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**AN OVERVIEW: STORAGE OF PHARMACEUTICAL PRODUCTS**

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**ABSTRACT**

This study emphasizes the importance of proper storage of pharmaceuticals in pharmacy premises till it reaches the consumer. The loss of potency during storage may influence the efficacy and safety of pharmaceuticals. Pharmaceutical products require controlled storage and transit conditions in order to ensure that their quality is not compromised. Storage is an important aspect of the total drug control system. Proper environmental control (i.e., proper temperature, light, and humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored in the premises.

**Key words:** Storage, Storage condition, vaccine storage, cold chain, Vaccine Vial Monitor.

**INTRODUCTION**

Drug storage is among the pharmacist's most important responsibilities. Therefore, adequate methods to assure that these responsibilities are met must be developed and implemented. The pharmaceutical are to be stored under conditions that prevent contamination and, as far as possible, deterioration. The stability of product retain within the specified limit, throughout it period of storage and use<sup>1</sup>. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat and light are indicated. During storage of the pharmaceutical products is one of the fundamental concerns in patient care<sup>2</sup>. The conditions under which pharmaceutical products are manufactured and stored can have a major impact on their

quality. High temperature and relative humidity (RH) are the most important factors involved in drug degradation<sup>3</sup>. Factors such as temperature, humidity, air quality, time and production process characteristics can all have a significant impact on the final quality, and therefore the saleability, of a product or batch of products. For many products requiring storage in cool conditions, refrigeration plant is widely used, which needs to be carefully monitored to ensure that the correct temperatures are maintained. Stock must be stored in appropriate and auditable environmental conditions.

Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorizations. Pharmacy stock should be stored under suitable conditions, appropriate to the nature and stability of the product concerned<sup>4</sup>. Particular attention should be paid to protection from contamination, sunlight, UV rays, moisture, atmospheric moisture and extreme temperatures. During storage, medicines should be retained in the manufacturer's original packaging. Good storage practice is applicable in all circumstances where pharmaceutical products are stored throughout distribution process.

Pharmaceutical products should be packed in a well closed container that protects the contents from contamination by extraneous solids, liquids or vapors and the loss of the products under normal conditions of handling and storage<sup>5</sup>. The following factors to be taken in consideration for proper storage:

1. Sanitation
2. Temperature
3. Light
4. Moisture
5. Ventilation
6. Segregation

Different pharmaceutical product storage temperature on the basis of stability studies as given below:

**Freezer:** A place in which the temperature is maintained thermostatically between -25°C and -10°C (-13 °F and -14 °F).

**Cold:** Any temperature not exceeding 8°C (46 °F). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C.

**Cool:** Any temperature between 8 °C and 15 °C. Any pharmaceutical products for which storage in a cool place directed may, alternatively, be stored in a refrigerator, unless otherwise specified in the individual monograph.

Good storage practice (GSP) is applicable in all circumstances where pharmaceutical products are stored through the distribution processes. For additional guidelines relating the general principles of storage of pharmaceutical products, refer to the WHO guidelines on good storage practices.

### **STORAGE CONDITION ON LABEL**

Storage conditions for pharmaceutical products and materials should be in compliance with the labelling, which is based on the results of stability testing. Storage conditions should be defined and described on the label of the product. All drugs should be stored according to the conditions described on the label. When specified on the label, controls for humidity, light, etc., should be in place. Storage areas should be designed or adapted to ensure good storage conditions<sup>6</sup>. The label should specify any special storage conditions required for the product. Written procedures should be available describing the actions to be taken in the event of temperature excursions outside the labeled storage conditions<sup>7</sup>. All excursions outside the labeled storage conditions must be appropriately investigated and the disposition of the stock in question must be evidence-based (for example, stability data and technical justification). Stability testing thus evaluates the effect of environmental factors on the quality of the a drug substance or a formulated product which is utilized for prediction of its shelf life, determine proper storage conditions and suggest labeling instructions<sup>8</sup>.

#### **Storage of Tablet**

Storage on label:

Store in a cool, protected from light and moisture.

Store in a cool and dark place, protected from light and moisture.

Keep in a dry dark place.

Store in cool dry and dark place.

#### **Storage of Capsule**

Storage on label:

Store in a cool and dry place, protected from light.

