

Product Code 17

A. Specific requirements

Product Code 17 consists of Injection Kanamycin (500 mg.) vial, Sterile Water for Injection ampoule and Disposable Syringe alongwith Disposable needle. The individual items contained in the product shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The individual items contained in the product shall also be currently registered in India and shall meet all the requirements of the licensing authority in India.

Kanamycin Injection:

Description:

Kanamycin Injection contains Kanamycin Acid Sulphate.

Each vial shall contain -

Kanamycin Acid Sulphate IP equivalent to Kanamycin 500 mg.

Inj. Kanamycin shall conform to the general requirements of parenteral preparations and the requirements under Kanamycin Injection given in IP.

The injection is constituted by dissolving the contents of the sealed container in the requisite amount of Sterile Water for Injections, immediately before use. The constituted solution shall comply with the requirements for clarity of solution and particulate matter stated under parenteral preparations (Injections) in IP.

The quality of Kanamycin Acid Sulphate and Sterile Water for Injection should conform to the requirements of IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Storage:


Streptomycin Injection should be stored in a cool and dry place. The reconstituted solution should be used immediately after preparation but, in any case, within the period recommended by the manufacturer.

Shelf-life:

Shelf life of the Kanamycin Acid Sulphate would be 24 months. At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package.


Labelling:

Vials:- The label on each vial shall conform to the requirements of I.P. All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the quantity of Kanamycin Acid Sulphate contained in the sealed container in terms of the equivalent amount of Kanamycin, the name of the manufacturer, manufacturing license number, address of manufacturer, Batch Number, Date of Manufacture and Expiry Date. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

INJECTION KANAMYCIN IP (500 mg.) Product Code - 17		
	SCHEDULE H DRUG	
	RNTCP CENTRAL GOVERNMENT SUPPLY NOT FOR SALE	
Each vial contains : Kanamycin Acid Sulphate IP equivalent to Kanamycin base 500 mg Add 3 ml or more Water for Injection IP for reconstitution. The reconstituted solution should be used immediately Store in a cool, dry place.		
SHAKE WELL BEFORE USE. Dosage: As prescribed by the physician. FOR INTRAMUSCULAR USE ONLY.	Manufactured by:	Mfg. Lic. No.: Batch No.: Mfg. Date: Expiry Date:

Labelling for Millboard/Greyboard boxes:

A label must be affixed either on the top and/or front surface of the Millboard/Greyboard Box. It should indicate the quantity of Kanamycin Acid Sulphate contained in the sealed container in terms of the equivalent amount of Kanamycin, the number of vials, the name of the manufacturer, batch number, date of manufacture, date of expiry and storage conditions. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act. The labels on the Millboard / Greyboard Box should be readable from a distance. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

MDR-TB TREATMENT DRUG INJECTION KANAMYCIN IP (500 mg.) X 80 vials (Product Code – 17)		
Box containing 80 vials of Injection Kanamycin (500mg) Store in a cool and dry place.		
<div style="border: 1px solid black; padding: 5px; display: inline-block;">SCHEDULE H DRUG</div>		
<div style="border: 1px solid black; padding: 5px; display: inline-block; color: red;">RNTCP CENTRAL GOVERNMENT SUPPLY NOT FOR SALE</div>		
SHAKE WELL BEFORE USE. Dosage: As prescribed by the physician. FOR INTRAMUSCULAR USE ONLY.	Manufactured by:	Mfg. Lic. No.: Batch No.: Mfg. Date: Expiry Date:

Quality Assurance;**Compliance:**

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) have been manufactured as per WHO GMP requirements.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package

The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of vials, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effects be also made available to the purchaser.

Packing:**Injection Kanamycin (500 mg.) vial**

IP Type 1 plain glass vial provided with compatible elastomer closure and crimp- on aluminium seal and plastic overcap.

Millboard/Greyboard Box:

The vials should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes for easy handling, transport and distribution. Each box shall contain 80 Inj. Kanamycin (500 mg) vials. It shall be fabricated from at least 3 mm corrugated card board, surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of box shall be Top and bottom tuck-in-flip type.

Sterile Water for Injections:

Description:

A clear, colourless solution; odourless, free from added substances.

