

वैक्सीन वाहक — सामान्य अपेक्षाएँ और  
परीक्षण पद्धतियाँ

Vaccine Carriers — General  
Requirements and Test Methods

ICS 11.040.01

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## FOREWORD

This Indian Standard was adopted by Bureau of Indian Standards, after the draft finalized by the Hospital Equipment and Surgical Disposable Products Sectional Committee and approval of the Medical Equipment and **Hospital Planning Division** Council.

The composition of the Committee responsible for formulation of this standard is given in [Annex E](#).

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

*Indian Standard***VACCINE CARRIERS — GENERAL REQUIREMENTS AND TEST METHODS****1 SCOPE**

**1.1** This standard specifies the essential requirements for thermally insulated vaccine carriers which are used to transport vaccines from cold chain point to immunization camps or outreach sessions, where refrigeration and ice is unavailable.

**1.2** This standard covers both short range and long-range vaccine carriers.

**2 REFERENCES**

The standards given below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

<i>IS No./Other Standards</i>	<i>Title</i>
IS 17550 (Part 1) : 2021	Household refrigerating appliances — characteristics and test methods: Part 1 General requirements ( <i>first revision</i> )
IS 17589 : 2021	Specification for water packs for use as ice-packs, cool-packs and warm-packs — Requirements and test methods
ISO 20282-1 : 2006	Ease of operation of everyday products — Part 1: Design requirements for context of use and user characteristics
IS/IEC 60529 : 2001	Degrees of protection provided by enclosures (IP code)

**3 TERMS AND DEFINITIONS**

For the purposes of this standard, the following terms and definitions apply.

**3.1 Cold Life** — When the empty container is stabilized at + 43 °C, loaded with ice-packs and the

lid closed, the time taken for the temperature of the warmest point in the vaccine storage compartment to first reach + 10 °C, at a constant ambient temperature of + 43 °C.

**3.2 Cool Life** — When the empty container is stabilized at + 43 °C, loaded with coolant packs which have been stabilized at + 5 °C for a minimum of 24 h and the lid closed, the time taken for the temperature of the warmest point in the vaccine storage compartment to first reach + 20 °C, at a constant ambient temperature of + 43 °C.

**3.3 Cool-Pack** — A water-pack pre-cooled to a temperature between + 2 °C to + 8 °C before use.

**3.4 Ice-Pack** — A water-pack frozen to a temperature between – 5 °C and – 20 °C before use is called ice-pack. Ice-packs are used frozen for the transport of oral polio vaccine (OPV), and used conditioned ice pack for the transport of all other vaccines specified temperature range between + 2 °C to + 8 °C.

**3.5 Long Range Vaccine Carrier** — Vaccine carriers with a minimum cold life of 30 h that can be used for transportation/storage for a longer period of time.

**3.6 Phase Change Material (PCM)** — A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

**3.7 Short Range Vaccine Carrier** — Vaccine carriers with a minimum cold life of 15 h that can be used for transportation/storage for only a short period of time.

**3.8 Vaccine Carriers** — Vaccine carriers are insulated containers that, when lined with water packs, keep vaccines and diluents safe and in specified temperature range during transportation.

**3.9 Vaccine Storage Capacity** — The total volume of the vaccine storage compartment, in liters. The measurement is equal to the volume of the largest rectilinear object that can be inserted into the

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compartment with all the manufacturer's specified packs in place.

**3.10 Vaccine Storage Compartment** — The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of ice-packs required to achieve the cold life specified in this standard.

**3.11 Warm Life** — When the empty container is stabilized at + 18 °C, loaded with warm packs which have been stabilized at the same temperature for a minimum of 24 h and the lid closed, the time taken for the temperature of the coldest point inside the vaccine storage compartment first reaches 0 °C at a constant ambient temperature of – 20 °C.

**3.12 Warm-Pack** — A water-pack typically stabilized at room temperature, up to a recommended maximum of + 24 °C. Warm-packs are used for the transport of freeze sensitive vaccines in places where sub-zero temperatures are common.

