

# Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

## Labeling, Packaging, Storage & Distribution: Ensuring Quality During Hand Sanitizer's Journey

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# Labels are Essential for Product Identification



“Labels are fundamental to material identification... Labels applied, even to small containers, should be clear, indelible, unambiguous, and permanently fixed in the format established by the manufacturer, packager, or repackager.”

General Chapter <1079> *Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products*



# Labeling - Definitions



## Labeling

“The term “labeling” includes all labels and other written, printed, or graphic matter on an article’s immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container.”

General Chapter <7> *Labeling*

## Label

“The term “label” is that part of the labeling on the immediate container.”

General Chapter <7> *Labeling*

# Labeling



<1079> Table 2. Mitigation Strategies Used by Organization within Supply Chain

Applicable Mitigation Strategies	Role of Organization within Supply Chain					
	Manufacturer	Wholesaler and Distributor	Pharmacy or Compounding Pharmacy	Hospital and Healthcare Provider	Broker	Logistics Service Provider (LSP)
<b>Documentation (Manuals, Procedures, Protocols, Records)</b>						
Quality manual	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	No	Yes
Procurement	Yes	Yes	Yes	Yes	Yes	Yes
Receiving	Yes	Yes	Yes	Yes	No	Yes

## Receiving hand sanitizer ingredients

- ▶ Labels of hand sanitizer ingredients should align with current FDA requirements detailed in the *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry*
- ▶ Specific details such as concentration and grade (e.g. USP, FCC) clearly stated on label and should be confirmed upon receipt

## Receiving hand sanitizer ingredients

- ▶ USP designation indicates that the product complies with a specific *USP-NF* monograph
- ▶ If complies with USP monograph it must have
  1. specific monograph name on label and
  2. any additional labeling requirements described in the specific monograph.

Example: **ISOPROPYL ALCOHOL (IPA) 99%, USP**

## Manufacture of hand sanitizer

- ▶ **Principal display panel** and **drug facts label** requirements in FDA Guidance
  - Principal display panel
    - Product name and strength, dosage form, identification, product description, volume of product in mL
  - Drug facts label includes
    - Active Ingredient(s), Use(s), Warnings, Directions, Storage Conditions, Other Information, and Inactive ingredients

## Manufacture of hand sanitizer – FDA Guidance

**Principal display panel and drug facts label** examples located in the Appendices of FDA Guidance document

- **Appendix A.** Labeling for Ethanol Formulation Consumer Use
- **Appendix B.** Labeling for Isopropyl Alcohol Formulation Consumer Use
- **Appendix C.** Labeling for Ethanol Formulation Health Care Personnel Hand Rub Use
- **Appendix D.** Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand Rub Use



# Labeling



## Compounding hand sanitizer

- ▶ “...expectation is that compounders follow USP General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations*, including:
  - The preparation to be appropriately labeled”<sup>1</sup>
- ▶ Follow specific labeling requirements according to the formulation

Formulation 1:	Formulations 2 and 3:
For external use only	For external use only
Percentage/concentration of ethanol	Percentage/concentration of isopropyl alcohol
Beyond-Use Date	Beyond-Use Date

1. United States Pharmacopeia (2020). Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic,

# Labeling



## Shipping of Hand Sanitizer

### Outer Shipping Container

- ▶ Product identification
- ▶ Lot number
- ▶ Wording or icons to emphasize:
  - Storage and transportation conditions
  - Handling requirements
  - Hazards



# Labeling



**Labeling documentation** according to the organization's role in manufacturing or compounding of hand sanitizers.

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Quality manual	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	No	Yes

# Thank You



**Empowering a healthy tomorrow**