**Storage of Emulsion**

An emulsion should be stored in air tight container, protected from light, high temperature or freezing. The emulsions are required to be in cool place.

**Storage of Suspension**

Suspension should be stored in a cool place but not be kept in a refrigerator. Freezing at a very low temperature should be avoided which may lead to aggregation of the suspended particles.

Storage on label:

Store in cool and dry place, protect from heat and light.

Store in a cool and dark place, protect from direct sun light.

Keep in dry place at a temperature not exceeding 30 °C. keep the bottle tightly closed.

Store below 25 °C, protected from moisture.

Store at temperature not exceeding 30 °C, protect from light.

**Storage of Ointment**

Ointment should be stored in well closed container so as to prevent the loss of volatile constituents. The ointment should be protected from high temperature or direct sunlight.

Storage on label:

Keep in a cool place.

**Storage of Paste**

The paste should be stored in well closed container and in a cool place so as to prevent evaporation of moisture present.

**Storage of syrup**

The syrup should be stored in well closed and stopper bottle in a cool dark place. The syrup should be stored at a temperature not exceeding 25 °C.

Storage on label:

Store in cool, dry and dark place.

Store in a cool and dry place, protected from light.

Store in a cool place, protected from direct sunlight.

**Storage of Oral Drop**

Storage on label:

Store at temperature not exceeding 30 °C.

Store in cool, dry place and protected from light.

Store at temperature not exceeding 30 °C, protect from direct sunlight.

Keep in a dry place, dark place.

Store in a dry place, away from light.

### Storage of injection

Storage on label:

Store below 30 °C, protected from light.

Store below 25 °C, protected from light.

Drugs products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specified stated deviation may be tolerated only during short term interruptions.

Improper storage of insulin decreases the potency and hence the pharmacological action of insulin. Patients should be educated on the proper methods of storage. Insulin is one such labile drug, sensitive to extreme temperatures and sunlight and hence needs to be stored under refrigeration between 2- 8°C<sup>9</sup>.

The uses of the following labeling instructions are given:

On the label	Means
Do not store over 30 °C	from +2 °C to +30 °C
Do not store over 25 °C	from +2 °C to +25 °C
Do not store over 15 °C	from +2 °C to +15 °C
Do not store over 8 °C	from +2 °C to +8 °C
Do not store below 8 °C	from +8 °C to +25 °C
Protects from moisture	no more than 60% relative humidity in normal storage condition.
Protect from light	to be stored in light resistant container.

The pharmaceutical supply chain is becoming increasingly complex, involving a number of storage and transit locations including airports and docks. At all of these points the shipments are often handled by a number of different parties, across multiple geographies which increases the risk to products integrity.

### Containers and Container Labeling

1. Any controlled transport and/or storage conditions as well as warning statements (for example, "Time and Temperature Sensitive", "Do Not Freeze") should be clearly stated on the label applied to shipping containers. This label should be securely affixed and indelible. The label and shipping documents should clearly state that these products should be transferred without delay to the specified storage temperature upon receipt.
2. Shipping containers should be qualified to meet the expected extremes of ambient temperature within the distribution environment, if they provide the primary means of environmental control for the drug product.
3. Selection of a shipping container and/or box should be based on:
  - ❖ The space required for the volume of drugs to be transported.
  - ❖ The anticipated extremes of ambient temperature.
  - ❖ The estimated maximum length of time required for transportation of the drugs, including any in transit storage.
4. When warm/cold packs are placed in containers used to transport drugs:
  - ❖ The type, size and number of packs should correspond to the shipping duration and temperature needed.
  - ❖ The location of the packs should ensure that the entire shipment of the product is maintained within the labeled storage conditions.
  - ❖ Adequate barrier materials should be used to prevent contact between the packs and the products, if the packs are at a temperature outside the range acceptable for product storage.
5. The use of dry ice in the transportation of drugs must not adversely affect the drug product or the primary package and must be handled in accordance with the indication.
6. Temperature monitoring devices or temperature indicators should be used when appropriate. If temperature excursions outside predetermined temperature conditions, as per the labelled storage conditions occur, these excursions must be assessed and documented to determine product disposition. Corrective action should be implemented where necessary and documented. Clear directions should be provided to the recipient for the evaluation of monitoring devices/indicators and disposition of the products.