**3.13 Water-Pack** — A flat, leak proof, plastic container, filled with tap water. It is a robust container designed to store water which, when frozen, cooled or warmed to an appropriate temperature, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens when carried inside a cold box or vaccine carrier.

## 4 REQUIREMENTS

### 4.1 General

Short range or long range insulated vaccine carriers, with insulated lid, designed for transporting vaccines. The product shall conform to the requirements for quality, safety and performance prescribed.

### 4.2 Performance

#### 4.2.1 Vaccine Storage Capacity

- a) Short range: 0.5 litre to 5.0 litre; and
- b) Long range: 1.0 litre to 5.0 litre.

#### 4.2.2 Cold Life

- a) Short range: minimum 15 h; and
- b) Long range: minimum 30 h.

#### 4.2.3 Shape

Vaccine carriers should be substantially square or rectangular in plan and section. Rounded corners are preferred.

#### 4.2.4 Design Principles

The design of the container, including the placement of the packs and of the load, should promote the free circulation of air within the container to ensure minimum temperature stratification. Container design should seek to minimize the weight of ice-packs required to meet the cold life requirement. Non-rigid and semi-rigid designs are acceptable provided they meet the required criteria for robustness. The product shall be designed in accordance with the general usability principles laid out in ISO 20282-1. All vaccine carriers shall be designed so that they can comfortably be carried, when fully loaded.

#### 4.2.5 Lid

Vaccine carriers shall be fitted with an insulated lid which fits securely to the body of the container when closed so as to minimize cold bridging and maximize structural strength. Hinged lids are acceptable, but are not mandatory.

#### 4.2.6 Hinges

Hinges, where fitted, shall allow the lid to open beyond 90° to give full access to the interior of the vaccine carrier. Preferably the hinges shall be recessed so that they are fully protected against damage during transport and storage. Hinges shall be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

#### 4.2.7 Closure Device

The lid should be fitted with a mechanism to secure it in place so that the vaccine carrier does not open if it is dropped onto its side or onto its lid when full. Acceptable closure devices include, but are not confined to, magnetic or mechanical catches. It shall not be possible for the catch to open accidentally once engaged. Mechanical catches shall be recessed so that they are fully protected against damage during transport and storage. Catches shall be maintenance-free, without need for lubrication and shall be secured to the container in a manner which prevents loosening due to vibration.

#### 4.2.8 Carrying Device

The body of the container shall be fitted with one or more of the following carrying devices arranged so that the vaccine carrier can be comfortably carried in a substantially upright position.

**4.2.8.1 Carrying handle**

A hinged, sliding or molded-in handle attached to, or forming an integral part of, the container body or lid. When folded away, moveable handles shall not extend beyond the maximum length, width or height of the container. The handle arrangement shall not prevent stable stacking of the boxes.

**4.2.8.2 Shoulder strap**

An adjustable strap arrangement, which allows the vaccine carrier to be carried over the shoulder.

**4.2.8.3 Backpack**

An adjustable padded strap arrangement which allows the vaccine carrier to be carried as a backpack. All carrying devices must be robustly constructed and firmly attached in order to survive rough handling.

**4.2.9 Vial Holder (Optional)**

The vial holders, if offered, must be located immediately below the lid and above the vaccine storage compartment. It should be designed to hold a maximum of five opened vaccine vials for use during immunization sessions when the lid of the vaccine carrier is open. The vial holder must fully close off the vaccine storage compartment so that there is minimal loss of cold life. Design solutions may include, but are not limited to, the following.

**4.2.9.1** Soft foam plastic pad, molded to receive vaccine vials. The indentations shall be designed so that vials are held from below and cannot be pushed through the pad.

**4.2.9.2** Molded plastic tray with indentations to receive vials.

**4.2.9.3** Molded plastic tray as previously described, but forming a separately hinged inner lid to the vaccine carrier. The vial holder shall be able to hold vials, with capacities ranging from one to fifty doses, in a stable position and without risk of overturning the vial.

