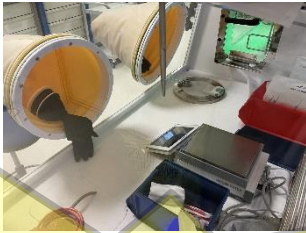


Qualification of containers for cold storage of cytotoxic vials remains in the isolator of a chemotherapy preparation unit

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Context



Access door for vials container

Built-in refrigerator

Existing Solutions

Our container

High cost
Size

Accessibility
Maintenance

Transparent walls
Sealed closure
Inexpensive

Different sizes
Sterilizable
With ice-packs inside



How to store remaining products in the isolator ?

Our Objectives: to verify that our container

- Is airtight
- Remains sterile
- Maintains temperature

Methods & Results

SEALING



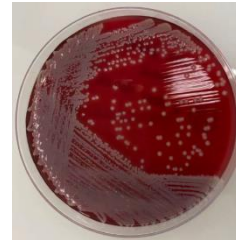
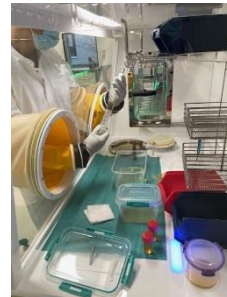
Peracetic acid test strips are placed inside and outside the containers
Sterilization is started



Peracetic acid darkens the test strip
The strip inside the container remains unchanged

The containers are airtight !

STERILITY



Trypticase soy microbiological culture medium is introduced into the sterilized containers
A positive control is obtained by inoculating 100 CFU of a reference strain of staphylococci
The containers are kept cold and observed daily



37 days later
The positive control is still cloudy
The culture medium in the containers remains clear

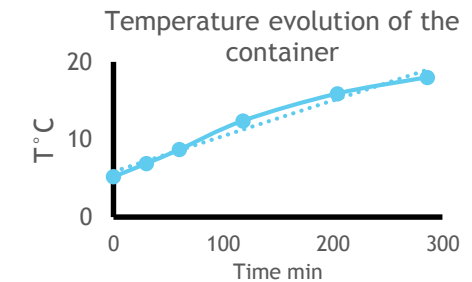


The containers remain sterile !

COLD STORAGE



A thermometer with external probe is inserted into the container in the middle of eutectic plates with NaCl bags and water vials
The container is stored in a cold room until the temperature stabilizes
The container is then taken out to room temperature and the temperature is measured every 30 minutes



The estimated temperature increase is 2.5°C per hour

The container maintains the temperature !

Conclusion

Our containers are airtight and sterile, but they cannot maintain the temperature beyond half a day and need to be refrigerated again at noon
The manufacture by suppliers of isolators with containers adapted to transparent walls, integrated insulation, and eutectic systems would help secure the storage of residues