

**BUREAU OF INDIAN STANDARDS**

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भारतीय मानक मसौदा

वैक्सीन वाहकों के लिए विशिष्टताएँ - सामान्य आवश्यकताएँ और परीक्षण विधियाँ

*Draft Indian Standard*

**Specification For Vaccine Carriers — General Requirements and Test Methods**

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Hospital Equipment and Surgical Disposable  
Products Sectional Committee, MHD 12

Last date for comments: 15 January 2024

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FOREWORD

*(Formal clauses will be added later)*

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

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*).

## 1 SCOPE

1.1 This Indian 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 REFERENCE

The standards listed 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 editions of the standards indicated below:

<i>IS. No/Other Publication</i>	<i>Title</i>
IS/IEC 60529 : 2001	Degrees of protection provided by enclosures (IP code)
ISO 20282-1 : 2006	Ease of operation of everyday products — Part 1 : Context of use and user characteristics
IEC 62552-1 : 2015	Household refrigerating appliances — Characteristics and test methods — Part 1 : General requirements
IS 17589 : 2021	Specification for water packs for use as ice-packs, cool-packs and warm-packs — Requirements and test methods

## 3 TERMS AND DEFINITIONS

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

**3.1 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.

**3.2 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.

**3.3 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.

**3.4 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.

**3.5 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.

**3.6 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.

**3.7 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 oralpolio vaccine (OPV), and used conditioned ice pack for



the transport of all other vaccines specified temperature range between + 2 °C to + 8 °C.

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

**3.9 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.

**3.10 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.

**3.11 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.

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

**3.13 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.

## 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 to 5.0 liters; and
- b) Long range: 1.0 to 5.0 liter.

#### 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 hypochlorite, 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 : IP 55.

#### **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 conform 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.
- 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 : 2006.

##### **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 23-105 mm.

## 5 TEST METHODS

Two samples of the product are required, together with empty water-packs, conforming to “IS 17588:2021 Specification for water packs for use as ice-packs, cool-packs and warm-packs — Requirements and test methods” Standard. The quantity of water-packs supplied shall equal the number recommended by the container manufacturer plus sufficient additional waterpacks to provide spares in the event of leakage or other eventuality. The S/No fall 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.

**Table 1 Faces, Edges and Corners for the Drop Test**

[ Clause 5.1.1, (c) ]

Face	Edges	Corners
1 Top	7 Front top	19 Front top left
2 Bottom	8 Back top	20 Front top right
3 Front	9 Left side top	21 Back top left
4 Back	10 Right side top	22 Back top right
5 Left side	11 Front bottom	23 Front bottom left
6 Right side	12 Back bottom	24 Front bottom right
13 Left side bottom		25 Back bottom left
14 Right side bottom		26 Back bottom right
15 Front left side		
16 Front right side		
17 Back left side		
18 Back right side		

- 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 2 Rating description for damage to casing and fitting**

[ Clause 5.1.1 (f) ]

<b>Rating</b>	<b>Damage to Casing</b>	<b>Rating</b>	<b>Damage to Fittings</b>
1	Heavy damage or lid pulled off	1	Hinges and/or catches and/or handles broken
2	Easily repairable damage	2	Hinges and/or catches become undone and/or handles distorted.
3	Superficial damage	3	Hinges, catches and handles function correctly.
4	Slightly marked		
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

5.2.2 Test Conditions

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

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

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

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

5.2.2.5 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:

**[(water-pack manufacturer’s rated water volume) x (designated no. of water packs)] (± 2.0 percent)**

5.2.2.6 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.

g) 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.

h) 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.

**Table 3 Volumetric Range and Weight Limits**

( Clause 5.2.2 )

**Type Vaccine Storage Capacity (L) Maximum Loaded Weight (kg)**

Short range 0.5 to 5.0 liter 7.0 kg

Long range 1.0 to 5.0 liter 8.0 kg

### 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)

### 5.3.2 Test Conditions

5.3.2.1 Test chamber at + 43.0 °C ( $\pm 0.5$  °C).

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

5.3.2.3 Assemble a dummy vaccine load comprising partially filled water filled  $10 \times 5$  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 ( $\pm 0.5$  °C).

5.3.2.4 Fully freeze the set of water-packs described in 5.2, Step 5.2.6 at – 20.0 °C ( $\pm 0.5$  °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.

5.3.2.5 Monitor temperatures at one minute intervals until the temperature of the warmest point in the vaccine load first reaches + 10.0 °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 °C.

### 5.3.3 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.

### 5.3.4 Rejection Criterion

Failure to achieve the minimum cold life.

