silicone oil and monitoring the steam concentration in the process atmosphere in a vacuum.

■ PC-based, multifunctional and versatile measuring system

The PC-based system is installed temporarily. It can be adapted to specific measuring tasks with the supplied adapters and tube segments. It detects all gaseous contamination and delivers a precise output signal (ppm, partial pressure). This multifunctional system is already a proven system, successfully used at the customer's, at HOF's technical centre and at maintenance visits and can be applied in different freeze-drying plants.





The HOF Massanalyser focuses on three test methods:

1 Product safety through silicone oil detection for optimised drying processes

Silicone oil leaked into the drying chamber has an impact on the product and leads to production losses. If a leak is detected with a visual check, it is usually no longer possible to determine when the silicone oil first leaked and consequently several product batches have to be examined.

The HOF Massanalyser uses mass spectrometry to detect even small quantities of silicone oil inside the dryer, enabling early detection of contamination. This helps to prevent product loss and the associated costs.

Whether measurements are carried out cyclically or continuously depends on the respective production concept and the corresponding process requirements.

2 Precise moisture monitoring for optimum drying processes

With the HOF Massanalyser, moisture and moisture content can be monitored precisely. Thanks to its high level of flexibility, the mass spectrometer can also be used to monitor the steam concentration and other occurring gases. This helps to optimise drying processes and prevent unnecessary drying times.

The system also enables monitoring of the moisture level during the drying cycle. In the beginning, saturated steam is used, which is quickly removed from the product. The moisture level reduces significantly later on during the drying process.

The HOF Massanalyser measures this drop accurately and correlates the measurement with the average actual product moisture. This information helps to refine the drying processes and minimise unnecessary drying times. Another advantage is that the drying curve of the product can be predicted based on the moisture content.

The drying progress of each batch can be compared with a "qualified batch" to confirm that the process is running as expected.

3 Efficient leak testing for optimum system integrity

The HOF Massanalyser makes it possible to significantly shorten the time for leak testing after critical tests or sterilisation. This test is indispensable for preventing contamination due to leaks in the system.

The HOF Massanalyser can be used to run leak tests for preventing all contamination due to leaks in the system. This standard procedure can take some time depending on the type. The very high response sensitivity of this device, however enables a significant reduction of the duration of this test.

If a leak is found during a test, a helium leak test has to be conducted to find the cause, which can take some time if external standard equipment is used.

As the system is permanently connected, a helium leak test can be started immediately, to save precious time and detect leaks more quickly.

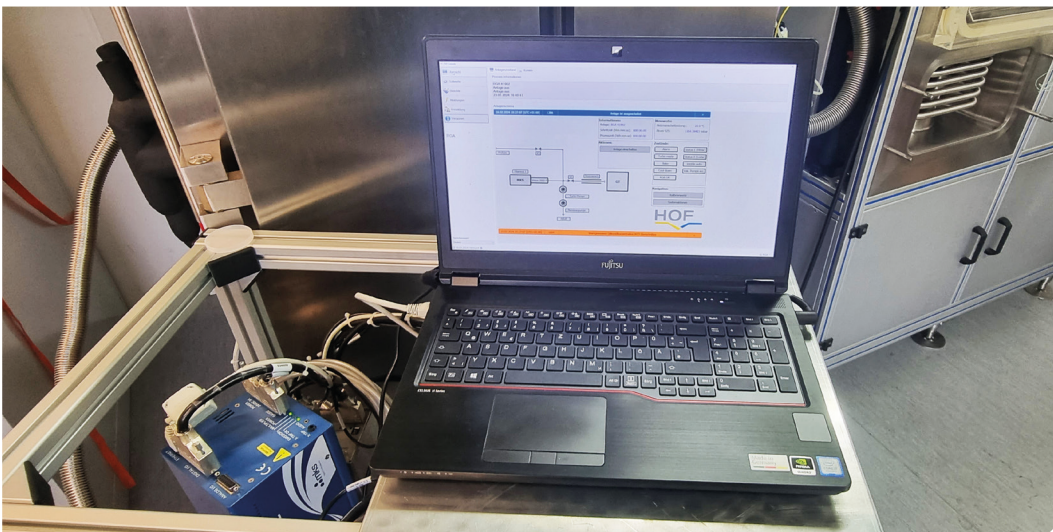
Highly precise, absolutely reliable and flexible

The HOF Massanalyser is a highly precise and reliable measuring device.

Based on an advanced technology, it enables easy and effective process monitoring. A special focus was placed on safe handling and high performance.

The versatile measuring device can be run independently or integrated seamlessly into existing control systems without impacting the active process.

The proven multifunctional system can be used flexibly on different freeze drying plants. Three application variants are available.





