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Short Communication

Nasal Spray is the Most Suitable Options to Replace Injectables for Microgravity and Packaging Challenges

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Introduction

As you know microgravity environment is too extreme and facing many problems in Injectable products. As per our experience we have seen bubble appears in injectable products since surface tension of the product is more than applying force(plunger in PFS). Due to high radiation product gets spoil before shelf life for that " gold foil coating" is a must on Glass vials, PFS and cartridges. Most suitable Packaging design is " Nasal spray" in which such kind of bubbles are infused duding spraying products inside the nose, ear and Eyes. All eye drops can possible to convert in spray form due to application limitations since drops are floating in microgravity environment during dispensing of doses. Protein adsorptions on glass surface is a critical problems. In-order to resolve multiple drug delivery difficulties packaging technology will play several important roles to make Astronauts and space travel visitors.

Wide ranges of packaging challenges and solutions

High radiation on microgravity

Figure 1

Gamma rays pass through the transparent glass vial/PFS/ cartridge and spoil the product. So we decided to coat Glass vials, PFS and cartridges with gold foil, black colour coating, silver coating and few more other colours coating, out of all options products were stable in Gold colour coating.

Protein adsorptions in microgravity

Rubber stoppers

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 absorbtion, 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.

Packaging challenges for rubber stopper/plunger

- Adsorption of protein
- Effect of different types of sterilization Process
- Effect of Extractable and Leachable
- Excessive moisture intake causes product degradation.

Adsorption of protein and solutions

- Option#1 Better to use “Flurocoated” stopper
- Option#2 Teflon coated stopper
- Option#3 Use siliconized stopper

Figure 2

Protein adsorption on PFS inner surface

Figure 3

Protein adsorption on cartridge inner surface

Figure 4

Adsorption of protein and solution

- Option#1 Coat with linear methoxylated polyglycerol and hyperbranched methoxylated polyglycerol.
- Option#2 The hyperbranched non-methoxylated coating performed best.
- Option#3 Coat with hyperbranched polyglycerol.
- Option#4 Right selection of Sterilization of glass vial/syringe.

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.

Figure 5

- The correct specification for the glass to ensure its suitability for the pH of the product.
- Use COC/COP vial
- Bubble Free Injection Syringe in Space a Big Challenge

Bubble free injection syringe in space a big challenge

Preparation of injectable medications in a non-micro gravity environment simplifies removal of air bubbles within the syringe.

This luxury is lost in micro gravity as isolation of bubbles becomes difficult due to the absence of a force greater than the surface tension of the medication.

The consequence of injecting an air bubble into a crewmember is harmful.

Figure 6

NASAL SPRAY is the Best solution in Microgravity Environment

Souces of extractables for plastic devics

Additives, anti oxidants, stabilizers, plasticizers, emulsifiers, colourants, monomars, oligomers residual catalysts, impurities UV absorbers fillers, anti fogging, antimicrobial etc.

Figure 7

Typical plastic additives

Lubricants, Antistatic Agents, Initiators, Stabilizers, Impact Modifiers Antioxidants, Bactericides, Catalysts, Blowing Agents, Processing Aids Plasticizers, Colorants, Brighteners, Release Agents, Vulcanizing Agents.

For an extractables from a device component the AET (µg/g) can be determined using following Equation

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

D_d- Doses per day

D_t- Total Labelled doses

m - mass of component

The AET (µg/device) for a drug delivery device (e.g. an MDI) can be determined from following Equation

$$AET = \frac{SCT.D_t}{D_{dm}}$$

D_d- Doses per day

D_t- Total Labelled doses.