

A worst-case assessment of injectable sterile preparation containers integrity in dynamic conditions to support microbiologic shelf-life extension

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Context



Current storage period for our sterile injectable preparations is limited to **8 days** (Precautionary principle regarding the risk of microbiological contamination)



Physicochemical stability for up to **1 month**, depending on the molecule and literature data



Can the shelf life of our preparations be extended without compromising their sterility?

Material and Methods

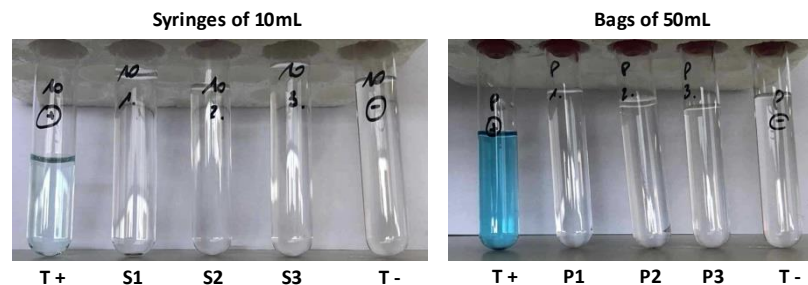
Dynamic methylene blue ingress test (according to the GERPAC¹ consensus)

- 35 syringes (1 to 50mL, Becton Dickinson TM)
10 bags (50mL Freeflex®+) NaCl 0,9%
- Immersion in a methylene blue bath
Agitation for 2 h at 100 rpm (Fisher Scientific Bioblock Rotatest + Pingpong 300)
→ Agitation step added to the baseline test
- Valid in the absence of dye penetration

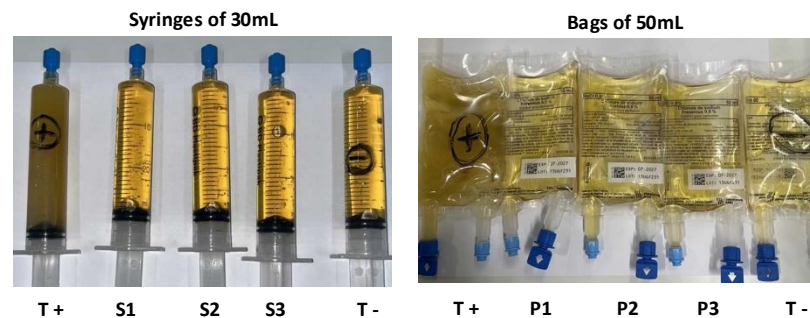
Microbiological integrity test (according to NHS² recommendations)

- 35 syringes (1 to 50mL, Becton Dickinson TM)
10 bags (50mL Freeflex®+) Sterile tryptic soy broth TSB – Class II BSC
- Immersion in a TSB bath inoculated with *E. coli* (> 10⁶ CFU/mL)
- Incubation 2h at room temperature + 14 days at 35°C
- Valid in the absence of visible bacterial growth

Dynamic methylene blue ingress test



Microbiological integrity test



Discussion/Conclusion

No dye penetration



No visible microbial growth



Hermetically sealed containers capable of maintaining sterility for 14 days



These results are part of a comprehensive assessment of practices (operators, facilities and equipment)

¹Crauste-Maniet S et Al. GERPAC Consensus Conference – Guidance on the Assignment of Microbiological Shelf-life for Hospital Pharmacy Aseptic Preparations. Pharm Technol Hosp Pharm. 2020;5(1): 20200001. doi:10.1515/ptph-2020-0001.

The use of **dynamic conditions** complement standardized protocols by providing a more accurate assessment of the **actual lifecycle** of sterile preparations, from preparation to administration

²NHS Pharmaceutical Quality Assurance Committee. Protocols for the integrity testing of syringes. 2nd ed. London: NHS Pharmaceutical Quality Assurance Committee; 2013.