

Packaging Challenge for Affordable Biosimilar Products

Anupam Chanda

Packaging and Polymer Science Technologist(PG), India

Abstract:

Abstract

Presently Packaging plays a significant role for Biosimilar product. The process of selecting materials and the type of packaging also offers an opportunity for the Packaging scientist to look for new biological delivery choices. Most injectable protein products were supplied in some sort of glass vial, prefilled syringe, cartridge. Those product having high Ph content there is a chance of “delamination” “from inner surface of glass vial. 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. The potential for these effects needs to be carefully considered in choosing the container and the container closure system to avoid putting patients in jeopardy.

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 increase 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

Present market demand is syringe barrel and/or plunger coated with silicone. Non-uniform silicone coatings can affect protein stability. The proteins can absorb into the walls of the container. While silicone can reduce absorption, excess silicone can form suspended oil-like droplets. Proteins can form around those droplets and change their natural state. New lubricant coatings, such as inert fluoropolymers, are being introduced to replace silicone. As a very inert material, fluoropolymer provides smoothness for the syringe plunger without the irregularities or the issues that have come with silicone. Other new coating materials are being introduced with new types of packaging related to self-injectors, especially injector pens, patches, and transdermal and wearable devices for self-infusion. Extractable and leachable are most important for inhalers and catheters.

For an extractables from a device component the AET ($\mu\text{g/g}$) can be determined using Equation 1: Equation 1

$$AET = \frac{SCT \cdot D_t}{D_d \cdot m}$$

$$D_d \cdot m$$

D_d - Doses per day

D_t - Total Labelled doses

m - mass of component

The AET ($\mu\text{g/device}$) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

$$AET = \frac{SCT \cdot D_t}{D_d}$$

$$D_d$$

D_d - Doses per day

D_t - Total Labelled doses

Biography:

Anupam Chanda has his expertise in creating innovative design in packaging material and device for Biologics, biosimilar, anti Cancer and HIV products. He is having two decades(approx. 25 years) of experience in India and abroad. He is a renowned speaker, widely travel throughout the world. Gain and share his thoughts with scientist from various institution and industry professionals. Author’s Technical book “Packaging Technology An advance Practical approach” Published from Germany and Amazon is distributing to 77 countries. Book is available in www.amazon.de, www.amazon.com and www.morebooks.de. He is attached with various charitable institutions and research institutes.

Publication of speakers:

1. Delamination of Glass and Probable Solution – Drug Packaging
2. Importance of Extractable and Leachable study for Primary Packaging Materials.
3. Criticality of Rubber stopper for Biologics and Biosimilar products.
4. Role of Borosilicate Glass for “oncology products(cancer)
5. Role of packaging for NDDS (Neval drug delivery system) and NCE(New chemical entity)products.

[World Biosimilars and Biologics Summit & 8th International Conference on Clinical Trials September 18-19, 2020](#)

Citation: Anupam Chanda; Packaging Challenge for Affordable Biosimilar Products; Biosimilars Summit 2020 and Clinical Trails 2020; September 18-19, 2020