



**DRUG DISCOVERIES AND CHALLENGES FOR GLASS DEVICES
(PACKAGING)****ANUPAM CHANDA**

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ABSTRACT

Presently Packaging plays a significant role for Drug discoveries. Delamination of pharmaceutical glass is a serious issue, as it can cause glass particles to appear in vials, a problem that has forced a number of drug product recalls in recent years. In Type I pharmaceutical glass vials, delamination occurs generally at the bottom and shoulder, where extensive flaming during the conversion process can favor a strong evaporation of alkali and borate species and the formation of heavily enriched silica layers. The contact with parenteral preparations dissolved in an alkaline medium increases the rate of glass corrosion, while the differential hydration of these layers can cause the detachment of flakes. The effect of the pH and the composition of the extraction solutions on the propensity of different glass types to delaminate. With protein-based drugs, the biggest issue is the effect of packaging derivatives on the protein's three-dimensional and surface structure. These are any effects that relate to denaturation or aggregation of the protein due to oxidation or interactions from contaminants or impurities in the preparation. Mostly using Borosilicate glass for packaging for injectables, ophthalmic and oral drugs for children. Alumino -silicate glass vial, cartridge and PFS are the latest innovation to avoid delamination of glass.

Keywords: Glass Devices (Packaging), Alumino -silicate glass vial, cartridge and PFS



Cause of Delamination:

- Formulations with a high pH include phosphate and citrate buffers increase the risk of glass delamination.
- High alkali content in glass could accelerate erosion.
- High temperature during the vial-forming process increases the risk of glass delamination.
- Terminal sterilization (irradiated at 20-40 kGy for 150 min) also is a risk factor for specific products (veterinary parenteral administration), could cause delamination.
- High product-storage temperatures and long exposure times can increase

the rate and severity of glass delamination.

How to prevent Delamination

- Treating the surface of the glass vials with materials, such as ammonium sulfate or siliconization can reduce the rate of glass erosion.
- Consider alternative sterilization methods only in rare cases.
- The correct specification for the glass to ensure its suitability for the pH of the product.
- Use COC/COP vial
- Can be used Alumino Silicate Glass vials, PFS or cartridges.

Inner surface Modification of Glass (for reduction of protein adsorption)

- 1) Coating of glass vials with thin layers of SiO₂ by Plasma Impulse Chemical Vapor Deposition (PICVD) strongly reduces the interaction between the vial surface and the drug.
- 2) Poly- or oligoethylene glycol (PEG/OEG)-based coatings are one of the most popular and best investigated coatings. The excellent protein repellent effects of these coatings were ascribed to a steric repulsion or excluded volume mechanism or the formation of a structurally stable interfacial water layer.
- 3) Coatings with polyglycerols, zwitterionic self-assembled monolayers and polymers. carbohydrate-derived polymers and dextran. Besides the ability to prevent the adsorption of proteins, a variety of other factors decide about the feasibility of a coating for industrial primary packaging materials for injectables.



Few options to reduce protein adsorption:

- The inclusion of high concentrations of an inert protein in the drug

formulation to saturate the glass surface

- The addition of carbohydrates, surfactants or amino acids to reduce interaction between container surface and protein
 - Silicone oil treatment of the glass vial surface to reduce the adsorption
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Use of multilayer COC or COP vial.

Recent Publications:

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3. Nasal Spray is the Most Suitable Options to Replace Injectables for Microgravity and Packaging Challenges.
4. Ophthalmic Drug Delivery Devices Packaging Problems & Solutions.
5. Mining on MARS and MOON for Primary Packaging materials.

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