STEPHY Publishers

SOJ Medical and Clinical Case Reports

Short Communication

ISSN: 2834-5517

Changes in Aluminosilicate Glass Vials During Lyophilyzation

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During Lyophilization we observed many changes in Glass vials like strain and breakage caused by the thermal expansion and contraction of the frozen solution, because of crystallization of excipients occurs during thawing. Also fogging or bubbling on the internal surface of the glass vials from poor wettability and solution splashing, surface defects or uneven thickness due to manufacturing defects such as molding.

- **Strain and breakage**: The most significant change is the physical stress on the vial.
- **Thermal contraction**: During the freezing phase, the solution contracts, creating negative strain on the vial.
- **Thermal expansion**: During the warming/thawing phase, the ice and any crystallized excipients (like mannitol) expand, driving the strain to positive values and potentially leading to vial breakage.
- **Crystallization**: Excipients such as mannitol can crystallize during freezing and/or thawing, and this rapid volume expansion puts additional stress on the vial, increasing breakage risk.
- **Surface issues**: The internal and external surfaces of the vials can be affected.
- **Fogging**: Water-repellent (hydrophobic) vials may show fogging or white veil formation, which is predicted by the surface energy of the vial and the surface tension of the formulation.
- Solution creeping: On hydrophilic vials, solution may creep up the walls, which can be a problem if the inner wall is not clean.
- **Bubbling/Defects**: Hydrophobic surfaces can prevent proper wetting and lead to bubbles forming during the process, particularly if degassing is not performed.
- **Manufacturing-related changes**: The manufacturing process itself can cause changes in the glass.
- **Vial thickness**: Molding processes create vials with a more uniform glass distribution and wall thickness compared to tubing vials.
- **Mechanical strength**: Aluminosilicate Glass vials are designed for inherently greater mechanical strength and are engineered to break in a more controlled way rather than cracking under severe damage.

1. Better to use “Blow back glass vial and blow back rubber stopper. Popping of rubber stopper during Lyophilization and stoppering
2. Selection of right kind of packaging material and innovative design which can be user friendly
3. Primary Packaging material has to be compatible with product
4. Select the right kind of sterilization in which product will be stable and there is no significant change in packaging material It’s advisable to use “Moulded Vial” with flat bottom surface to avoid hot air circulation at the bottom
5. Lyophilizing a drug in dual chamber systems can be challenging compared withlyophilization in a standard vial due to differences in package configuration, heat flow, and lyophilizer trays

Quick Response Code:

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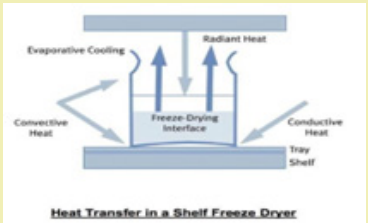
Received: 09 October, 2025 **Published:** 17 October, 2025

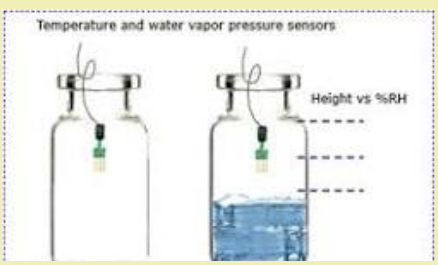
Citation: Anupam Chanda. Changes in Aluminosilicate Glass Vials During Lyophilyzation: Short Communication. *SOJ Med Clin Case Rep*. 2025;5(1):1–2.
DOI: 10.53902/SOJMCCR.2025.05.000532

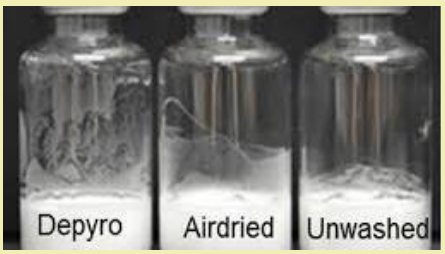
6. One of the main benefits of dual chamber packaging is that the reconstitutionstep is built into the package and thereby improves patient convenience and safety

Flat bottom Vial –Right choice for Lyo products



Crystallizing of product During freeze-drying





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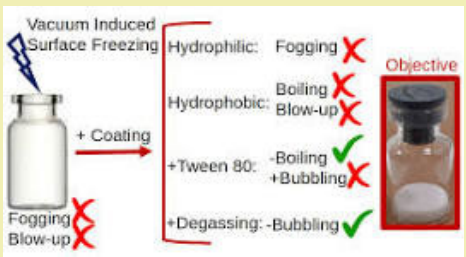

Bublling inside the glass surface

Acknowledgements

None.

Funding

This Short Communication received no external funding.

Conflict of Interest

Regarding the publication of this article, the author declares that he has no conflict of interest.