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SHELF LIFE OF STERILIZED MEDICAL DEVICES PACKAGED IN HEAT-SEALED PLASTIC HEALTH CARE PACKAGING: RESULTS OF A 15-MONTH STUDY

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Plan

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1. Introduction
2. Origin of the project
3. Material and method
4. Results
5. Discussion and conclusion

1. INTRODUCTION

Introduction

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- One year of work in Central Sterilization Service
  - ➔ Project: assessing the **maintenance of MD sterility**

- Roles of a packaging system:
  - ✓ Allow the sterilization of MD
  - ✓ Physical protection of MD
  - ✓ Aseptic presentation of MD
  - ✓ **Maintenance of sterility**

Introduction

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- Packaging system:
  - Sterile barrier system
  - Protective packaging
    - → **biological barrier preventing contamination**

- The determination of MD's shelf life depends on:
  - Packaging (quality, efficiency)
  - Sterilization process
  - Real working conditions
    - Transportation
    - Storage
    - Manipulation

Aim of the study

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- Validation of MD's shelf life after **6 months** of conservation in *usual conditions of transportation and storage*
- Extending shelf life for up to **12 months**

In the background

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- When shelf life can be extended

→Better management of peremptions

→Decrease in direct and indirect sterilization related costs

2. ORIGIN OF THE PROJECT

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Determination of the shelf life

- No concrete recommendations

- ISO -11607 Norm:
  - « *The packaging system must provide* ***physical protection*** *and* ***maintain the integrity*** *of the sterile barrier system.* »
  - « *The sterile barrier system must* ***maintain sterility*** *until the point of use or until the expiry date.* »
  - « ***Maintaining the integrity of the sterile barrier*** *can be used to* ***demonstrate maintenance of sterility****.* »

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Determination of the shelf life

- Empirical determination
  - Transportation, storage and manipulation conditions ⇨ predominant criteria affecting the maintenance of sterility
- Shelf life is often shorter ⇨ that cause costs
- Different shelf life from one hospital to the other

→ Set at 6 months at CHBA

3. MATERIAL AND METHOD

Material and method

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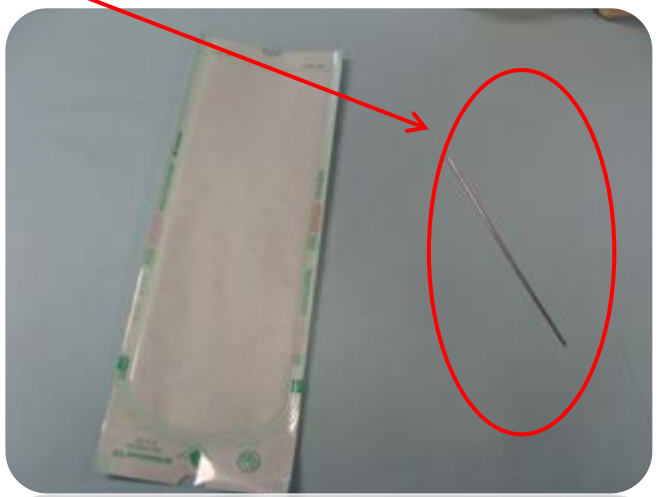
- **Population**: medical packaging → paper / plastic bags with stainless steel double-ended probes inside



- **Simple** and **double** packaging
  → Bags from the same batch

Material and method

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- **Packaging and sealing**: 2 different sealing machines



- **Sterilization:** with saturated steam at 134°C for up to 18 minutes → 2 different autoclaves



Material and method

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Storage

- CHBA
- CHR Citadelle
- CHU of Liège

Storage location inside the hospital

- Central Sterilization Service
- Operating room
- Emergency room

Material and method

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- **Storage time**

Tests	*Before sterilization*	*After sterilization*	*After 3 months*	*After 6 months*	*After 12 months*	*After 15 months*
Methylene blue test	☑	☑	☑	☑	☑	☑
Traction test	☑	☑	☑	☑	☑	☑
Plastic impermeability test		☑		☑	☑	☑
Paper impermeability test in wet and dry conditions		☑		☑	☑	☑
Sterility test		☑	☑	☑	☑	☑