### Storage area<sup>10</sup>

1. Storage areas should be of sufficient capacity to allow the orderly storage of the various categories products, namely bulk and finished products, products in quarantine, and

- released, rejected, returned or recalled products.
2. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, checked.
  3. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection.
  4. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
  5. Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
  6. Narcotic drugs should be stored in compliance with international conventions, and national laws and regulations on narcotics.
  7. Radioactive materials, dangerous drugs, psychotropic substances, and cytotoxic drugs should be stored in dedicated areas that are subject to appropriate additional safety and security measures.

### **Temperature-controlled storage**

Pharmaceutical manufacturers have long realized the importance of a robust and efficient, temperature controlled supply chain. In some areas, notably in the storage of pharmaceutical products, it has been necessary for the regulatory authorities to introduce guidelines or legislation to ensure compliance to temperature limits. The storage environment needs to be temperature-mapped and have relevant controls in place to avoid extremes of temperature<sup>11</sup>. Probes monitoring the environmental conditions need to be calibrated to a certified internal standard and be regularly checked and maintained to ensure continued accuracy of data recorded. Time- and temperature-sensitive pharmaceutical product (TTSP) which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended<sup>12</sup>.

### **VACCINE STORAGE**

Vaccines are expensive and fragile, and storing them at the proper temperature is essential to providing effective immunizations. The vaccines should always be stored in their original packaging until point of use to protect them from light. Immunization programs have had a major impact on the health status of the world's population by preventing many cases of



infectious diseases through immunization. The vaccine temperature must be maintained in an insulated container between +2°C to +8°C at all times. Vaccine storage and handling are key components in maintaining the efficacy of immunization programs. Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and with administration of the vaccine. The optimum temperature for refrigerated vaccines is between 2°C and 8°C. For frozen vaccines the optimum temperature is -15°C or In addition, protection from light is a necessary condition for some vaccines. Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. Vaccines exposed to temperatures above or below the recommended temperature range experience some loss of potency with each episode of exposure. All vaccines have a predetermined shelf life and the potency of vaccines is guaranteed by the manufacturers up to the expiry date as stated on the product, if stored within the safe temperature range of between 2°C and 8°C.

Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage. Storage outside of the recommended temperature range, including during transport and storage, may speed up loss of potency, which cannot be reversed. Inappropriate storage may results in vaccines wastage, or if undetected, failure of the vaccine to protect. All individuals involved in the cold chains from manufacturer, through pharmacy within the optimum temperature range of +2 °C to +8 °C. Aim to maintain vaccine fridge as close as possible to 5°C as this gives a safety margin of + or - 3°C<sup>13</sup>.

In general, there are two types of vaccines: live attenuated and inactivated. Live attenuated vaccines consist of a weakened form of the virus itself. They are easily damaged or destroyed by heat and light, making it even more important that they be stored and handled with extreme care.

Refrigerators and freezers used for storing vaccine must comply with the following requirements.

1. Be able to maintain required vaccine storage temperatures year-round:

Refrigerator: 2° to 8°Celsius (C) (35° to 46° Fahrenheit (F))

Freezer: -15°C or colder (5°F or colder)

2. Be large enough to hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures.

### Freezer

All varicella-containing vaccines should be stored in a continuously frozen state at the manufacturer recommended freezer temperature until administration.

### Refrigerator

All inactivated vaccines require refrigerator storage temperatures between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C). The following live attenuated vaccines must also be kept at refrigerator temperature: influenza (LAIV, FluMist); rotavirus (RV1, Rotarix and RV5, RotaTeq); typhoid (Ty21-A, Vivotif); and yellow fever (YF-Vax).

Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect.

