Pharmacie des Hôpitaux Universitaires de Genève

What are the minimal working protective measures to apply to guarantee the sterility of an injectable drug reconstituted in a laminar airflow hood in wards?

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INTRODUCTION

The sterility of injectable drugs is essential for immuno-suppressed patients. Nurses usually prepare these drugs (except cytotoxic drugs) in a classical uncontrolled air room in the ward. Laminar airflow hood (LAFH) could improve the asepsis of preparations. The aim of this study was to evaluate the asepsis level of injectable preparations prepared in LAFH in wards applying three different levels of working protection.

MATERIALS & METHODS

Media-fill testing (Tryptic Soy Broth (TSB)) was used to estimate potential microbial contaminations during preparation. Protocol was performed by a single operator in a vertical-LAFH in a paediatric onco-haematologic ward.

Fig.1: *Manip. 1)*

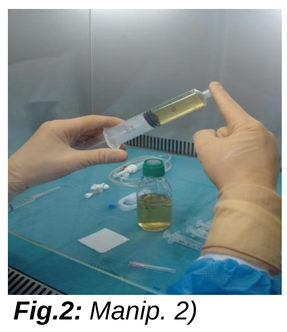

Fig.2: *Manip. 2)*

Fig.3: *Manip. 3)*

1) connecting tubes to **infusion bags** filled with TSB *(Fig.1)*,
2) filling syringes with TSB including an **handling error** (touching the syringe's hub with a finger) *(Fig.2)*,
3) filling syringes with TSB **without error** *(Fig.3)*

→ Each manipulation was repeated **100 times** for each protective working conditions:

Fig.4: *« Clean »*

Fig.5: *«Intermediate »*

Fig.6: *« Dirty »*

1) "**Clean**": sterile gloves and protective sleeves, decontamination of LAFH and material *(Fig.4)*,
2) "**Intermediate**": similar as clean without the sleeves *(Fig.5)*,
3) "**Dirty**"**:** no protective measures nor decontamination *(Fig.6)*

Incubation:

7 days at room temperature (25±1°C) then 7 days at 32±2°C.

Analysis:

Positive contaminations were declared when any turbidity of the growth medium was observed

Additional contamination controls:

Sedimentation plates (Trypticase Soy Agar (TSA)) in LAFH (5 days incubation at room temperature)

- **Gloves control** at the end of working session with "blood agar" plates (5 days incubation at 26.5°C)
- **"Count tact" plates** to analyse working surfaces (3 days incubation at room temperature without light and 3 days with day light)

RESULTS

No contamination was observed for the "clean" and the "intermediate" working conditions. In "dirty" conditions, 4% syringes with handling error and 1% without handling error were contaminated *(Tab.1).*

Additional contamination controls also showed more contaminations for "dirty" conditions *(Tab.2).*

Tab. 1 *: Number of contaminations*

	« Dirty » conditions		« Intermediate » conditions		« Clean » conditions	
Nb of plates	Tested	Contaminated	Tested	Contaminated	Tested	Contaminated
Front of LAFH	10	2	10	0	10	0
Back of LAFH	10	3	10	0	10	0
Count-tact plate	10	5	10	1	10	1
Blood agar plate	10	9	10	0	10	0

Tab. 2*: Additional contamination controls*

	« Dirty » conditions		« Intermediate » conditions		« Clean » conditions	
	Tested	Contaminated	Tested	Contaminated	Tested	Contaminated
Nb of infusion bags	100	0	100	0	100	0
Nb of syringes with error	100	4	100	0	100	0
Nb of syringes without error	100	1	100	0	100	0

CONCLUSION

When no protective measures are applied to prepare injectable drugs in LAFH placed in an uncontrolled air room, sterility of the end-product cannot be guaranteed. Working in a LAFH can improve the aseptic safety if protective measures are applied. Wearing sterile gloves and applying decontamination of materials and surfaces seem to be the minimal protective measures to be recommended.

They appear to be compatible with the daily practice of nurses.

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