

Drug Discoveries and Challenges for Accurate dose Applications by Packaging Devices

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Abstract:

Accurate Dose dispensing of any particular drugs is most important which is directly linked with speedy recovery of patients, for that packaging design of drug delivery devices are most critical. Validation of Packaging design need to carry out methodically as per regulatory guidelines. Wide ranges of drug delivery devices are available like: Glass and polymeric bottles and droppers (with marking) for Oral drugs, Polymeric and glass bottle and droppers (with marking) Ophthalmic products. Polymeric dropper bottle and Polymeric spray bottles for Nasal spray, Glass and Polymeric Prefilled (with marking) for Injectable products, Glass and polymeric bottles (with marking) are using for IV products.

Keywords: drug discoveries; pharmaceutical; chlorobutyle

A. Oral Drug Products Devices

Following steps to follow:

Practical Problems:

- Delamination observed inside the glass bottle surface.
- Discoloration of the product.
- Melting of “polymeric Bottle & droppers.
- Melting of Polymeric Droppers due to highly Acidic products.
- Product Leakage.
- Inaccurate product dispenses.

Solutions

- If product is acidic in nature never use “Polymeric bottle” and polymeric droppers.

- Amber color bottle to use for “Light sensitive products”.
- “Dropper with proper marking” is must for accurate dose measurement.
- “Extractable and leachable testing” should carry from USFDA approved lab or in-house if the company is USFDA approved for products export to regulated markets.
- Strictly monitor the “stability studies” for delamination of glass, discoloration of the product etc. Use silicon coated vial of PET vial.
- Dropper quality need to check with water and the actual product to ensure accurate dose pick up.



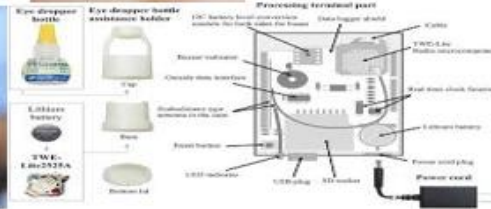
B. Ophthalmic Drug Products Devices

Practical Problems:

- Discoloration of the product.
- Inaccurate dispense of the product.
- Bottle wall is very hard to squeeze.
- Product Leakage.

- Inaccurate dispensing of “Preservative free product”.
- Solutions**

- Extractable and Leachable for bottle need to check thoroughly.
- It’s advisable to use “Meter dose dropper “
- “Bottle wall squeeze ability” need to check.
- “Cap fitment” checking is must.
- Need to revalidate the “Cap design” with product.



C. Nasal Drug Products Devices

Practical Problems:

- Discoloration of the product.
- Inaccurate dispense of the product.

- Bottle wall is very hard to squeeze.
 - Product Leakage.
- Solutions**

- Extractable and Leachable for bottle need to check thoroughly.
- It’s advisable to use “Meter dose dropper “
- “Bottle wall squeeze ability” need to check.



A. Injectable Drug Products Devices

Practical Problems:

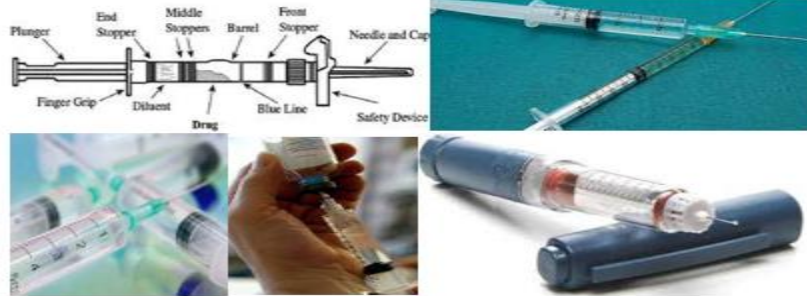
- Delamination of glass produces “glass flex” which will get stuck inside the “Needle”.
- “Protein Adsorption” inside the glass surface and Rubber stoppers.
- Inaccurate dispense of the product

- Silicon oil drops observe in the product.
 - Gliding force is not uniform.
 - Plunger movement is not smooth inside the syringe.
- Solutions**

- Advisable to use “coated plunger” in order to get the accurate gliding force.

- Syringe inner surface should be “coated”. Especially for “**Lyophilized products**” coated Syringes, vials and cartridges are must. Else we will not get the appropriate doses.
- Needle should be rust proof.
- Advisable to use “Fluro coated” rubber stoppers. or plungers.

- In case of “Auto injectors” we need to revalidate the design with product or replace the old Auto injector with New one, if we not get the right dispensing doses.
- Use “Blow back vials and Blow back Rubber stoppers to avoid product leakage and perfect crimping as well.
- For “**Double chamber PFS**” Accurate doses of the product depends on the smooth movements of the Plunger Rod and “inner Plunger”.



D.I.V Drug Products

Practical Problems:

- Discoloration and lumps observed.
- Inaccurate dispense of the product
- Silicon oil drops observe in the product.
- Improper fitment of the pipe with the cap.

- Leakage observed in the pouch.
- Solutions**

- Product is not compatible with the Glass bottle inner surface or Polymeric pouch. Need to look the extractable and leachable study report and rectify accordingly. Such cases advisable to use silicon or polymeric coatings inside the glass surface.
- Change the cap and pipe.



B. Replace the pouch and need to take care during “Leak test” of the pouch.

C. Recent Publications:

1. Double chamber Devices and their Advantages.
2. Challenges for Alternate Packaging materials for Injectable Devices.
3. Nasal Spray is the Most Suitable Options to Replace Injectables for Microgravity and Packaging Challenges.

4. Packaging Challenges for “Multi-planets”.
5. Mining on MARS and MOON for Primary Packaging materials.

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