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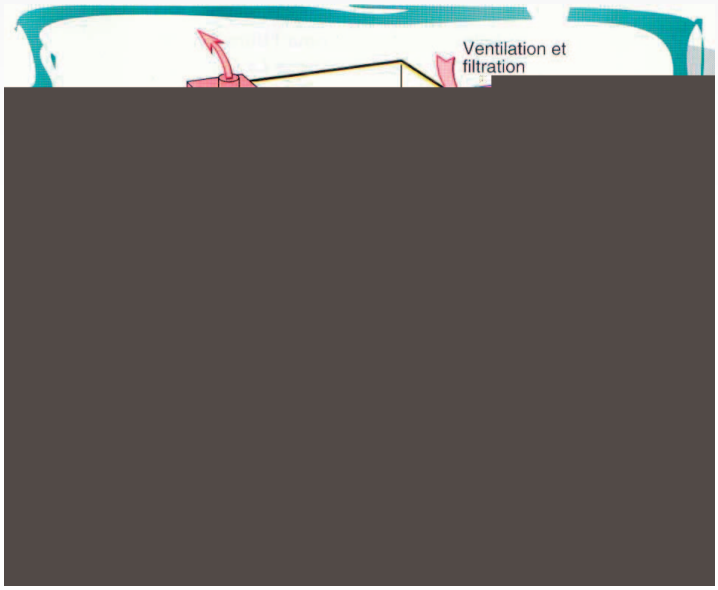
AIR MONITORING IN ISOLATOR



Application Note n. 99/85

CONNECTION TO "SAS ISOLATOR"

Introduction: The "SAS Isolator" microbiological air sampler has been specifically developed and produced to be adapted to any type of isolator ... >>>

Application Note n. 677

THE BIOAEROSOL MONITORING IN ISOLATOR

Introduction: Active microbial air sampling to monitor the isolator performances in preparation of sterile bulk drugs, sterility testing and containment of material is a fundamental step ... >>>

Application Note n. 2003

BIOAEROSOL MONITORING IN ISOLATORS STANDARD OPERATING PROCEDURES

Introduction: The microbiological monitoring of the bioaerosol inside an isolator to check the sterility is a critical task. It is in fact imperative to avoid contamination and to reduce the space occupied by the air sampler ... >>>

Application Note n. 2015

THE ISOLATOR DECONTAMINATION AND CONTROL OF THE RESULT OF DECONTAMINATION

Glossary: Biodecontaminant, biodecontamination cycle, cleanroom, D-value, biological indicator, chemical indicator, isolator, hydrogen peroxide, peracetic acid, spore, sporicide, sterilisation, total kill, validation, VHP ... >>>

Application Note n. 99/89

STANDARD OPERATING PROCEDURE FOR AIR IN ISOLATOR

Introduction: Microbial monitoring is mandatory inside the isolators according to several international bodies ... >>>

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Question:
How long it takes ti sample 1 cubic metre of air (1000 litres) inside an isolator?
Answer:
"Time is money" >>>
Working with ***SAS Isolator Super 180*** (180 lts/minute) the time requested is 5 minutes.
Working with ***SAS Isolator Super 100*** (100 lts/minute) the time requested is 10 minutes.

Question:
The ***"SAS Isolator"*** microbiological air sampler has been specifically developed and produced to be adapted to any type of isolator. Which are the most suitable connectors for the pass-through wall of the isolator?
Answer:
Different options are reported in the following documentation: >>>

Question:
The stainless steel aspirating head of the microbiological air sampler "SAS Isolator" (inside the isolator) is separated from the command unit (outside the isolator) and connected by a protected electric cable. What is the maximum possible distance of cable inside the isolator?
Answer:
Zenone DallaValle, International PBI
There is no limitation of the length of the cable inside the isolator. It is important to calibrate the instrument with the cable that will be used.
The ***"SAS Isolator"*** is delivered with a standard 3 metres cable.

Question:
How is it possible to monitor the microbiological conditions of the air of the isolator in its small space and to avoid contamination risk?
Answer:
The microbiological monitoring inside an isolator involves several considerations: the limited space, the potential contamination risk, the sterilisation cycle, the simplicity and convenience of the use of the air sampler.
All these possible problems have a solution adopting the ***"SAS Isolator"*** air sampler.
(a) the aspiration chamber of the air to be monitored is separated from the command unit (that is outside of the isolator) and therefore the space for the sampler is drastically reduced;
(b) the stainless steel construction of the aspiration chamber enables the sterilization by VHP or other agents;
(c) all sampled air remains inside the isolator and therefore there is no risk of contamination due to an irregular activity of the air valves to the outside of the isolator;
(d) the command unit outside of the isolator simplifies the activity of the operator;
(e) "SAS Isolator" sampler is available for ***Contact Plate*** and Petri dish;
(f) The stainless / steel total construction and the compactness of the aspiration chamber enable the fixing of it in the more convenient space inside the isolator (e.g.: on the wall, on a support, etc.). >>>

Question:
How to decontaminate and control the result of decontamination in isolator?
Answer:
Glossary
Biodecontaminant, biodecontamination cycle, cleanroom, D-value, biological indicator, chemical indicator, isolator, hydrogen peroxide, peracetic acid, spore, sporicide, sterilisation, total kill, validation, VHP.
Introduction
The use of isolators is day by day more frequent in the pharmaceutical and food fields, in total or partial replacement of Clean Room.
The official definitions of isolator for pharmaceutical use are reported in the following documents:
- PICS 014-1 "Isolators used for aseptic processing and sterility testing" (5.1 e 5.2.)
- PDA Technical Report 34 "Design and validation of Isolator Systems for the manufacturing and testing of health care products".
- USP <1208> "Sterility testing validation of isolators systems".
The biodecontamination cycle of the isolator and the related control are fundamental for its correct use.
Isolator biodecontamination
The used and more frequent typical germicidal agents are peracetic acid and hydrogen peroxide (VHP). The biodecontaminants are toxic and therefore should be use with precaution.
The biodecontamination parameters of the gaseous cycle are its concentration, permanence time, final aeration time. It is also very important to consider the amount of items inside the isolator to avoid non homogeneous concentration of the sporicide gas and its presence at the end of the decontamination period.
The use of chemical indicators
The chemical indicators should be inserted in different positions inside the isolator to find areas that are not adequately treated by the sporigen gas.
The use of biological indicators
The sterilization should reach the reduction of the microbial population of at least 6-log.
The biological indicator to be used is Geobacillus stearothermophilus ATCC12980
with a starting population of 106 spores and a D-value between 1 and 2 minutes.
The used method is the "total kill". The ideal "Carrier" for the microbial population of the biological indicator is the stainless steel.
The periodic microbiological monitoring of the isolator
The isolator should be regularly monitored using an active microbiological air sampler like ***"SAS-ISO"*** using contact plate (RODAC) o Petri dish.
The advantages of the use of ***"SAS-ISO"*** in isolator are: very compact, easy to use, stainless steel construction, robustness, sporicide resistance.

Question:
Why to chose the ***"SAS Isolator"*** microbiological air sampler in the isolators?
Answer:
The answer is given by the technicians of the Company Bristol Myers Squibb.
"After conducting a comparative analysis with seven other isolator systems, the SAS Isolator was chosen because it was the only isolator system that did not push the air inside the isolator back out into the room. Therefore, it protects both the integrity of the products as well as the safety of scientists by preventing a leak of the isolator air. All the other seven competitive isolator systems had tubing system that sent the isolator air back into the room."

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