Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

Packaging, Storage & Distribution: Ensuring Quality During Hand Sanitizer’s Journey

Desmond G. Hunt, Ph.D.
February 2021
Function

- To contain, preserve, protect & deliver a quality product, such that at any time point before expiration.
  - Ensure the product is safe and effective
  - Contain the product
    - Spillage or leaks
  - Maintain the quality of the product
    - Compatibility of the product with the packaging system
  - Protect the product from external factors
    - Mechanical (e.g. shock, vibration, etc)
  - Facilitate transportation and storing
Packaging: Types

- **Primary packaging:** Packaging that is in direct contact with or may come into direct contact with the product.

- **Secondary packaging:** Packaging that is in direct contact with a primary packaging component and may provide additional protection for the product.

- **Tertiary packaging component:** Packaging that is in direct contact with a secondary packaging and may provide additional protection for the product during transportation and/or storage.
Primary Packaging

Material Types Used
- Glass
- Plastics
- Metals
- Elastomer

Material Selection Depends On
- The degree of protection required
- Compatibility with the product
- Customer convenience (e.g. size, weight)
Glass has been widely used to package products for over 100 years

- **Advantages**
  - Transparent
  - Non-reactive
  - Impermeable
  - Variety of sizes and shapes

- **Disadvantages**
  - Fragility
  - Weight
Packaging: Glass Types*

- **Type I-Highly resistant borosilicate glass**
  - Highly resistant glass
  - High melting point so can withstand high temperatures
  - More chemically inert than the soda lime glass
  - Can resist strong various solvents. Reduced leaching action

- **Type II-Treated soda lime glass**
  - Type II containers are made from soda lime glass that has been treated to remove surface ions
  - Treatment renders glass more chemically resistant similar to Type I

- **Type III-soda lime glass**
  - Same composition as Type 2 glass, minus the chemical treatment.

*(660) Containers—Glass, USP-NF, 2021*
Plastics are synthetic material made from a wide range of organic polymers that can be molded into shape while soft and then set into a rigid or slightly elastic form.

Advantages
- Flexible
- Variety of sizes and shapes
- Less weight than glass,
- Extremely resistant to breakage

Disadvantages
- Highly permeable
- Material – Product Interaction (Leachables)

1. <671> Containers—Performance Testing, USP-NF, 2021
2. <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems, USP-NF, 2021
Commonly Used Plastic Materials

- Cyclic Olefin
- Polyamide (Nylon)
- Polycarbonate
- Polyethylene
- Polyethylene Terephthalate
- Polyethylene Terephthalate G
- Polyethylene Vinyl Acetate
- Polyvinyl Chloride, Non-Plasticized
- Polyvinyl Chloride, Plasticized

1. <661> Plastic Packaging Systems and their Materials of Construction, USP-NF, 2021
2. <661.1> Plastic Materials of Construction, USP-NF, 2021
3. <661.2> Plastic Packaging Systems for Pharmaceutical Use, USP-NF, 2021
Packaging: Metals and Elastomers

- Metals commonly used for packaging are aluminum, tin plated steel and stainless steel

Advantages
- Impermeable
- Rigid unbreakable containers or flexible film
- Less weight than glass

Disadvantages
- Expensive
- Reaction with certain chemicals

Elastomers* are used mainly for the construction of closure meant for vials, transfusion fluid bottles, dropping bottles and as washers in many other types of product.

- Isobutylene/isoprene
- Polyisoprene
- Styrene butadiene rubber
- Ethylene propylene rubber
- Acrylonitrile butadiene rubber (nitrile)
- Polychloroprene (neoprene)
- Polysiloxane
- Silicone Rubber

*<381> Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems, USP-NF, 2021
A product’s supply chain is inherently complex with its many supply chain partners: distributors, third-party logistic suppliers, retail, pharmacies, hospitals and clinics.

With the various exchange and drop-off points, distribution environments often involve several modes of transportation, climate zones and seasonal changes.

Product shipments can experience vast temperature swings, and other environmental impacts, while sitting on a warm, open-air dock, waiting to be loaded; or while resting in an overcooled cargo-hold, waiting to be unloaded.

Proper storage and transportation are critical aspects of an integrated supply chain.
There are two aspects of product deterioration caused by unsatisfactory temperature* during storage and transport

- **Chemical changes**: as a result of accelerated chemical reactions leading to loss of potency or possible changes in other formulation constituents
  - Chemical changes are usually related to time

- **Physical changes**: leading to damage such as a result of freezing or melting
  - Physical changes are often much more immediate

ALL PRODUCTS SHOULD BE STORED AND TRANSPORTED ACCORDING TO THE LABEL STORAGE REQUIREMENT!!
Beside temperature there are other environmental factors that can have an impact on the product as it moves through the supply chain

- **Light**
  - Ultraviolet light can cause oxidation, hydrolysis, and loss of potency

- **Shock**
  - **Dropping**: risk for primary and tertiary packaging during handling, storage, and distribution
  - **Thermal**: glass can crack due to sudden changes in temperature

- **Vibration**
  - Encountered during shipping (vehicle vibration, rough roads, etc.)

- **Compression**
  - Crushing of a package, stack of packages, or a unit load
Storage vs. Transport

**Storage**
- Static handling of a drug product
- Typically a controlled process
- Complete documentation of the process is an industry standard

**Transport**
- Dynamic handling of a packaged product
- Typically uncontrolled process
- Documentation not usual or technically difficult
Good Distribution Practices (GDP)

GDP Pillars

- Quality Management System (QMS)
  - Integration of GDP principles
- Environmental Control Management
  - Label claim storage
- Good Importation and Exportation Practices
  - Procurement of authentic and quality materials and products
- Supply Chain Integrity and Security
  - Adulteration, counterfeit, misbranded, expired
Risks

- Procurement and Sales
- Receiving and Shipping
- Storage
- Picking

Mitigation Strategies

- Documentation (Manuals, Procedures, Protocols, Records)
- Training
- Resources
- Qualification and Validation

1<1079> Risk and Mitigation Strategies for the Storage and Transportation of Finished Products, USP-NF, 2021
2<1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products, USP-NF, 2021
Summary

- Function of packaging is to contain, preserve, and protect the product
- Primary packaging is critical because of the potential product-packaging interacting that could impact quality
- Glass, Plastic, Metal, and Elastomer are the common materials used for the primary packaging system
- Each packaging material has its advantages and disadvantages and selection should be based on the protection required, compatibility with the product and customer convenience (e.g. size, weight)
- All products should be stored and transported according to their label
- Other environmental factors need to be considered, such as shock, vibration and compression
- Robust QMS that incorporate the 4 pillars of GDP
Thank You

Empowering a healthy tomorrow