Material and method

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- **Random distribution** between storage locations
- Different **manipulations** according to hospitals: daily or weekly manipulation

Study parameters

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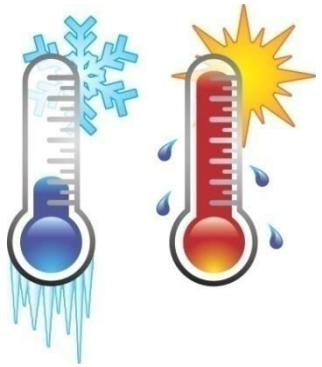
- In order to guarantee the sterility of the MD → need to analyze the integrity of the bags
- Parameters:
  - Environmental parameters: temperature, humidity, light, physical strain





→ ⚠ Transport, storage and manipulation conditions

- Testing the bags allows the measurement of these parameters
  - 6 different tests can show the integrity of the packaging

Tests performed at CHBA

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- *Methylene blue test*

- *Traction test*

- *Sterility test*

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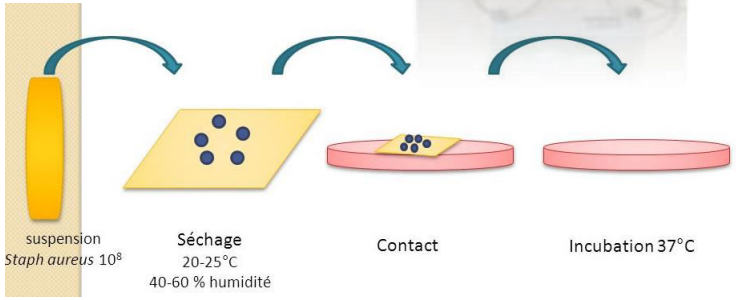
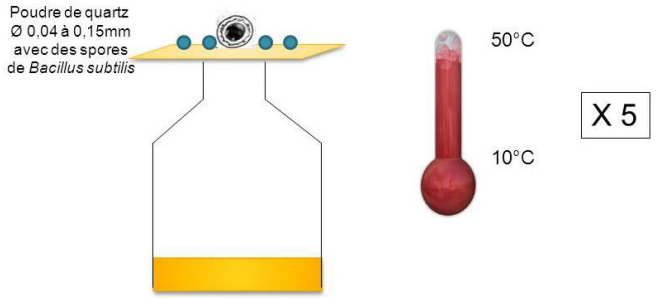
Subcontracted tests

- *Plastic impermeability test*

- *Paper impermeability test in wet conditions*



- *Paper impermeability test in dry conditions*



Test 1: *Methylene blue test*

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- According to ASTM-F 1929
- Dye (methylene blue) is applied to the seals for assessement of their impermeability
  - ✓detection and location of leaks generated by a channel of at least 50 µm diameter

MATERIAL:

- Methylene blue 1%
- Syringe 60 mL
- Needle 21 G

Test 2: *Traction test*

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- According to EN 868-5
- Evaluation of the strength of the sealings upon opening the packagings by peeling
  - Measuring the tensile force required to open the welds
  - Minimal strength: 1,5 N / 15 mm
- With a calibrated device

(Hawo ht150scd)

