

Filter Test Module

For use with Modular-Lab **easy**



For testing of pressure holding capabilities of sterile filters

Introduction

Integrity testing of sterile filters and the corresponding documentation are fundamental requirements of several guidelines when working with radiopharmaceuticals. Eckert & Ziegler has developed a Filter Test Module as an add-on to the synthesizer Modular-Lab easy. It allows monitoring of the pressure holding capabilities of sterile filters after each synthesis with Modular-Lab easy.

Attention: The described filter test does not replace the filter integrity test that is required to be performed after the aseptic filling of a ready-to-use drug.

Method

The working principle of the Filter Test Module is based on a non-destructive pressure holding test and suitable for pre-wetted, non-vented sterile filters. The filter test is performed after each synthesis. It can be executed at the same time as other quality control procedures without the need to remove the filter from the cassette.



Different parameters of pressure holding capacity of filters with intact membrane are used for evaluation. A pressure holding test is a recognized alternative to the bubble point and diffuse gas flow test. Depending on filter type, filter preparation and membrane wetting in particular, the measured values may underlie slight variations. The filter integrity is however not compromised.

Prior to the actual filter test the device is checked for leaks by a system test. The actual filter test can only be performed if the previous system test has passed.

A pressure sequence in the range of 500 to 2400 mbar is applied to the previously used filter and the pressure holding capability is monitored. The pressure drop must be in correlation to the typical filter characteristic. The complete cycle will take about 5 min for the generation of all pressure drop values according to the pre-defined values. After finishing the measuring cycle a special diffusion analysis is performed and ends with the final statement "passed" or "failed".

The final result of the filter test (passed or failed) is displayed in the HMI-scheme and reported in batch protocol.

In case of a failed filter test, the user will be informed and instructions for further steps including testing for loose connections and repetition of the filter test will be given.

Included Hardware components

- Filter Test Module
- Tubing set (C-FTM-VS1)
- Sterile kit (C-FTM-VS2)

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