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 - ✓ Unit 3
 - ✓ Unit 4
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 - ✓ Unit 2
 - ✓ Unit 3
 - ✓ Unit 4
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 - ✓ Unit 2
 - ✓ Unit 3
 - ✓ Unit 4
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- ✓ Unit 1
 - ✓ Unit 2
 - ✓ Unit 3
 - ✓ Unit 4
 - ✓ Unit 5
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 - ✓ Unit 2
 - ✓ Unit 3
 - ✓ Unit 4
 - ✓ Unit 5
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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.