Validation of the air circuit decontamination efficiency of the bioMérieux *air IDEAL 3P* air sampler

bioMérieux Industry Culture Media Group, Chemin de l'Orme, 69280 Marcy L'etoile, France

The validation of the efficiency of the decontamination of the air IDEAL 3P air circuit was third party validated by JohsonDiversey. This document summarises and discusses the report N° AT 294504401, (dated 28th November 2005) from JohnsonDiversey.

Abstract

air IDEAL 3P is provided with a simple and efficient procedure to decontaminate the equipment's air circuit with Isopropylic Alcool (IPA). The efficiency of this decontamination using JohnsonDiversey product, ClearKlens IPA has been validated following the recommendation of the NF EN 1040 standard (ref. 1). This procedure allow the reduction of 4.6 log of *Pseudomonas aeuruginosa*. This performances is fully compatible with the natural bioburden of Pharmaceutical clean rooms.

Material and methods

Air sampler: The *air IDEAL 3P* from bioMérieux. It's an impactor type of instrument based on the principle described by Andersen *et al*. (ref. 2), in which air is aspirated through a grid perforated with a pattern of 286 calibrated holes. The resulting air streams containing microbial particles are directed onto the agar surface in a bioMérieux irradiated Trypcase Soya Agar plate.

Disinfectant: 70% Isopropylic Alcohol from JohnsonDiversey (ClearKlens IPA). This product is a bag on valve sterile disinfectant aerosol: the bag inside the can protects the IPA solution from the propellant gas and the metal particles. ClearKlens IPA is bactericidal and fungicidal (NF EN 1040 and NF EN 1275), 0.2µm filtered, gamma irradiated and double bagged.

Decontamination procedure: in order to reach all the area of the air circuit, two pulverizations of the disinfectant have been sprayed on the instrument at rest. One on the front of the instrument trough the suction fan. One in the exhaust of the air-sampler. The aerosol was placed at 30 cm of the instrument. Two duration of pulverization have been studied: 5s and 10s. A constant pressure on the valve was maintained during all the duration of the pulverization. The contact time was fixed at 5 min.

Strain of references: *Pseudomonas aeruginosa* CIP 103.467. This strain is recommended by the NF EN 1040 standard to test the bactericidal activity of the antiseptics. Two bacterial suspensions of $2.4.10^8$ CFU/ml and $2.5.10^8$ CFU/ml were prepared, one for each pulverization duration. The concentration of each suspension was checked by numeration. The solution of bacteria was then place on the most critical point of the instrument's air circuit. The assay was performed in duplicate.

Sampling method: after decontamination of the air circuit following the predefined procedure, the residual bacteria present on the equipment are sampled with a sterile swab. A positive control is sampled following the same methodology before decontamination. The concentration of bacteria present on the instrument before (positive control) and after decontamination (Assay) were checked by numeration (table 1).

Table 1: Validation of the air circuit decontamination efficiency

Pulverisation duration	Bacterial suspension	Positive control	Assay n°1	Assay n°2
5 s	$2.4.10^8$ CFU/ml	$1.5.10^4$ CFU/ml	2 CFU/ml	1.5 CFU/ml
	Log reduction		3.9 log10	4 log10
			4 log 10	
10 s	$2.7.10^8$ CFU/ml	$4.3.10^4$ CFU/ml	0 CFU/ml	1.5 CFU/ml
	Log reduction		4.6 log10	4.5 log10
			4.6 log 10	

Results and Discussion

The contamination procedure allow a bacterial reduction of:

- 4 log for a pulverization of 5s.
- 4.6 log for a pulverization of 10s. (table1)

This level of disinfection, is fully compatible with bioburden observed in Pharmaceutical clean room. According to US and European cGMP (ref. 3 and 4), the bacterial contamination of clean rooms has to be included between 1 to 100 CFU/m^3 following the classification of the area.

Thus, this procedure of decontamination of the air circuit is complementary to other *air IDEAL 3P* features:

- Perfect cleanability due to its smooth surface, free of dead angles.
- Compatibility with disinfectants.
- Autoclavable grids.

All together these features ensure a reliable disinfection of *air IDEAL 3P* for use in aseptic environments.

1. Andersen, A.A. "New sampler for the collection, sizing and enumeration of viable airborne particles." J. Bacteriology. (1976).
2. NF EN 1040 "Antiseptics and chimical desinfctants – bactericidal activity". (1997).
3. European Direction Directorat Genral III "Good manufacturign Practice. Medicinal products for human and veterinary use". (1998)
4. US Departement of Health and Human Services Food and Drug Administration "Curent Good Manufacturing Practice".