**4.2.10 Vaccine Storage Advice**

Vaccine carriers shall carry factory-fitted non-removable labels designed to last the lifetime of the equipment. Labels should be in the language most appropriate to the country of use (that is, English, or other language, by special order) and should carry the following information:

- a) On the outside of the lid, and/or on the front face of the vaccine carrier as specified in [Annex A](#); and

- b) On the inside of the lid as specified in [Annex B](#).

**4.2.11 Stacking**

The design of the base and lid of rigid containers should include molded features that allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container shall be designed to withstand repeated dragging across hard rough floor surfaces.

**4.2.12 Corrosion Resistance**

All metallic components and their fixings must be constructed in stainless steel or a suitable non-ferrous metal.

**4.2.13 Chemical Resistance**

The external and internal surfaces of the container must be resistant to chemicals used for disinfecting (for example, sodium hypo chlorate, 5.25 percent in water).

**4.2.14 Ingress Protection Rating**

Protection of the container with lid closed and latched shall comply with the specifications provided in IS/IEC 60529.

**4.2.15 Robustness**

The container shall withstand a one meter drop on to each face, edge, and corner at its rated fully-loaded weight. At the end of the test there shall be no damage that affects the performance of the product and the lid shall still be closed and latched properly.

**4.3 Environmental Requirements****4.3.1 Ambient Temperature Range**

The ambient temperature range during transport, storage and use of the vaccine carrier should be from  $-30\text{ }^{\circ}\text{C}$  to  $+55\text{ }^{\circ}\text{C}$ .

**4.3.2 Humidity Range**

The ambient humidity range during transport, storage and use of the vaccine carrier boxes should be from 5 percent to 95 percent RH.

**4.4 Physical Characteristics**

**4.4.1** The overall dimensions shall confirm as per [4.5.1](#) to [4.5.3](#).

**4.4.2** The weight of the container must not exceed the following specifications:

- a) *Short Range* — Maximum loaded weight, inclusive of the recommended number of water filled packs is 7.0 kg.; and
- b) *Long Range* — Maximum loaded weight, inclusive of the recommended number of water filled water-packs is 8.0 kg.

## 4.5 Interface Requirements

### 4.5.1 Dimensional Compatibility with Packs

The internal dimensions of the container shall be compatible with any of the three standard types of water-pack. However, it is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these three types.

### 4.5.2 Dimensional Compatibility with Vaccine Packaging

Vaccine carriers are generally used to transport vaccine in individual vials. The net dimensions of the storage compartment (length, breadth and height, with water-packs in place) should accommodate all types of pre-filled vaccine presentation and the complete range of standard vaccine vials and ampoules up to 50 dose size.

### 4.5.3 Dimensional Compatibility with Distribution Vehicles

Vaccine carriers shall be designed so that they can easily be strapped, upright, to the luggage rack of a bicycle or light motorcycle.

## 4.6 Human Factors

### 4.6.1 General

The product shall be designed in accordance with the general usability principles laid out in ISO 20282-1.

### 4.6.2 Portability

All vaccine carriers shall be designed so that they can comfortably be carried, when fully loaded, for periods of several hours by a male or female health worker wearing traditional dress. Backpack units may be incompatible with some types of clothing.

## 4.7 Material

### 4.7.1 Casing Material Selection

Internal and external casing materials and all joints

between the molded components must be water and vapor proof, must resist UV degradation, shall be easy to clean and must be selected with environmentally safe end-of life disposal in mind. Chlorinated plastics and composites containing epoxy resins are not permitted.

### 4.7.2 Thermal Insulation Foaming Agents

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals. Cyclopentane and similar foaming agents with a low global warming potential (GWP) are preferred:

- a) Insulation material CFC-free polyurethane; and
- b) Insulation thickness 23 mm to 105 mm.

## 5 TEST METHODS

Two samples of the product are required, together with empty water-packs, conforming to IS 17589. The quantity of water-packs supplied shall equal the number recommended by the container manufacturer plus sufficient additional water packs to provide spares in the event of leakage or other eventuality. The serial number for the testing equipment and instruments should be listed in the test report along with the calibration status of the equipment and instruments used in testing.