## 5.4 Cool life Test (Optional)

### 5.4.2 Test Conditions

5.4.2.1 Test chamber at + 43.0 °C ( $\pm 0.5$  °C).

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

5.4.2.3 Reuse the dummy vaccine load described in Test 5.3, Step 5.3.3. Condition the load in a refrigerator at + 5.0 °C ( $\pm 0.5$  °C).

5.4.2.4 Stabilize the set of water-packs described in Test 5.2, Step 5.2.5 at + 5.0 °C ( $\pm 0.5$  °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.

- 5.4.2.5 Monitor temperatures at one minute intervals until the temperature of the warmest point in the vaccine load first reaches + 20.0 °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 °C.

#### 5.4.3 *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)**

#### 5.5.2 *Test Conditions*

- 5.5.2.1 Test chamber at –20.0 °C (± 0.5 °C) and + 18.0 °C (± 0.5 °C).
- 5.5.2.2 Stabilize the container in the + 18 °C test chamber for a minimum of 24 h, with the lid open.
- 5.5.2.3 Reuse the dummy vaccine load as described in Test 5.3, Step 5.3.3. Condition the load in a refrigerator at + 5.0 °C (± 0.5 °C).
- 5.5.2.4 Stabilize the set of water-packs described in Test 5.2, Step 5.2.5 at + 18.0 °C (± 0.5 °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.
- 5.5.2.5 Place the loaded vaccine carrier in the –20 °C test chamber.
- 5.5.2.6 Monitor temperatures at one minute intervals until the temperature of the coldest point in the vaccine load first reaches 0 °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 °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**

#### 5.6.2 *Test Conditions*

- 5.6.2.1 Use sample 2, if IP test is required;
- 5.6.2.2 Obtain an independent test report from the manufacturer showing full conformity with IS/IEC 60529 : IP 55. Only if this is not available; and
- 5.6.2.3 Carry out an IP 55 test on a single sample. Record results.

#### 5.6.3 *Acceptance Criterion*

IP 55 test passed.

#### 5.6.4 *Rejection Criterion*

IP 55 test failed.

**5.7 Lining Integrity Test (To be done with Sample2 after Completing all other Tests)**

*5.7.2 Test Conditions*

- 5.7.2.1 Fill the vaccine carrier with water to the top of the lining. Leave for two hours.
- 5.7.2.2 Empty the vaccine carrier and thoroughly dry the interior with tissue paper and/or warm air without applying pressure to the inner lining.
- 5.7.2.3 Apply firm hand pressure to the inner lining. Check for evidence of moisture extruded through pinholes in the lining.
- 5.7.2.4 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.
- 5.7.2.5 Examine the construction closely. Photograph and record the following:

- 5.7.2.5.1 The presence of voids in the insulated core.
- 5.7.2.5.2 Evidence of moisture penetration through the inner lining.
- 5.7.2.5.3 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.

#### 5.7.3 *Acceptance Criteria*

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

#### 5.7.4 *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; or
- 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 product(s) 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

