PARTICULATE AIR QUALITY IN THE ISOLATOR THROUGHOUT A PRODUCTION PERIOD. FACTORS IMPACTING CONTAMINATION.

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Introduction

- Microbiological contamination (risk for the sterility for our preparations) is intimately linked to particulate contamination, as particles are possible vectors for micro-organisms.
- To control air quality, French Good Preparation Practices (GPP; enforceable text for preparation in hospital pharmacies) require that the air inside the work area to be qualified as Class A, but does not impose air monitoring in activity as specified in the GMP

Objectives

1. Demonstrate that our isolators meet Class A GPP standards at rest
2. Assess the particulate contamination in activity to approach the more drastic GMP criteria.
3. Highlight the different factors impacting the particulate contamination within the isolators in order to take the necessary corrective measures and control this contamination as well as possible.

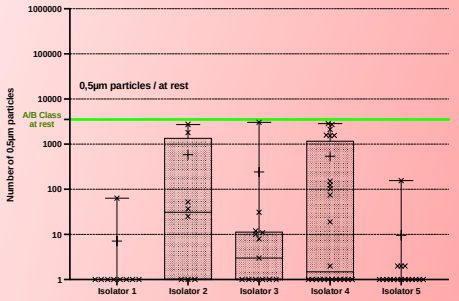
Materials and methods

- Particle counter PMT Aerotrack Portable 9510-012
- Continuous sampling during an active day, values taken every 10 minutes
- Particles monitored : 0.5µm and 5µm
- Repeated 2x (i.e. 2 days) for the 5 isolators in the preparation area.
- Specific factors followed and validated by Kruskal Wallis' test.

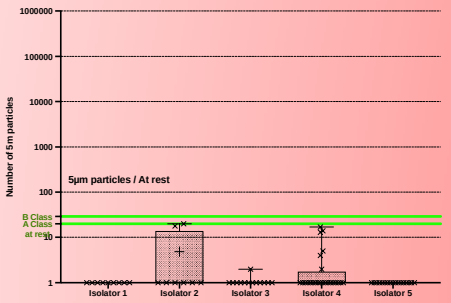
Results

INACTIVITY PERIODS

- Particulate contamination by isolators
  - o *Particles of 0.5 µm*



  - o *Particles of 5 µm*



ACTIVITY PERIODS

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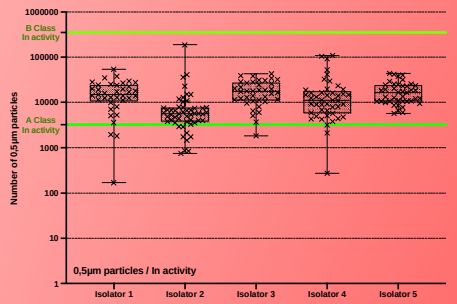
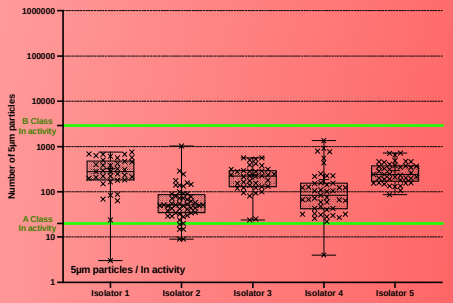
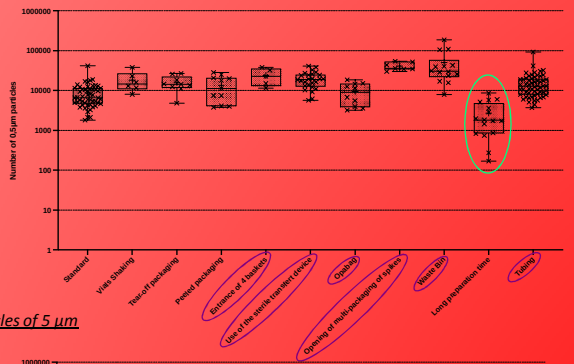


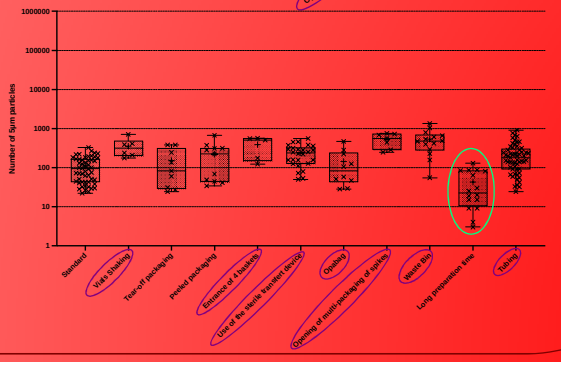
  - o *Particles of 5 µm*



- Particulate contamination by factors
  - o *Particles of 0.5 µm*



  - o *Particles of 5 µm*



Conclusion/Discussion

Respect of GPP Class A standards at rest but not in activity as recommended in GMP

Factors impacting particulate contamination :

- Entrance of 4 baskets
- Use of the sterile transfet device between isolators
- Opening of multi-packaging of spikes
- Use of waste bin
- Use of tubing

Areas for improvement :

- During preparation steps, limit use as much as possible of waste bin, tubing and sterile transfet device between isolators.
- Assessing the impact of multi-packaging