### 5.1 Robustness Test (to be Done with Sample 1)

#### 5.1.1 Test Conditions


- a) Test chamber shall be at + 18.0 °C to + 24.0 °C and ambient humidity. Record conditions at time of test;
- b) Line the perimeter of the container with filled water-packs in accordance with the container manufacturer's instructions. Fully fill the central void with a non-breakable dummy load 2 and suitable soft packaging arranged to prevent the load from shifting during the test [5.1.1\(d\)](#) drop test. The total weight of the water-pack lining and the dummy load when added to the weight of the empty box must equal the maximum loaded weight established in test [5.2\(h\)](#);  
NOTE — Water-packs, gel-packs or sand bags may be used as a dummy load.
- c) Mark the faces, edges and corners of the container with the test numbers as given in [Table 1](#);
- d) Using a free fall drop tester, drop the container 26 times from a height of one

- meter (measured from the lowest part of the container at the start of each test) onto a smooth dense concrete floor in the exact order set out in the following table. Cancel the relevant test number marking after each drop so as to avoid inadvertent duplication.
- e) Stop the test after the 26<sup>th</sup> drop or when part of the load falls out, whichever is the sooner. If the load falls out prematurely due to failure of the hinges and/or catches, re-secure the lid and continue the test.
- f) After each drop note any damage that has occurred. Assess the overall damage at the end of the test as given in [Table 2](#).

**Table 1 Faces, Edges and Corners for the Drop Test**[Clause [5.1.1\(c\)](#)]

SI No.	Face	Edges	Corners
(1)	(2)	(3)	(4)
i)	1 Top	7 Front top	19 Front top left
ii)	2 Bottom	8 Back top	20 Front top right
iii)	3 Front	9 Left side top	21 Back top left
iv)	4 Back	10 Right side top	22 Back top right
v)	5 Left side	11 Front bottom	23 Front bottom left
vi)	6 Right side	12 Back bottom	24 Front bottom right
vii)	13 Left side bottom		25 Back bottom left
viii)	14 Right side bottom		26 Back bottom right
ix)	15 Front left side		
x)	16 Front right side		
xi)	17 Back left side		
xii)	18 Back right side		

**Table 2 Rating Description for Damage to Casing and Fitting**[Clause [5.1.1\(f\)](#)]

SI No.	Rating	Damage to Casing	Rating	Damage to Fittings
(1)	(2)	(3)	(4)	(5)
i)	1	Heavy damage or lid pulled off	1	Hinges and/or catches and/or handles broken
ii)	2	Easily repairable damage	2	Hinges and/or catches become undone and/or handles distorted
iii)	3	Superficial damage	3	Hinges, catches and handles function correctly
iv)	4	Slightly marked		
v)	5	Unmarked		

**5.1.2 Acceptance Criteria**

Minimum acceptable ratings are: casing 2, fittings 2. Results to be reported.

**5.1.3 Rejection Criteria**

Failure to achieve rating 2 or above for either or both of the casing and fittings tests.

**5.2 Test for Dimensions, Weights and Vaccine Storage Capacity****5.2.1 Test Conditions**

**5.2.1.1** Test chamber between + 18.0 °C and + 24.0 °C at ambient humidity. Record conditions at the time of the test.

**5.2.1.2** Record maximum external dimensions in centimeters (length, width and height, with handle folded, (± 0.5 cm).

**5.2.1.3** Record minimum internal dimensions in centimeters, without water-packs [length, width and height, (± 0.5 cm)].

**5.2.1.4** Record the empty weight of the container, without water-packs, in kilograms (± 0.1 kg).

**5.2.1.5** Take the number of water-packs designated by the container manufacturer. The total volume of water in the set of water-packs must equal the following formula:

$$[(\text{water-pack manufacturer's rated water volume}) \times (\text{designated no. of water packs})] (\pm 2.0 \text{ percent})$$

**5.2.1.6** Fill each water-pack in the set with the equal volumes of tap water, stabilize data temperature of + 20.0 °C (± 2.0 °C). Record the total volume of water used and the total weight of the filled water-packs.