Test 2: *Traction test*

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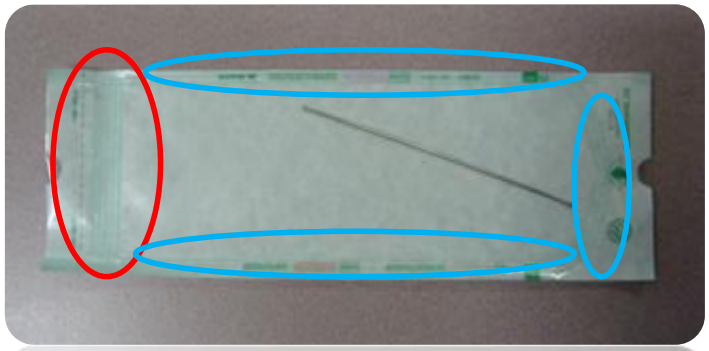
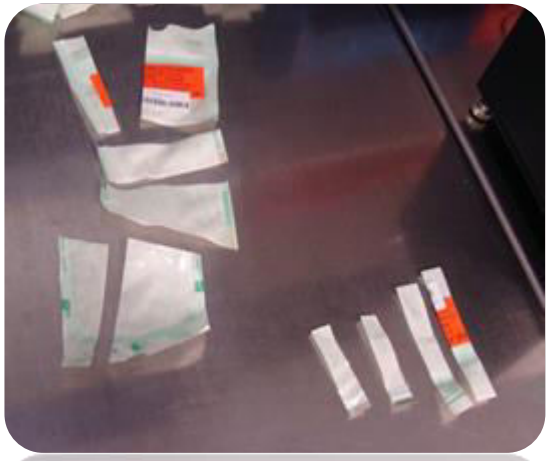
- Applied to each seal
  - 3 industrials seals
  - 1 homemade seal
- Samples of 15 mm





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Test 3: *Plastic impermeability test*

- According to ISO 5636-5
- Evaluation of the permeability and the resistance of the plastic film to the passage of air with a specific machine called densometer
  - No apparent movement should be observed (±1 mm)

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Test 4: *Paper impermeability test in wet conditions*

- According to DIN 58953-6
- Solution of *Staphylococcus aureus* spores applied on specimens
- Aseptic drying (6 to 16h at 22°C ± 3°C)
- Contact with a nutrient broth
  - Incubation at 37°C during 24h
- Pass or fail: max 5 CFU / sample

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Test 5: *Paper impermeability test in dry conditions*

- According to DIN 58953-6
- Contact with powdered quartz contaminated with *Bacillus subtilis* spores
- The uncontaminated paper side is above a vial containing a sterile nutrient broth
- Variation of temperature and pression
- Contact with a nutrient broth
  - Incubation at 37°C during 24h
- Pass or fail: max 15 CFU / 10 specimens - max 5 CFU / sample

Test 6: *Sterility test*

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- Test based on European Pharmacopoeia
- Immersion of the probes in nutrient broth at the end of each storage period
  - ✓ TCS nutrient broth (Trypto-Casein-Soja)

- Incubation 14 days at ambient temperature
  - ➢ In case of growth signs, re-incubation (2 different)
    1. Incubation at ambient temp during 14 days
    2. Incubation at 30-35°C during 4 days

4. RESULTS

Results – Test 1

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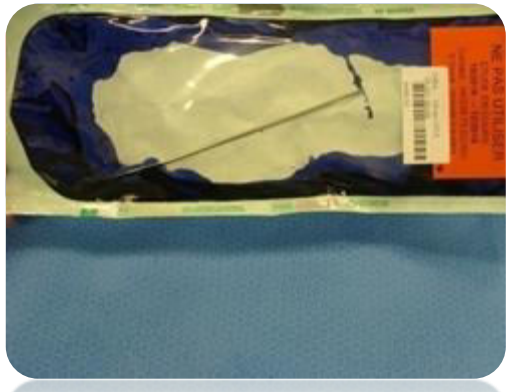
- Methylene blue test

TEST 1	*Samples tested after sterilization*	Tests *after 3 months*	Tests *after 6 months*	Tests *after 12 months*	Tests *after 15 months*
Number of tested samples	4	9	13	12	6
Number of compliant samples	4	9	13	12	6
Success rate	100%	100%	100%	100%	100%



