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Short Communication

Drug Discoveries and Challenges for Elastomer devices (Packaging)

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Abstract:

Selection of rubber stoppers, plungers are playing a major role for packaging for pharmaceutical products especially for "Drug Discoveries" i.e for New products. In this case scientist don't have any bench marked samples. These are few most important points those need to take care during selection of right kind of Rubber stoppers; those are whether to use Bromobutyle or Chlorobutyle Rubber stoppers, coated or uncoated, Blow back Rubber stopper is a must to use for Lyophilyzer products, what kind of "Sterilization" need to use, proper fitments of the Rubber stopper is the most critical to ensure product stability. It's advisable to use blow back vial while use "Blow back Rubber stoppers". Rubber stopper is most critical since this is considering as most critical source of product contamination. Most commonly used ingredients, Ready to use and ready for sterilized rubber stopper.

Keywords: drug discoveries; pharmaceutical; chlorobutyle

Impact or Importance it has for Industry and Market

This has huge impact on product quality as a result of fact market recall and huge loss of the company.

Remedies

- Right formulation and right design of rubber stopper to use.
- Blow back vial and blow back rubber stopper to use.
- The correct specification for vial and rubber stopper is a must.
- Need to maintain all necessary parameters during Lyo cycle.
- Glass manufacturers ensuring that appropriate process controls are in place.
- Forming temperatures and correct annealing and due diligence in the quality testing and assurance of their glass.
- Durability analyses are conducted to assess the compatibility of the glass with the specific product that will be stored within the container.

Understanding

- Correctly decide the "sterilization" is best suited for product stability and low risk.

Following steps are ideal for selection of Rubber stoppers and plungers for " Drug discoveries" else high chances of failure:

a. During stability studies both " Bromobutyle" and " Chlorobutyle" rubber stoppers to use and Vials have to keep in invered form in order to touch the product with the rubber stopper.

b. Both Coated and uncoated Rubber stoppers and Plungers need to use.

c. Both Siliconized and non-Siliconized rubber stoppers and plungers to use.

d. Sterilization plays an important role in product stability studies. This has been observed one particular product is stable in "Gamma or ETO or Steam sterilization of Rubber stoppers and plungers. So, all three sterilized rubber stoppers and plungers samples to keep for product stability studies.

e. Leak test: Stoppering and crimping need to do perfectly inorder to prevent moisture go inside the container and spoil the product before expiry.

f. Need to use "Coated rubber stoppers/plunges" if protein adsorption observe.

Couple of USFDA warning letters

1) Identify particulate matter when performing tests. Defective rubber stoppers/plungers observed in production line.

2) Must use statistically sound sampling plan for AQL inspection.

3) Company has not established scientifically sound and appropriate specifications, standards and sampling plans, and test procedures.

4) Few analytical test data is go beyond the standard limit related to leachable is concern.

5) Filled vial not placed in inverted form during stability study.

BSE/TSE Certification from Vendor is must

BSE (Bovine spongiform Encephalopathy)

commonly known as mad cow disease, is a transmissible **spongiform encephalopathy** and fatal neurodegenerative disease in cattle that may be passed to humans who have eaten infected flesh. **BSE** causes **spongiform** degeneration of the brain and spinal cord.

TSE (Transmissible spongiform Encepnalopathy)

commonly known as mad cow disease that affect the brain and nervous system of humans and animals. The diseases are characterised by a degeneration of brain tissue giving it a sponge-like appearance.

As per USP regulatory guidance "BSE/TSE" Certification required from vendor to make sure Rubber stopper should be free from "Cow disease' virus.

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