- a) Fully freeze the set of water-packs at –20.0 °C (± 2.0 °C). Line the container with the ice-packs in accordance with the manufacturer's instructions. Record the

minimum rectangular dimensions of the vaccine storage compartment measured between straight edges placed over the bulging internal faces of the water-packs (length, width and height, (± 0.5 cm). This is the vaccine storage capacity; and

- b) Weigh the vaccine carrier, in kg, with the ice-packs in place. Multiply the vaccine storage capacity, measured in liters by 0.55 kg. Add this figure to the measured empty weight. Record the total weight in kilograms (± 0.1 kg) as the maximum loaded weight.

**5.2.2 Acceptance Criteria**

The container shall conform to the volumetric ranges and weight limits set out in the [Table 3](#).

**5.2.3 Rejection Criteria**

Maximum empty weight or maximum loaded weight outside designated ranges. Vaccine storage capacity below the minimum designated volume. If the vaccine storage capacity exceeds the designated maximum, but empty and loaded weights remain within the designated upper limits, the container can be accepted.

**5.3 Cold Life Test (to be Carried Out with Sample 2)****5.3.1 Test Conditions**

**5.3.1.1** Test chamber at + 43.0 °C (± 0.5 °C).

**5.3.1.2** Stabilize the container in the + 43 °C test chamber for a minimum of 24 h, with the lid open.

**5.3.1.3** Assemble a dummy vaccine load comprising partially filled water filled 10 ml × 5 ml dose glass vaccine vials with a combined density of 0.4 kg per liter of the measured vaccine storage capacity. The vials should be arranged so that they substantially fill the vaccine storage compartment. Condition the load in a refrigerator at + 5.0 °C (± 0.5 °C).

**Table 3 Volumetric Range and Weight Limits**

(Clause [5.2.2](#))

SI No.	Type	Vaccine Storage Capacity	Maximum Loaded Weight
		(litre)	(kg)
(1)	(2)	(3)	(4)
i)	Short range	0.5 litre to 5.0 litre	7.0 kg
ii)	Long range	1.0 litre to 5.0 litre	8.0 kg



**5.3.1.4** Fully freeze the set of water-packs described in [5.2](#), step [5.2.1.6](#) at  $-20.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ). Line the container with the ice-packs in accordance with the manufacturer's instructions. Place the conditioned vials in the vaccine storage compartment together with the [Annex D](#) temperature sensors laid out as shown in the [Annex C](#) diagram. Close the lid of the vaccine carrier.

**5.3.1.5** Monitor temperatures at one min intervals until the temperature of the warmest point in the vaccine load first reaches  $+10.0\text{ }^{\circ}\text{C}$ . Record the temperature of the coldest point in the load at this time. The cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches  $+10\text{ }^{\circ}\text{C}$ .

### **5.3.2 Acceptance Criterion**

The cold-life must be a minimum of 15 h for short range containers and a minimum of 30 h for long range containers.

### **5.3.3 Rejection Criterion**

Failure to achieve the minimum cold life.

## **5.4 Cool Life Test (Optional)**

### **5.4.1 Test Conditions**

**5.4.1.1** Test chamber at  $+43.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ).

**5.4.1.2** Stabilize the container in the  $+43\text{ }^{\circ}\text{C}$  test chamber for a minimum of 24 h, with the lid open.

**5.4.1.3** Reuse the dummy vaccine load described in test [5.3](#), step [5.3.1.3](#). Condition the load in a refrigerator at  $+5.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ).

**5.4.1.4** Stabilize the set of water-packs described in test [5.2](#), step [5.2.1.5](#) at  $+5.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ). Line the container with the cool-packs in accordance with the manufacturer's instructions. Place the conditioned vials in the vaccine storage compartment together with the [Annex D](#) temperature sensors laid out as shown in the [Annex C](#) diagram. Close the lid of the vaccine carrier.

**5.4.1.5** Monitor temperatures at 1 min intervals until the temperature of the warmest point in the vaccine load first reaches  $+20.0\text{ }^{\circ}\text{C}$ . Record the temperature of the coldest point in the load at this time. The cool-life is defined as the time interval from the moment when the lid is closed until the temperature of the warmest point first reaches  $+20.0\text{ }^{\circ}\text{C}$ .