Results – Test 1

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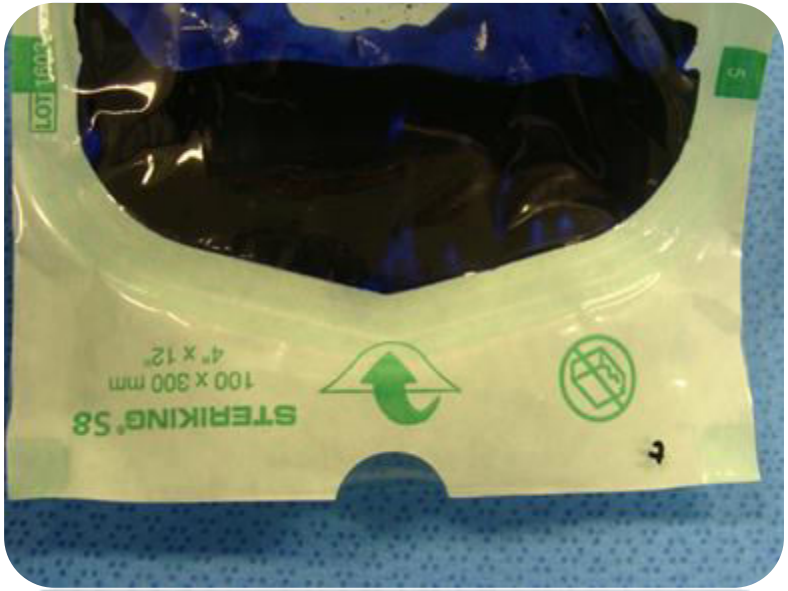

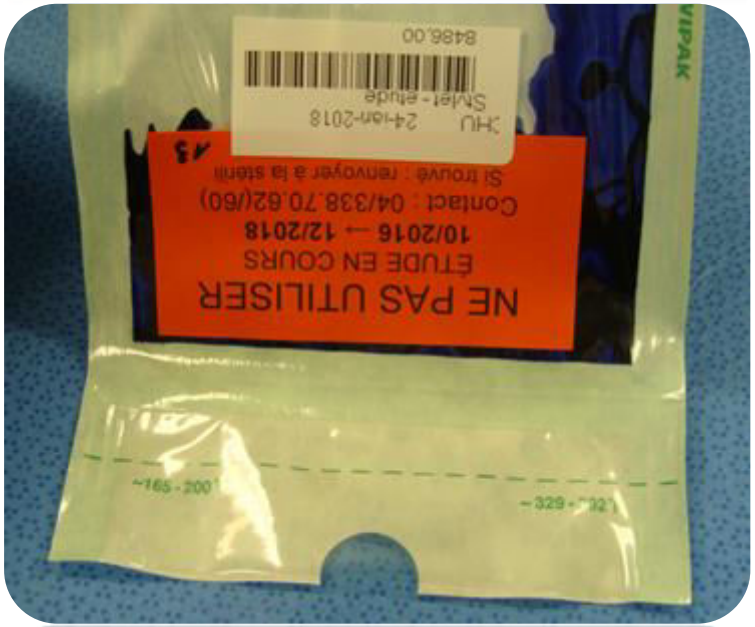

Results – Test 1

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1 year after sterilization

Contact time > 20 sec ➔

Results – Test 2

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- Traction test

TEST 2	*Samples tested after sterilization*	Tests *after 3 months*	Tests *after 6 months*	Tests *after 12 months*	Tests *after 15 months*
Number of tested samples	4	8	12	13	6
Number of compliant samples	4	8	12	13	6
Success rate	100%	100%	100%	100%	100%

Results – Test 2

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Results – Test 3

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- Plastic impermeability test

TEST 3	***Samples tested after sterilization***	**Tests *after 3 months***	**Tests *after 6 months***	**Tests *after 12 months***
Number of tested samples	2	3	6	6
Number of compliant samples	2	3	6	6
Success rate	100%	100%	100%	100%

Results – Tests 4 and 5

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- Paper impermeability tests in wet and dry conditions