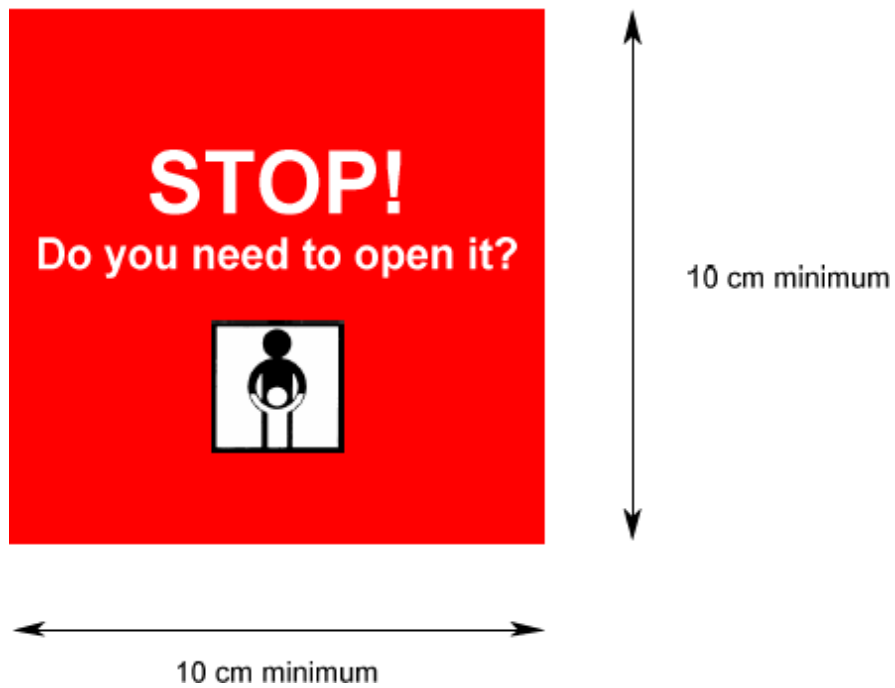


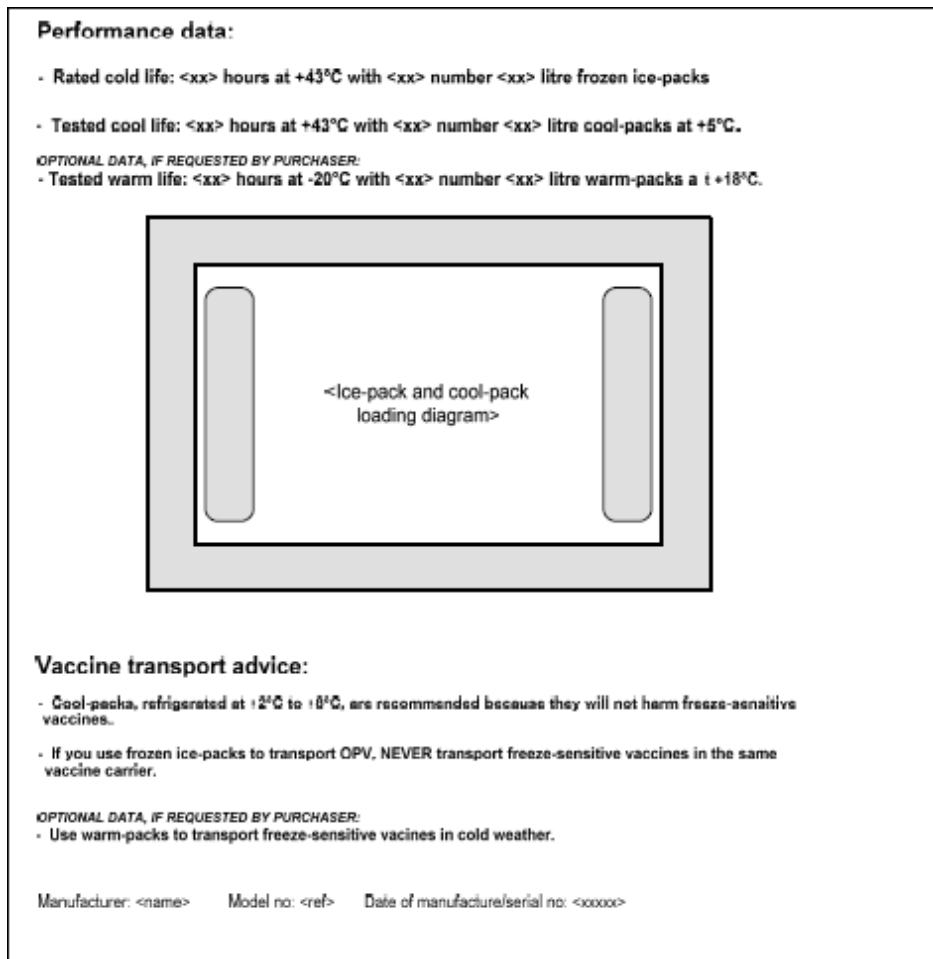
FIG. 1 LABEL ON OUTSIDE OF THE LID, AND/OR  
FRONT FACE OF VACCINE CARRIER



## ANNEX B

[ Clause 4.2.10, (b) ]

### LABEL ON INSIDE OF LID



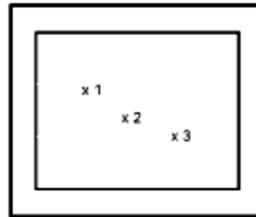
#### NOTES

- 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**  
**[ Clause 5.3.1, (d) ]**  
**TEMPERATURE SENSOR POSITIONS**

**Vaccine carrier: topview**



**Vaccine carrier: sideview**

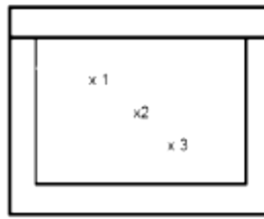


FIG. 3 POSITION OF THE TEMPERATURE SENSORS

**NOTES**

- 1** All measuring points, with the exception of the center one, must be 25-30 mm from the nearest ice-pack. 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.
  - b) Through a hole in the geometric center of the lid, taking care to seal the outer and inner openings adequately.

## **ANNEX D**

[ *Clause 5.3.1, (d)* ]

### **TEMPERATURE SENSOR SPECIFICATION**

Complying with IS/IEC 62552, **8.7.1**. A standard temperature sensor probe, accurate to  $\pm 0.5$  °C, inserted into brass or tin-covered copper mass of  $25 \text{ g} \pm 5$  percent and of minimum external area (diameter = height = about 15.2 mm).