**Table: 2. Storage condition of Vaccines**

Vaccine	Storage temperature range	Warning
Oral Polio Vaccine	2 -8 °C	Check VVM status Cannot be frozen and thawed
Bacilles Calmette Guerin (BCG)	2-8 °C	Check VVM status Cannot be frozen and thawed
Measles Vaccine	2-8 °C	Cannot be frozen and Cannot be frozen & thawed
Tetanus Toxoid (TT)	2-8 °C	Freeze-sensitive : Do not freeze
Hepatitis B Vaccine (HBV)	2-8 °C	Freeze-sensitive : Do not freeze
Cholera Vaccine	2-8 °C	Freeze-sensitive : Do not freeze
Smallpox Vaccine	2-8 °C	Freeze-sensitive : Do not freeze

### COLD CHAIN

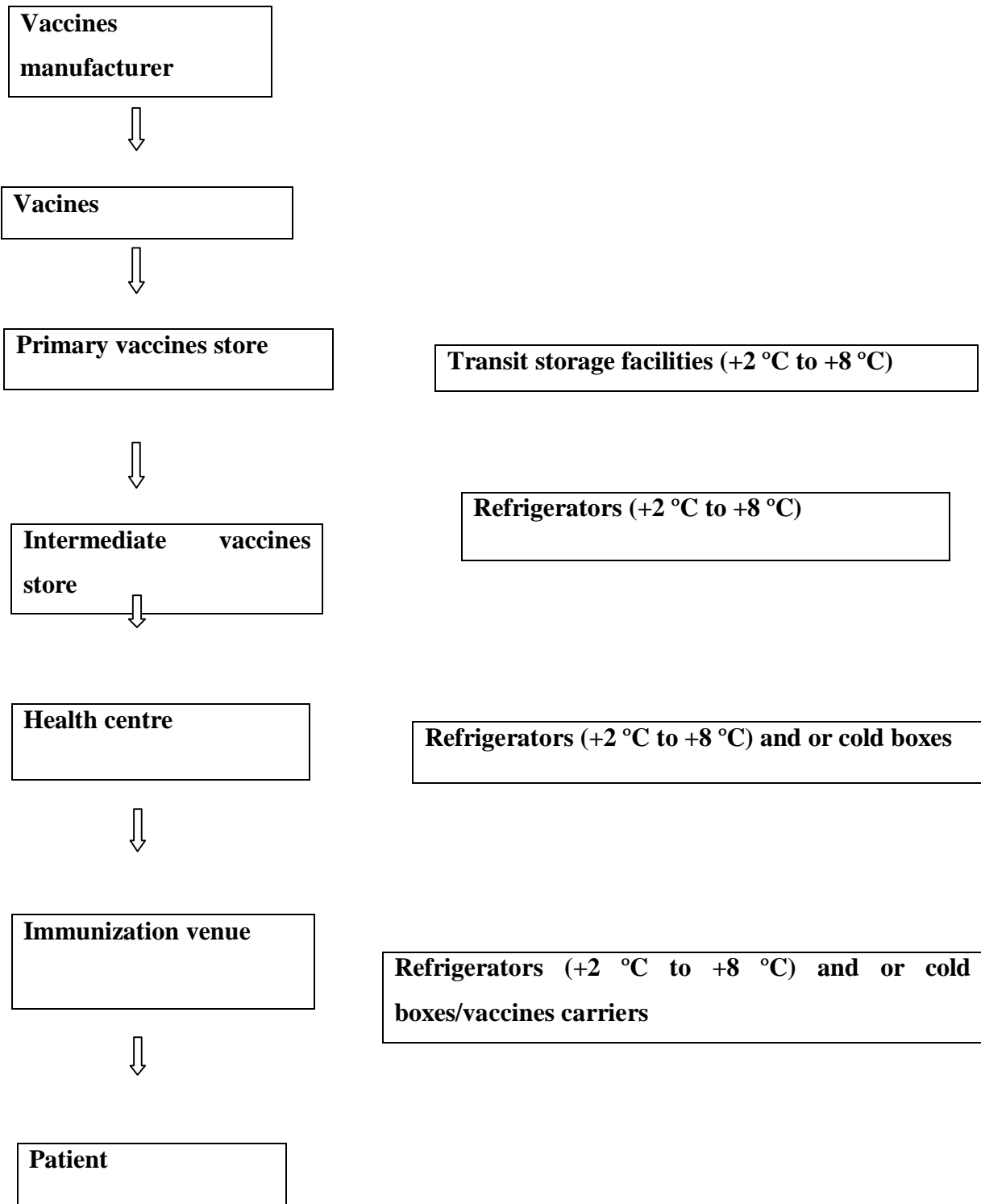
The pharmaceutical products storing and distributing environmentally sensitive product focus is to provide cold chain management for temperature pharmaceuticals to ensure that the quality and efficacy of the product will not be compromised<sup>14</sup>. All vaccines are sensitive