TESTS 4 and 5	Nbr of CFU / agar plate (5 plates)	Nbr of CFU / specimen (10 specimens)	Compliance
SP, test after sterilization	0	1	Yes
DP, test after sterilization	0	2	Yes
SP, after 6 months	18	11	Incomplete
DP, after 6 months	7	6	Yes
SP, after 12 months	nc	4	Incomplete
DP, after 12 months	nc	4	Incomplete
SP, after 15 months	nc	0	Incomplete
DP, after 15 months	nc	12	Incomplete

Results – Test 6

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- Sterility test

TEST 6	*Samples tested after sterilization*	Tests *after 3 months*	Tests *after 6 months*	Tests *after 12 months*	Tests *after 15 months*
Number of tested samples	4	13	12	12	7
Number of compliant samples	3 (1 by contamination)	12 (1 positive after **loss of integrity** of the paper side during storage)	12	12	7
Success rate	75%	92%	100%	100%	100%

Results – Test 6

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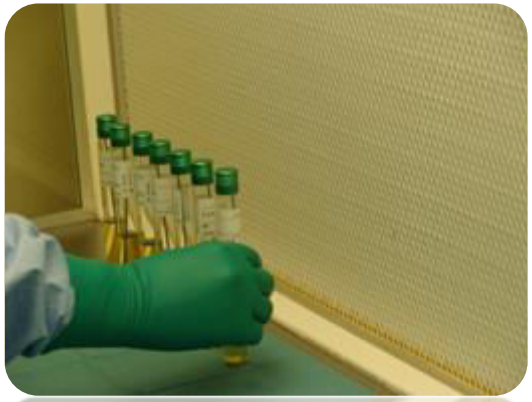