Each ampoule shall contain 05 ml of Sterile Water for Injection.

Sterile water for Injection shall conform to the general requirements of parenteral preparations and the requirements under Sterile water for Injection given in IP.

The quality of Sterile Water for Injection should conform to the requirements of IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Storage:

Store in a single dose container in a cool, dry place.

Shelf-life:

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The shelf life should not be less than shelf life of Inj. Kanamycin. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package.

Labelling:

Ampoule:-The label on each ampoule shall conform to the requirements of I.P.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, batch number, date of manufacture and expiry date.

STERILE WATER FOR INJECTION IP

Product Code – 17

Each ampoule contains :
Sterile Water for Injections IP 05 ml
Store in a cool, dry place.

RNTCP
CENTRAL GOVERNMENT SUPPLY
NOT FOR SALE




Manufactured by:
Mfg. Lic. No.:

Batch No.:
Mfg. Date:
Expiry Date:

Labelling for Millboard/Greyboard Boxes:

A label must be affixed either on the top and/or front surface of the box. It should indicate the number of vials, the name of the manufacturer, batch number, date of manufacture, date of expiry, and storage conditions. The labels on the Millboard / Greyboard Box and 5 – Ply shipper should be readable from a distance. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

STERILE WATER FOR INJECTION IP X 80 Product Code – 17	
Box containing 80 ampoules Each ampoule containing Sterile Water for Injections 05 ml Store in a cool & dry place	<div style="border: 1px solid black; padding: 5px; text-align: center;">RNTCP CENTRAL GOVERNMENT SUPPLY NOT FOR SALE</div>
Manufactured by: Mfg. Lic. No.:	<div style="text-align: center;"></div> <div>Batch No.: Mfg. Date: Expiry Date:</div>

Quality Assurance:**Compliance:**

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) have been manufactured as per WHO-GMP requirements.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of ampoules, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

Packing:**Water for Injection Ampoule:**

IP Type 1 clear plain glass ampoules or PE ampoule based on BFS technology. Each ampoule shall contain 05 ml of sterile water for injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Millboard/Greyboard label box:

The ampoules should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes for easy handling, transport and distribution. Each box shall contain 80 ampoules. It shall be fabricated from at least 3 mm corrugated card board, surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of box shall be Top and bottom tuck-in-flip type.

Disposable Syringe and Disposable Needle:**Description (Disposable Syringe):**

Disposable Syringes are Sterile Hypodermic Syringes for Single Use and are fabricated from virgin plastic. They shall conform to the standards given in IS 10258:2002. These are medical device intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The plastics and elastomer materials (**polypropylene and polyethylene**) of which the barrel and piston are made comply with the relevant specifications issued by BIS. The Syringes comply with the following standards regarding dimensions including dead volume:-

Capacity of the Syringe ml	Tolerance eq. or ex. to cap.	Tolerance < half of cap.	Max. Dead Vol. ml	Length Of long Graduation Mark, mm	Minimum overall length of scale, mm	Scale Interval MI	Increment. Between Graduation lines ml
05	+_4% of expelled vol	+_1.5% nominal Cap, +1% of expelled vol	0.075	8	36	0.50	1

Polydimethylsiloxane (Silicone Oil) is applied to the internal walls of the barrel to assist in the smooth operation of the syringe but no excess be ensured capable of contaminating the contents at the time of use.

Description (Disposable Needle):

Sterile Hypodermic Needle for Single Use comprises of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. The other end of the tube is sharpened at the tip as per IS requirements. They shall conform to the standards given in IS 10654:2002. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The Hypodermic needles shall comply with the following standards regarding Dimensions:-

Needle Gauge	Colour of the hub	Nominal Length of the tube mm	Tolerance In length mm	Nominal outside diameter Of needle Mm	Diameter of stylet for normal walled tubing Mm
22	Black	25	+ 1, -2	0.7	0.30

Storage:

Disposable Syringes and Disposable Needles should be stored in a clean, cool, dry and adequately ventilated place.

Shelf-life:

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The shelf life should not be less than shelf life of Inj. Kanamycin. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package.

