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

Packaging

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.

*<659> Packaging and Storage Requirements

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)

Packaging: Glass

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 with stand 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

Packaging: Plastics

- 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[1]
  - Material – Product Interaction (Leachables[2,3])

1. <671> Containers—Performance Testing, USP-NF, 2021
2. <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems, USP-NF, 2021
3. <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems, USP-NF, 2021

Packaging: Plastics[1,2,3]

- **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

Supply Chain

- 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

Environmental Impact on Product Quality

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!!

*<659> Packaging and Storage Requirements

Environmental Impact on Product Quality

- **Beside temperature there are other environmental factors that can have an impact on to 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

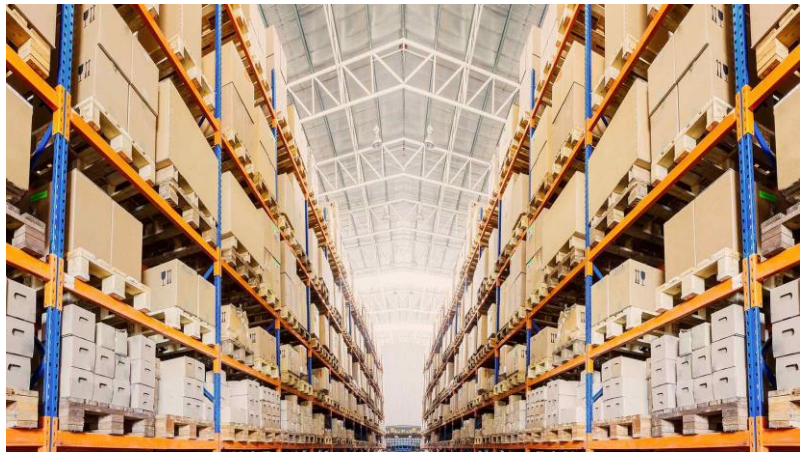
Storage vs. Transport

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

Risk and Mitigation Strategies for the Storage and Transportation of Finished Products[1,2]

- 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 it 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 it label
- Other environmental factor 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