ChargePoint AseptiSafe® | Sterility Challenge

FULL STUDY REPORT AVAILABLE UPON REQUEST

Microbiological study of aseptic transfer of vial stoppers with ChargePoint® AseptiSafe split butterfly valve.

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TEST BY: SKAN AG
Basel, Switzerland

INTRODUCTION

The spilt butterfly valve has a number of practical advantages over existing transfer techniques although for years lacked the microbiological data to support its use. This study aims to gather this data by means of qualifying the technology.

The ChargePoint butterfly valve consists of half ports – an Active and a Passive. During the operation, the Passive is docked to the Active port in such a manner that the previously exposed surfaces of both ports are locked against each other. In this way, two different controlled environments (class C and class A, for example) should be kept separated, and an aseptic transfer of material should be assured through the valve.

This study investigates investigate its suitability to achieve an Aseptic transfer of material, in this case vial stoppers, through the valve thus keeping controlled environments separate and free form migration of microbiological contamination.

TEST PROTOCOL

The practical qualification involved challenging the split butterfly valve with class C bioburden (20-25 spores per 2826 mm^2, i.e. area of a standard contact agar plate), using *Geobacillus stearothermophilus* spores, and transfer vial stoppers through the valve. The transferred stoppers where then incubated in a growth medium to detect any bacterial growth.
The microbial study was further divided into two test parts (A and B).

In the test (B), Class-C bioburden exposed surfaces of the valve (valve plates) was disinfected with 6 % H2O2 prior to the assembly of the valve. Whereas, in test (A), no prior decontamination of Class-C exposed surfaces was carried out. For each test, the experiment was conducted in triplicates using 3 valves with multiple make and breaks under identical experimental conditions in a Pharmaceutical sterility isolator (PSI).

Figure 1: Loaded isolator chamber and airlock.

Figure 2: Example of bulk transfer of stoppers in IBC form autoclave to Filling Line via split valve at each stage (not part of this study).

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RESULTS

- ✓ Bacterial growth was observed in positive controls for both parts of the test (A and B)
- ✓ Negative controls remained clear.
- ✓ No turbidity (implying no bacterial growth) was observed in any of the test containers.

This means that non of the contamination inoculated onto the faces of the discs had managed to migrate onto the stoppers during the transfer.

DISCUSSION

With the results of this study it could be clearly demonstrated that aseptic transfer of stoppers through the valve assembly can be achieved in routine pharmaceutical processes wherever required.

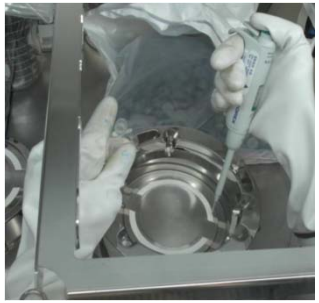

Figure 3: inoculation of valve plates with class C bioburden.

ASEPTISAFE BENEFITS

- ✓ Ergonomically, docking and actuation is unhindered by gloveport or gloves. (operated from outside the enclosure)
- ✓ No intervention into the line and less operations to perform the transfer.
- ✓ No intervention means less risk (particle generation and damage)
- ✓ No intervention means no additional gloveports to access the device internally.
- ✓ No intervention means no additional cost from the RABs / Isolator supplier (glass /port/ glove)
- ✓ No opening parts inside the line means no disturbance to the laminar flow inside the aseptic core and no particle generation over the stopper bowl.
- ✓ Passive can be reused after transfer. Autoclaved or SIP if mounted to a Stopper transfer vessel.
- ✓ Contamination free transfer.

Figure 4: Transferring stoppers through the valve.

Figure 5: Example of small scale stopper transfer from ChargeBag PE via AseptiSafe split valve mounted to filling line isolator (not part of this study).

FURTHER INFORMATION

Contact us for further information or a copy of the full study report.

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