Method Validation in preservation of sterile agar plates beyond the manufacturer's recommandations for use in a compounding unit

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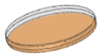
INTRODUCTION

GPC 2007
NF EN ISO 14644-1

→ 2 agar plates (AP) used per production campaign for the microbiological monitoring of a class A isolator in a compounding unit



Trypticase-Soja sterile agar plates

10 agar plates packed in a triple sterile packaging → up to 5 days stock with one package

⚠ **Fertility beyond 2 days after opening is not guaranted by the supplier**

OBJECTIVE

Study the fertility of the AP beyond the 2 days recommanded by the supplier using a gastight box initially intended for microbiological culture in anaerobic conditions

MATERIAL AND METHODS

Fertility test

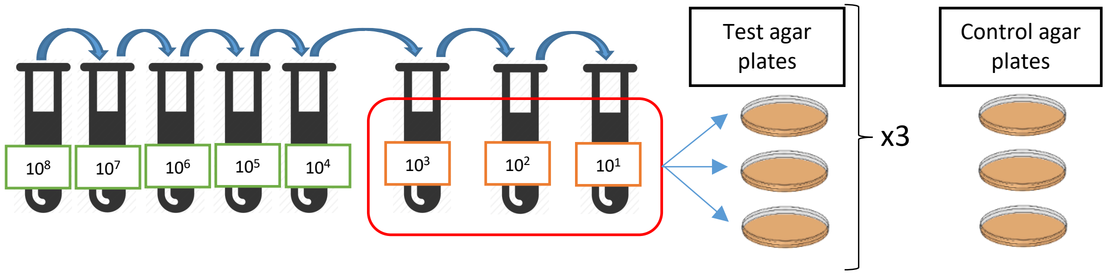
Manufacturer's quality test (European Pharmacopoeia compliant)

3 bacteria	2 fungi
Staphylococcus aureus CIP4.83 Pseudomonas aeruginosa CIP82.118 Bacillus subtilis CIP52.62	Candida albicans CIP48.72 Aspergillus brasiliensis CIP1431.83

100 CFU maximum (USP)

Bioballs® (Biomérieux) ref. 412646 → 2-3 colonies + 9 mL NaCl (+/- polysorbate 80) ~ 10^8 CFU/mL

Visual turbidity / McFarland 0,5 standard
+ OD measurement = 0,1 (λ=530nm except *A.brasiliensis* λ=635nm)



Test agar plates placed in the isolator in a gastight box (Gaspak® EZ BD ref 260672) then opened 4h during production before being inoculated at D5

Agar coverage rate $\tau = \frac{\text{average number of test agar plates CFU}}{\text{number of control agar plates CFU}}$

Statistical analysis : Student's t test ($\alpha \leq 0.05$)

Weighing of agar plates

Secondary criterion → assessment of possible water losses

Kinetics assessed between D0 and D5 : gastight box inside isolator; outside isolator (n=30 each)

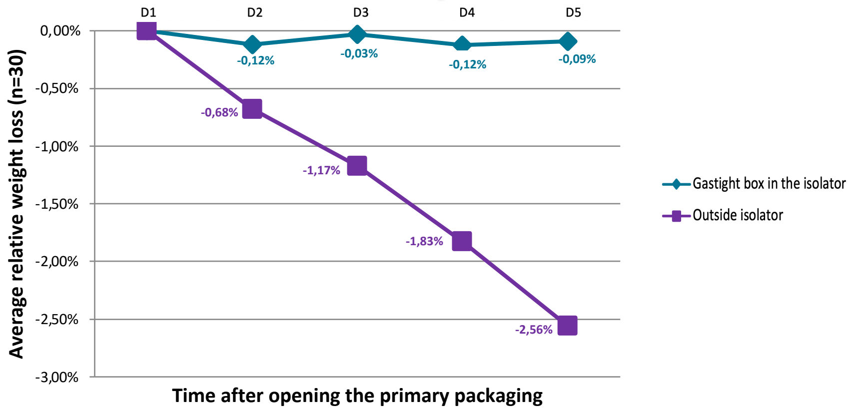
RESULTS

Fertility test

Microorganism	Average agar coverage rate at D5
Staphylococcus aureus	100%
Pseudomonas aeruginosa	158%
Bacillus subtilis	94%
Candida albicans	79%
Aspergillus brasiliensis	83%

All agar coverage rate > 70%

Weighing of agar plates



RELEVANCE/CONCLUSION

The results of the fertility test are congruent with the expected results in accordance with USP recommendations (chapter 1227) suggesting that the use of an airtight plate allows preserving the fertility of agar plates 5 days after opening the primary packaging in our study conditions.

With the gastight box, fertikity test is confruent at day 5.