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# PHARMACEUTICAL BIOTECHNOLOGY

## UNIT 3

TOPIC :

- e) Storage conditions and stability of official vaccines



# Storage and Stability of Vaccines

- Vaccine stability is the ability of a vaccine to retain its potency, safety, and effectiveness during storage and transportation.
- Because vaccines are biological products, they are highly sensitive to environmental conditions.

## Storage Conditions of Vaccines

### 1. Cold Chain Maintenance

Cold chain is a temperature-controlled system used for vaccine storage and transportation.

#### Temperature

Most vaccines must be stored continuously at:

**2°C to 8°C**

#### Importance

Maintains:

- Potency
- Safety
- Effectiveness

From manufacture to administration.

### 2. Temperature Requirements

| Vaccine                 | Storage Temperature |
|-------------------------|---------------------|
| Most Vaccines           | 2°C – 8°C           |
| OPV (Long-Term Storage) | -15°C to -25°C      |
| DPT Vaccine             | Must not be frozen  |
| Hepatitis B Vaccine     | Must not be frozen  |
| Tetanus Toxoid          | Must not be frozen  |

### 3. Storage Equipment

#### Ice-Lined Refrigerators (ILR)

- Used in immunization centers.

#### Deep Freezers

- Used for specific vaccines requiring freezing.

#### Cold Boxes

- Used during transportation.

#### Vaccine Carriers

- Used for outreach immunization programs.

#### **4. Protection from Light**

Some vaccines are highly light-sensitive.

##### **Examples**

- BCG Vaccine
- Measles Vaccine

These vaccines should be stored:

- In original packaging
- Away from direct sunlight

#### **Transportation of Vaccines**

Vaccines are transported using:

- Cold boxes
- Vaccine carriers

Required temperature must be maintained throughout transport.

#### **Stability of Vaccines**

##### **Factors Affecting Stability**

###### **1. Heat**

- Decreases vaccine potency
- Causes antigen degradation

###### **2. Freezing**

- Damages adsorbed vaccines
- Reduces effectiveness

###### **3. Light**

- Inactivates live vaccines
- Causes loss of potency

# Lyophilized (Freeze-Dried) Vaccines

- These vaccines are prepared by freeze-drying to improve stability.

## Advantages

- Longer shelf life
- Better stability

## Important Points

After reconstitution:

- Must be used within 4–6 hours.
- Unused vaccine should be discarded.

## Monitoring Vaccine Stability

### Vaccine Vial Monitor (VVM)

A VVM is a label that indicates cumulative heat exposure of a vaccine.

## Importance

- Shows whether vaccine has been damaged by heat.
- Helps ensure vaccine quality.

## Temperature Monitoring

Regular monitoring is essential to ensure vaccines remain effective.