biological substances and all will lose their potency that is, their ability to give protection against disease with time. This loss of potency accelerates as vaccines are exposed to higher or lower temperatures. In order to, maintain their quality, all vaccines must be continuously stored within the appropriate temperature range from the time they are manufactured until the moment of use. Once a vaccine's potency is lost, it cannot be regained or restored and without proper care, any vaccine may eventually lose all its potency. When vaccines lose potency, they can no longer protect individual from disease. The vaccine will lose its potency faster if stored in unfavourable conditions. It is therefore to store at the correct recommended temperature so that full potency is retained till its administration or expiry date.

Vaccines are sensitive to heat and freezing and must be kept at the correct temperature from the time they are manufactured until they are used. The system used for keeping and distributing vaccines in good condition is called the cold chain. The cold chain consists of a series of storage and transport links, all designed to keep vaccines within an acceptable range until it reaches the user. The system of transporting and storing vaccines within the recommended temperature range of +2 °C to +8 °C from the place of their manufacture to the point of vaccine administration is called the 'cold chain'. The term cold chain is the name given to the system of transporting and storing vaccines within the safe temperature range of between 2 °C and 8 °C<sup>15</sup>. The success of any immunization programme depends on administering effective vaccines. Vaccines quickly lose effectiveness if they get too hot or cold during transport and storage. It is therefore essential to maintain an unbroken cold chain for the vaccines from the point of manufacture, during transport and during storage in a refrigerator until they are used to vaccinate someone. Storage temperature never exceeds 8 °C or fall below 2 °C. Aim to maintain vaccine fridge as close as possible to 5 °C as this as safety margin of + or - 3 °C. Vaccines should always be stored in trays in the middle of the refrigerator or freezer, never in the doors. The reason for this is that items stored in the door are frequently exposed to warm temperatures when the unit is opened<sup>16-18</sup>.

### **Sensitivity to Heat**

Although all vaccines are sensitive to heat, some vaccines are more sensitive to heat than others. Polio vaccine is the most sensitive to heat, while tetanus toxoid is the least sensitive. Vaccines do not change their appearance when potency is lost. A complete laboratory test is the only means to assess whether a vaccine in a vial has lost its potency. The following vaccines are listed in order of heat sensitivity<sup>19</sup>.



**Fig. 1: Typical vaccines cold chain**

- ❖ Oral Polio Vaccine (OPV)
- ❖ Measles (lyophilised)
- ❖ Diphtheria, Tetanus and Pertussis (DTP),
- ❖ Yellow Fever

- ❖ Bacillus Calmette Guerin (BCG)
- ❖ Haemophilus Influenzae Type b (Hib),
- ❖ Diphtheria and Tetanus toxoid (DT)
- ❖ Tetanus and Diphtheria toxoid (Td)
- ❖ Tetanus toxoid (TT) and Hepatitis B

### **Sensitivity to Freezing**

Some vaccines are also sensitive to extreme cold. For these vaccines, freezing or exposure to temperatures below zero degrees Celsius can also cause loss in potency and render the vaccines useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing. The vaccines sensitive to freezing (as well as to heat) are :

- ❖ Hepatitis B
- ❖ Hib (liquid)
- ❖ DTP
- ❖ DT
- ❖ Td
- ❖ TT

### **COLD CHAIN EQUIPMENT**

All cold chain equipment has to comply with a set of performance standards defined by the WHO EPI program and United Nations Children's Fund (UNICEF), or national policy. Only proven methods should be used to transport or store vaccines: for example, insulated containers proven through electronic temperature logging as reliable in maintaining the recommended temperature (solid wall transport containers, double walled transport containers and polystyrene containers)<sup>20</sup>.

- ❖ The recommended equipment typically used for vaccine storage are :
  - (a) cold rooms,
  - (b) refrigerators
  - (c) freezers.
- ❖ For transporting vaccines equipment such as are commonly used.
  - (a) cold boxes,
  - (b) vaccine carriers and
  - (c) international containers

### Vaccine Cold boxes

A cold box is an insulated container that can be lined with ice-packs to keep vaccines and diluents cold during transportation and/or short period storage (from two to seven days). Cold boxes are used to collect and transport monthly vaccine supplies from district stores to the health facility. They are also used to store vaccines when the refrigerator is out of order or being defrosted and for outreach and mobile sessions in addition to vaccine carriers. Different models of cold boxes have different vaccine storage capacities.