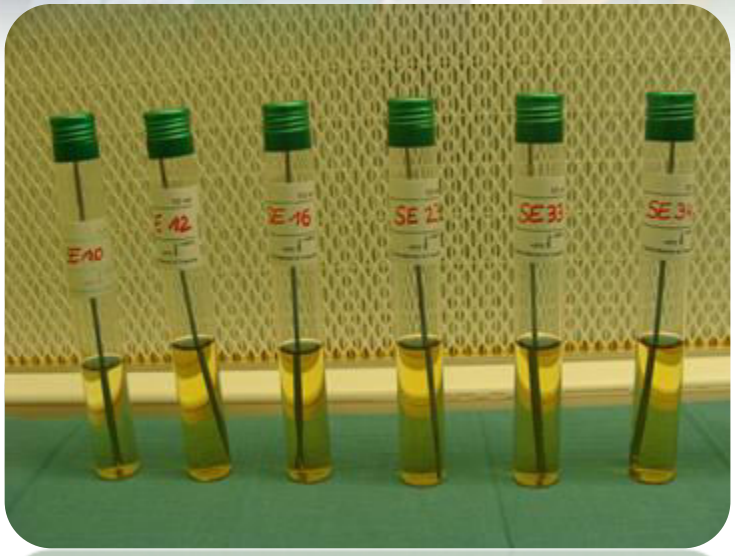

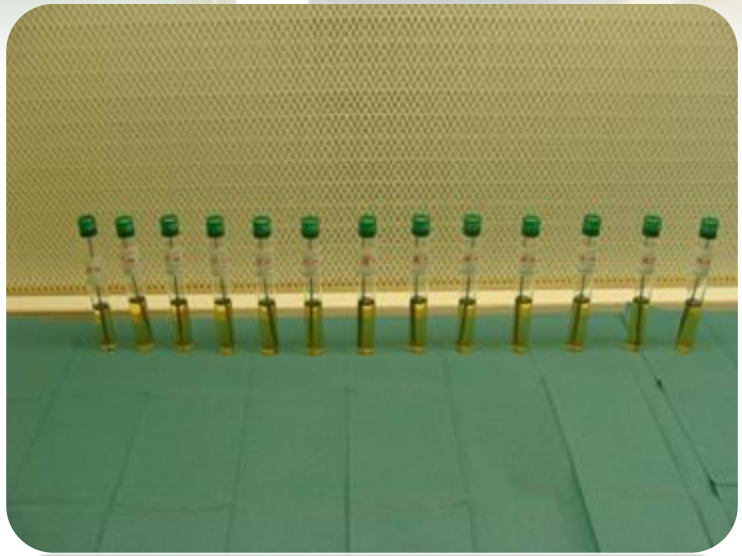

Results – Test 6

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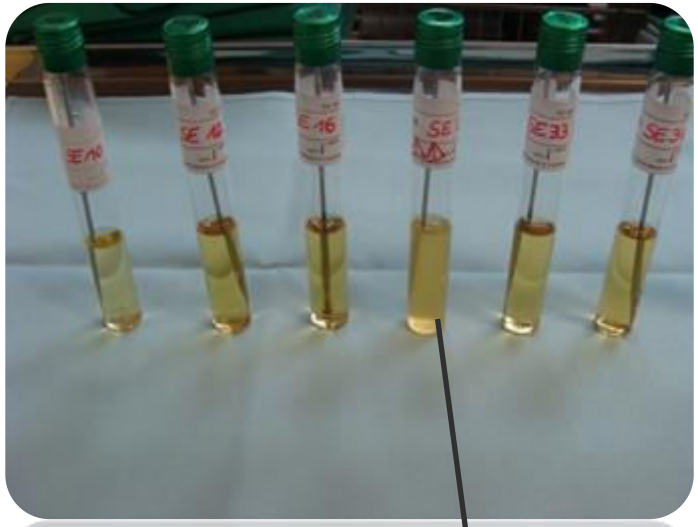
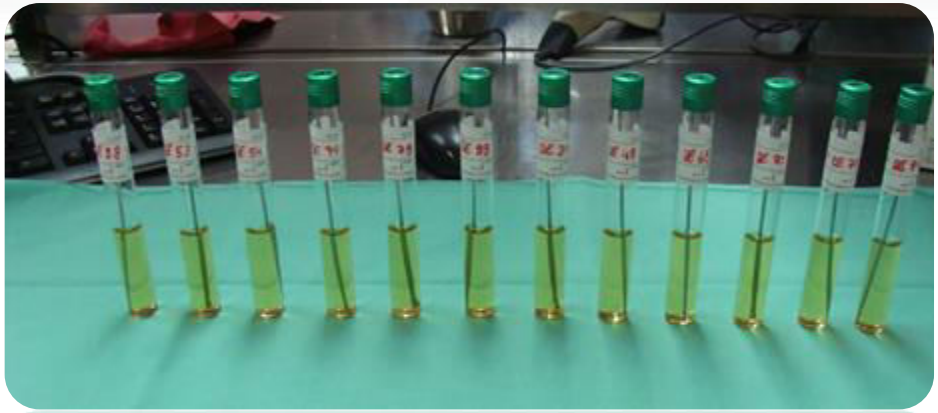


Positive



5. DISCUSSION AND CONCLUSION

Discussion

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- Test results: global perspective on the integrity of packaging systems based on handling and storage conditions
  - Highlighting the different characteristics of the sterile barrier

Discussion

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- Results leading to an extension of the shelf life

ONLY IF

- ✓ Respect of good storage and transportation conditions
- ✓ Handling with care, packaging must be intact

- ➢ Consider the use of protective packaging in case of incident risks during transportation and / or storage

Conclusion

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- Establishing shelf life will depend on **manipulation, storage conditions** and **events** that may break the sterile barrier, more than the effect of time.

- Integrity of the packaging: major determinant of the maintenance of sterility

Conclusion

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- Under usual conditions and in the absence of an event deteriorating the barrier role of the packaging, the shelf life can be extended up to 12 months

THANK YOU FOR YOUR ATTENTION