### **5.4.2 Acceptance Criterion**

There is no standard criterion for the acceptance. However, the results of the test may be reported as agreed between the manufacturer and user.

## **5.5 Warm Life Test (Optional)**

### **5.5.1 Test Conditions**

**5.5.1.1** Test chamber at  $-20.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ) and  $+18.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ).

**5.5.1.2** Stabilize the container in the  $+18\text{ }^{\circ}\text{C}$  test chamber for a minimum of 24 h, with the lid open.

**5.5.1.3** Reuse the dummy vaccine load as described in test [5.3](#), step [5.3.1.3](#). Condition the load in a refrigerator at  $+5.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ).

**5.5.1.4** Stabilize the set of water-packs described in test [5.2](#), step [5.2.1.5](#) at  $+18.0\text{ }^{\circ}\text{C}$  ( $\pm 0.5\text{ }^{\circ}\text{C}$ ). Line the container with the warm-packs in accordance with the manufacturer's instructions. Place the conditioned vials in the vaccine storage compartment together with the [Annex D](#) temperature sensors laid out as shown in the [Annex C](#) diagram. Close the lid of the vaccine carrier.

**5.5.1.5** Place the loaded vaccine carrier in the  $-20\text{ }^{\circ}\text{C}$  test chamber.

**5.5.1.6** Monitor temperatures at 1 min intervals until the temperature of the coldest point in the vaccine load first reaches  $0\text{ }^{\circ}\text{C}$ . Record the temperature of the warmest point in the load at this time. The warm-life is defined as the time interval from the moment when the lid is closed until the temperature of the coldest point first reaches  $0.0\text{ }^{\circ}\text{C}$ .

### **5.5.2 Acceptance Criterion**

There is no standard criterion for the acceptance. However, the results of the test may be reported as agreed between manufacturer and user.

## **5.6 Ingress Protection Rating Test to IS/IEC 60529**

### **5.6.1 Test Conditions**

**5.6.1.1** Use sample 2, if IP test is required.

**5.6.1.2** Obtain an independent test report from the manufacturer showing full conformity with IS/IEC 60529. Only if this is not available.

**5.6.1.3** Carry out an IP 55 test on a single sample. Record results.

**5.6.2 Acceptance Criterion**

IP 55 test passed.

**5.6.3 Rejection Criterion**

IP 55 test failed.

**5.7 Lining Integrity Test (to be Done with Sample 2 After Completing All Other Tests)**

**5.7.1 Test Conditions**

**5.7.1.1** Fill the vaccine carrier with water to the top of the lining. Leave for two hours.

**5.7.1.2** Empty the vaccine carrier and thoroughly dry the interior with tissue paper and/or warm air without applying pressure to the inner lining.

**5.7.1.3** Apply firm hand pressure to the inner lining. Check for evidence of moisture extruded through pinholes in the lining.

**5.7.1.4** Cut the sample in half laterally and vertically, including the lid. Cut one of the two halves at 45 degrees and vertically through the bottom corner of the container and through the corner of the lid.

**5.7.1.5** Examine the construction closely. Photograph and record the following:

**5.7.1.5.1** The presence of voids in the insulated core.

**5.7.1.5.2** Evidence of moisture penetration through the inner lining.

**5.7.1.5.3** Measure the thickness of the inner and outer casing at key points, including flat areas and corners ( $\pm 0.1$  mm). Note any weak points in the moldings and sudden changes of thickness.

**5.7.2 Acceptance Criteria**

No evidence of water penetration through the inner lining. No significant voids in insulated core. No weak points in the moldings.

**5.7.3 Rejection Criteria**

Water penetration through inner lining. Insulation

voids or molding weaknesses that adversely affect thermal performance or long-term robustness.

**6 ACCOMPANYING DOCUMENTS**

The accompanying documents shall include the following:

- a) Instructions for use; and
- b) Instructions for maintenance, cleaning and disinfection.