Health facilities usually need one or more cold boxes that can hold:

- ❖ a one-month supply of vaccines and diluents ; and
- ❖ a one-to-two week reserve stock of vaccines and diluents.

In addition to their vaccine storage capacity, cold boxes are selected according to their cold life. Different models have a cold life of two to seven days depending on the temperature outside.







**Figure : 2 Symbol on vaccine vial monitor**

### VACCINE VIAL MONITOR

It contains a chemical that becomes darker in response to heat over time. This indicator is printed as a small square against a larger circular background, which itself has a pre-printed reference colour. The colour of the preprinted background square can also be increased or decreased. As a result, the VVM can be set to approximately track the time-temperature sensitivity curve of materials. This permits minor breaks in the cold chain to be accommodated without undue vaccine wastage and ensures that heat- compromised vaccine is “flagged” to be discarded. A VVM is a low cost indicator that is printed onto the label of a

vaccine vial, attached to the vaccine vial cap, or affixed on the ampoule neck. The indicator changes color when the vial has been exposed to warm temperature over an extended period of time. The VVM does not measure the actual potency of the vaccine inside the vial but instead indicates if unacceptable heat exposure has occurred and probably damaged the vaccine in that specific vial.

**Table: 2. The vaccine vial monitor**

Symbol	Explanation	Stage
	The inner square is lighter than the outer circle. If the expiry date has not passed, USE the vaccine	<b>I</b>
	As time passes the inner square is still lighter than the outer circle. If the expiry date has not passed, USE the vaccine.	<b>II</b>
	Discard point: Inner square matches the color of the outer circle. DO NOT use the vaccine	<b>III</b>
	Beyond the discard point: inner square is darker than the outer circle.  DO NOT USE THE VACCINE	<b>IV</b>

### IMPORTANCE OF MAINTAINING THE COLD CHAIN

Vaccines are sensitive biological products which may become less effective, or even destroyed, when exposed to temperatures outside the recommended range. Cold-sensitive vaccines experience an immediate loss of potency following freezing. Vaccines exposed to temperatures above the recommended temperature range experience some loss of potency with each episode of exposure. Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible. However, information on vaccine degradation is sparse and multipoint stability studies on vaccines are difficult to perform. In addition, information

from manufacturers is not always available, so it can be difficult to assess the potency of a mishandled vaccine.

Maintaining the potency of vaccines is important for several reasons.

- ❖ There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine preventable disease.
- ❖ Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccines may result in the cancellation of immunization clinics resulting in lost opportunities to immunize.
- ❖ Revaccination of people who have received an ineffective vaccine is professionally uncomfortable and may cause a loss of public confidence in vaccines and/or the health care system.

Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range and/or on exposure to direct sunlight or fluorescent light.

**Cold Chain Monitor Card (CCM):** A heat sensitive indicator in the form of a strip with four windows (A, B, C and D). The indicator operates above 10°C and 34°C. The higher the temperature above the CCM threshold, the more rapidly the colour changes to blue, which is irreversible even when exposed to lower temperatures again.

**Chemical Temperature Indicators:** these units are mostly single use devices, with average accuracy. Some chemical monitors can be permanently affected by temperature exposure, while others are reversible. Advantages are very low cost and size, while disadvantages include low accuracy and limited temperature ranges. Ex: Cold Chain Monitor Card. (coolpack).

## CONCLUSION

Maintaining proper storage conditions at hospital and community pharmacies is essential to reduce such impact caused by environmental factors. The pharmaceutical products were found to retain their potency when stored in pharmacies having good storage facilities. Hence the regulatory authorities and pharmaceutical organizations should highlight the importance of maintaining good storage conditions in hospital and community pharmacies. All vaccines are sensitive biological substances which are susceptible to heat, light and/or freezing. They



will lose their potency with time but this becomes more rapid if vaccines are not continuously stored at the temperature appropriate for them from the time they are manufactured till the time of use.

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