Shipping, Handling & Storage Overview

Current as of December 6, 2020

Breakthroughs that change patients' lives

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

Change Log

Version	History of Changes
01	Initial version
02	• New content includes Overview of Shipping, Storage & Handling, Key Timing Considerations, and Re-icing Thermal Shipper • Modified temperature of Thermal shipper from -75+15°C (-103° to 5°F) to -90ºC to -60ºC (-130ºF to -76ºF)

Overview of Shipping, Storage & Handling

1

Thermal Shipper Arrival

The thermal shipper that the vaccine arrives in can be used as temporary storage, so long as dry ice is replenished upon receipt and every 5 days (up to 30 days).

The thermal shipper maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

2

Storage & Handling

Storage options for vials/trays include:

1. **Ultra Low Temperature Freezer at** -80° and -60°C (-112 to -76°F) for up to 6 months
2. **Thermal Shipper at** -90ºC to -60ºC (-130ºF to -76ºF) for up to 30 days from delivery, if replenished with dry ice upon receipt and every 5 days
3. **Refrigerator** at 2 to 8 °C (35.6° to 46.4°F) for up to 120 hours (5 days)

Vial are glass and should be handled with care. Visual inspection prior to use should be carried out.

Vials should be protected from light and kept in the original packaging.

Vials should always remain upright in trays during storage.

3

Returning Thermal Shipper

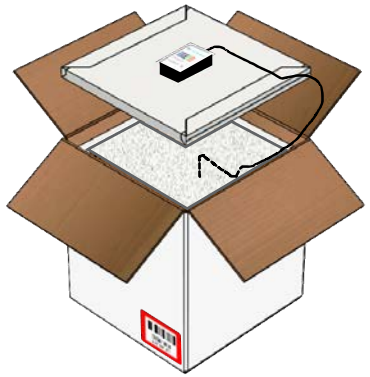
The thermal shipping container may be used as temporary storage for up to 30 days from delivery, including temperature data logger.

Direct Shipment to Points of Vaccination

Direct Shipments* to Vaccination Center by Transport Courier

Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation



Controlant Reusable RTM Logger

- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the government.
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Product Packaging Overview

Vials

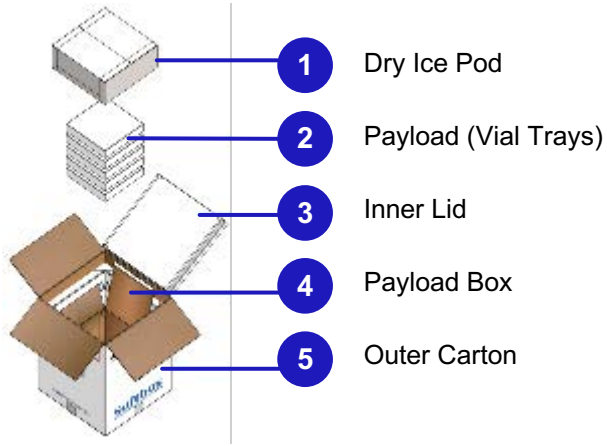
2 mL Type 1 glass preservative-free

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

Trays

- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

Thermal Shipper



- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -90ºC to -60ºC (-130ºF to -76ºF) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice.

Key Timing Considerations

TRAYS

3 MINS

Open-lid vial trays, or vials trays containing less than 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **3 minutes** for transfer between ultra low temperature environments or to remove vials for thawing or use.

5 MINS

Closed-lid vial trays containing 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **5 minutes** for transfer between ultra low temperature environments.

2 HRS

After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least **2 hours** before they can be removed again.

VIALS

Once an individual vial is removed from a vial tray at room temperature, it should not be returned to frozen storage and should be thawed for use.

Re-icing Thermal Shipper

Handling instructions

- Re-ice at a minimum of every 5 days (based on normal use). No restriction to number of re-icing. If box is left open for longer than 3 minutes, recommendation is to re-ice more frequently, as needed.
- If re-icing occurs and a holiday or weekend, plan ahead to re-ice the thermal shipping container.
- Thermal shipping container may be used as temporary storage for up to 30 days from delivery.
- Sites are required to maintain temperature monitoring.

3 MINS

Thermal Shipper opening:
twice daily, max 3 minutes each

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- Shipper arrives with 80% energy
- Upon receipt and after opening, the box should be replenished/inspected with dry ice within 24 hours
- Re-ice shipper
- Re-ice shipper
- Re-ice shipper
- Re-ice shipper
- Re-ice shipper
- Return shipper

SHIPPER ENERGY LEVEL

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