**7 PACKING, MARKING AND LABELLING**

**7.1** Materials used for packaging the finished product are to be free of ozone depleting compounds as defined in the Montreal protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

**7.2** The following shall be clearly and permanently marked on the container:

- a) The manufacturer's name or trade-mark;
- b) Shall be marked with the Indian Standard applicable;
- c) The model (or commercial designation);
- d) Serial number; and
- e) Date of manufacture.

**8 DISPOSAL AND RECYCLING**

The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/ recycling and/or environmentally safe disposal.

**9 BIS CERTIFICATION MARKING**

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

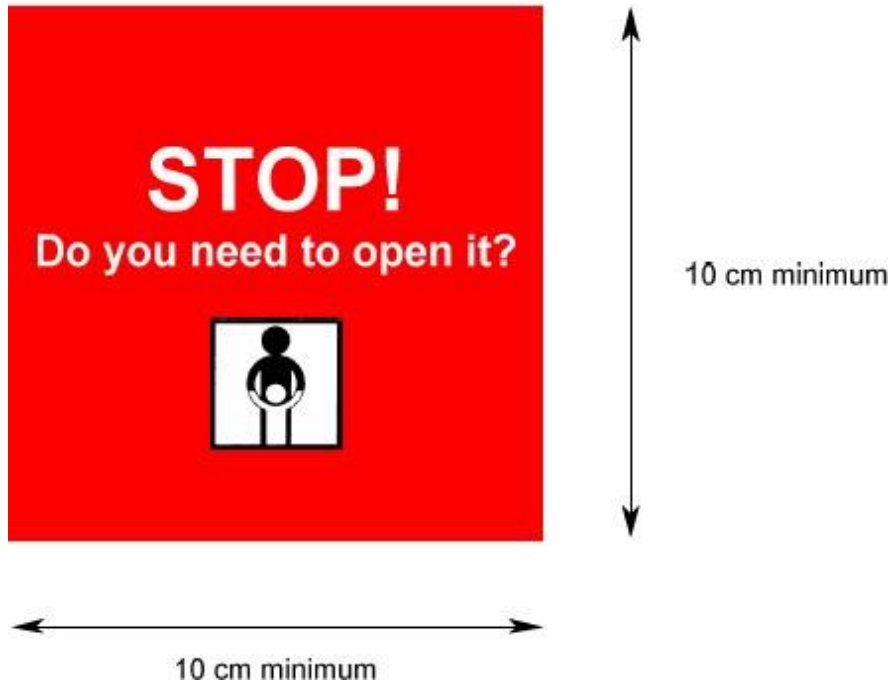
ANNEX A

[Clause 4.2.10(a)]

**LABEL ON OUTSIDE OF THE LID, AND/OR FRONT FACE OF VACCINE CARRIER**

White lettering on red ground.