Multifunctional measuring system for more safety in production

HOF offers three application variants for the HOF Massanalyser:

HOF Massanalyser <i>mobil</i>	HOF Massanalyser <i>smart</i>	HOF Massanalyser <i>integrated</i>
1 device for several lyos	short connecting cable	short connecting cable
not integrated into the process	not integrated into the process	fully integrated into the process

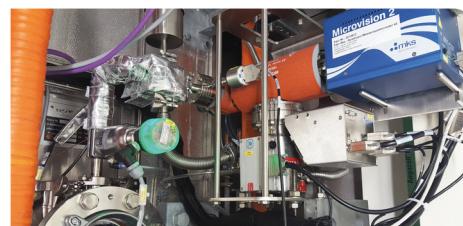
HOF Massanalyser mobile

- used for several lyos
- minimum qualification effort due to no intervention in the lyo software
- separate PC and test report



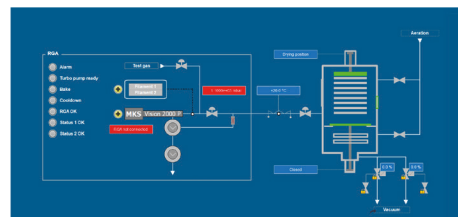
HOF Massanalyser smart

- stationary version with own software
- minimum qualification effort due to no intervention in the lyo software



HOF Massanalyser integrated

- stationary version with software link to the freeze drying plant
- fully integrated into the sterilisation process sequence or plant self-test



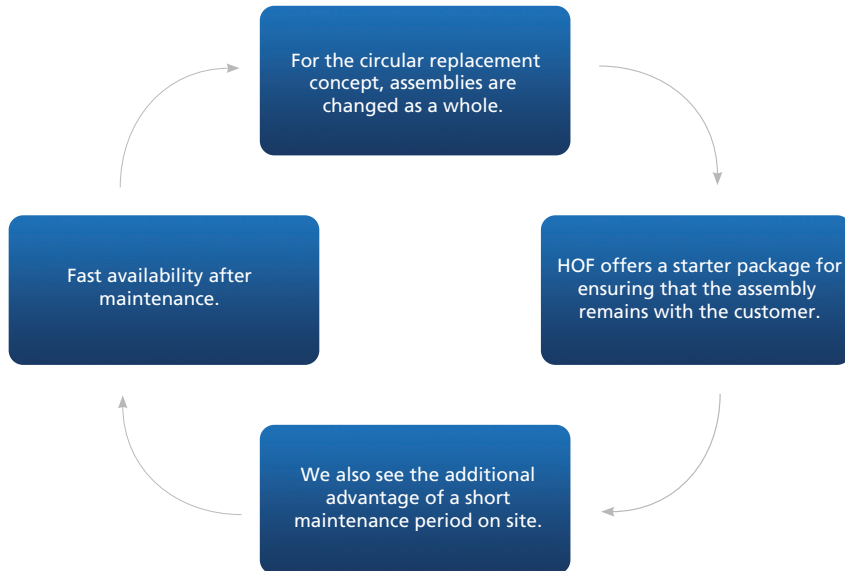
Efficient maintenance with HOF Service⁺

As a mass spectrometer like the HOF Massanalyser is a highly sensitive measuring device, it is advisable to service the system regularly.

HOF recommends to replace at customer's especially the sensitive components as an assembly using a circular concept and then having these cleaned/refurbished and checked at HOF according to the manufacturer's instructions.

This procedure ensures short maintenance periods, ensuring fast availability of the system for production.

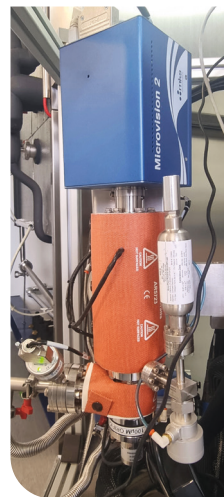
For the circular replacement concept, complete assemblies are replaced and then re-installed during the next maintenance. HOF offers a starter package for maintenance to ensure that the assembly always remains with the customer and that the most important assemblies are always available.



Overview of services

- Measurements with mobile devices at the customer site
- Maintenance/repair of RGAs to manufacturer's specifications by trained qualified personnel
- Training courses at the HOF factory or on site
- Measuring of the background contamination for specification in production

HOF⁺ Service



The HOF Massanalyser:

Efficient product safety with optimum process monitoring



Benefits at a glance

- Optimum detection of silicone oil



- Precision moisture monitoring



- Effective leak testing



- Automatic detection with integration into the turnaround without changing the process sequence of the FD
- Low validation effort as the main process remains unaffected
- Verification of the calibration and measuring sensitivity thanks to automatic calibration and function test during detection
- Generation of a separate batch log
- Optimum service and maintenance products



- Reliable customer support
- The HOF Massanalyser meets all criteria of the EU GMP Guide Annex I, offering the required reliability for easy and efficient quality monitoring.

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