Black and white EPI logo 

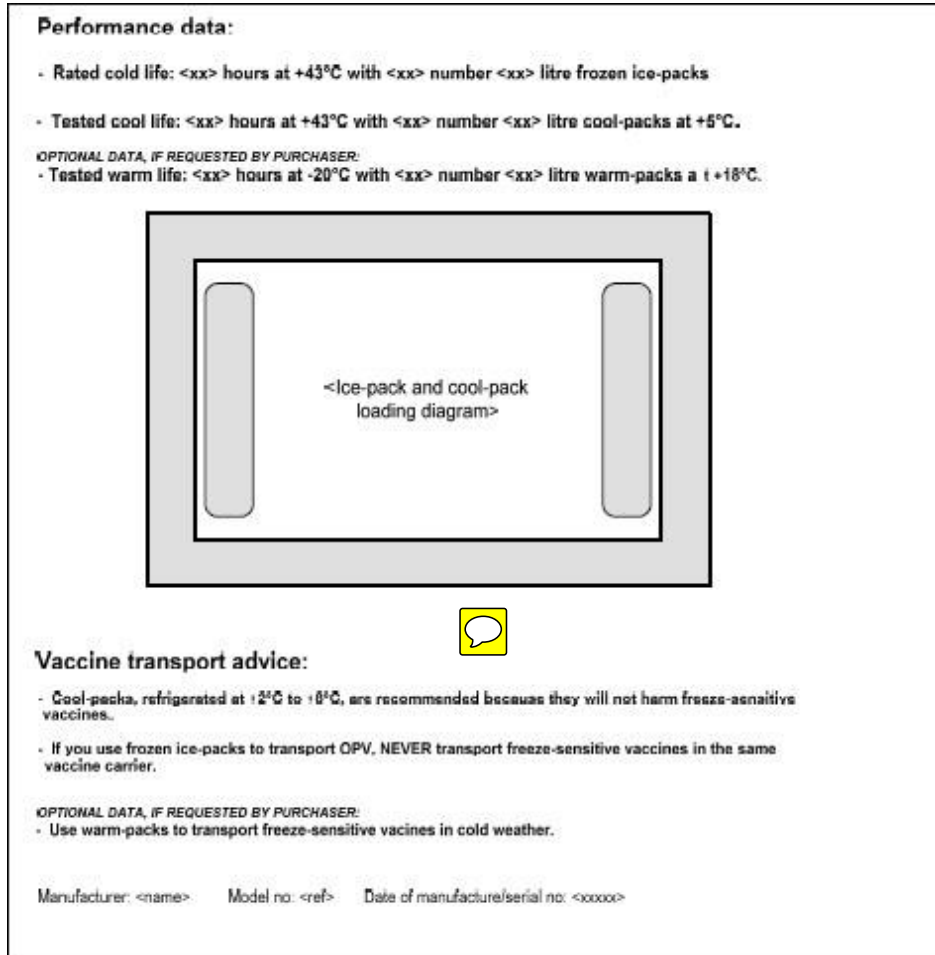


**FIG. 1 LABEL** ON OUTSIDE OF THE LID, AND/OR FRONT FACE OF VACCINE CARRIER

ANNEX B

[Clause 4.2.10(b)]

LABEL ON INSIDE OF LID



NOTES

1 The layout of the label must suit the shape of lid in order to ensure maximum legibility.

2 Language: As required.

3 Optionally, the manufacturer's name, model number and date of manufacture/serial number may be permanently fixed elsewhere on the container instead of inside the lid.

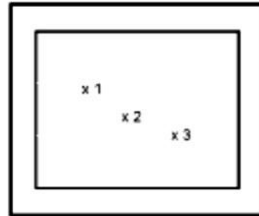
FIG. 2 LABEL ON INSIDE OF THE LID

## ANNEX C

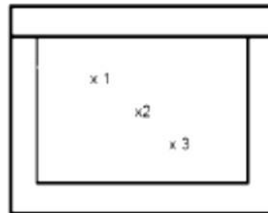
[Clauses [5.3.1.4](#), [5.4.1.4](#) and [5.5.1.4](#)]

## TEMPERATURE SENSOR POSITIONS

## VACCINE CARRIER: TOP VIEW



## VACCINE CARRIER: SIDE VIEW



## NOTES

1 All measuring points, with the exception of the center one, must be 25 mm to 30 mm from the nearest icepack. Ensure that this is achieved using suitable fixing devices attached to the dummy vials. Ensure that the vials cannot rotate, or otherwise become displaced once the sensors are in place.

2 Sensor leads can be introduced into the container using one of two methods:

- a) Through the lid seal, taking care not to affect the quality of the seal; and
- b) Through a hole in the geometric center of the lid, taking care to seal the outer and inner openings adequately.

**FIG. 3 POSITION** OF THE TEMPERATURE SENSORS

## ANNEX D

(Clauses [5.3.1.4](#), [5.4.1.4](#) and [5.5.1.4](#))

## TEMPERATURE SENSOR SPECIFICATION

**Complying** with IS 17550 (Part 1). A standard temperature sensor probe, accurate to  $\pm 0.5$  °C, inserted into brass or tin covered copper mass of 25 g  $\pm$  5 percent and of minimum external area (diameter = height = about 15.2 mm).

## ANNEX E

*(Foreword)*

## COMMITTEE COMPOSITION

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

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