Labelling:

The label on the packing of disposable syringe and needle each shall conform to the requirements of I.P.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Drugs & Cosmetics Act 1940 and Rules thereunder, following information should be available:-

- A description of the syringe including the capacity
- A description of the Needle including the Gauge and the nominal length
- The word 'Sterile'
- The syringe/needle is for single use only
- A solvent incompatibility
- The batch number
- Name and address of the manufacturer
- Date of Manufacture and Date of Expiry
- Warning that the syringe is not to be used if the packaging is damaged or sterility protector is loose
- CE marking
- ISO symbol for "do not re-use"

STERILE HYPODERMIC SYRINGE 5 ml. FOR SINGLE USE	
Product Code – 17	<div style="border: 1px solid black; padding: 5px; text-align: center;">RNTCP CENTRAL GOVERNMENT SUPPLY NOT FOR SALE</div>
For single use only. Store in a cool, dry place.	
	Manufactured by:
	Mfg. Lic. No.: Batch No.: Mfg. Date: Expiry Date:

STERILE HYPODERMIC NEEDLE FOR SINGLE USE
22 gauge

Product Code – 17

Store in a cool, dry place.
For single use only

RNTCP
CENTRAL GOVERNMENT SUPPLY
NOT FOR SALE



Manufactured by:


Mfg. Lic. No.:
Batch No.:
Mfg. Date:
Expiry Date:

Millboard/Greyboard Box containing Sterile Hypodermic Syringes and Needles (80 each)

A label must be affixed either on the top and/or front surface of the secondary package. It should indicate:

- A description of the syringe including the capacity and the type of nozzle/ A description of the needle including the gauge and the nominal length
- Quantity of primary packages of Syringes and Needles
- The word 'Sterile'
- That the syringe/needle are for single use only
- The batch number
- The date (month and year) of sterilization
- Name and address of the manufacturer
- Date of Manufacture and Date of Expiry
- Information for handling, storage and transportation
- The labels on the Millboard / Greyboard Box should be readable from a distance.

- The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

STERILE HYPODERMIC SYRINGES & HYPODERMIC NEEDLES FOR SINGLE USE X 80 each		
Product Code – 17		
Box containing 80 Sterile Hypodermic Syringes 5 ml and 80 Hypodermic Needles 22 gauge		
	<div style="border: 1px solid black; padding: 5px; text-align: center;"> RNTCP CENTRAL GOVERNMENT SUPPLY NOT FOR SALE </div>	
Store in a cool, dry place.		
	Manufactured by:	Mfg. Lic. No.:
	Master Batch No.	Batch No.:
		Mfg. Date:
		Expiry Date:

Quality Assurance:

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) have been manufactured as per WHO-GMP requirements and (f) should conform to ISO 13485.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a documentary evidence that the sterilization of the syringes has been carried out by validated sterilization procedures (with appropriate controls and recording devices) in case it has been carried out in their premises. If the facilities of other institution is used for sterilization, the approval of the licensing authority and documentary evidence for validated sterilization procedure should be made available.

The supplier shall provide a documentary evidence that the inks, glues and adhesives for the marking on the package and on the assembly of the syringe and its package (Wherever necessary) do not migrate across the walls.

The supplier shall provide documentary evidence in regards to bio-compatibility of the device as per the requirements given in "Biological Evaluation of Medical Devices" IS 12572.

The supplier shall provide a certificate of analysis of Polydimethylsiloxane (used for lubrication) conforming to the requirements of IP.

The supplier shall provide a copy of CE certificate.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The Supplier shall retain a sample of fifty syringes from each lot shipped for two years beyond the printed expiration date.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of syringes/needles, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

Packing:

Syringe & Needle

Each syringe and needle shall be packed and sealed separately in primary containers. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure:

- a) The maintenance of sterility under dry, clean and adequately ventilated storage conditions;
- b) The minimum risk of contamination of the contents during opening of the container and removal of the contents;
- c) Adequate protection of the contents during normal handling, transit and storage;
- d) That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.

Paper-PVC Blister:

- PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns.
- Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm

Millboard/Greyboard Box:

The primary package should be packed in Millboard/Greyboard box for easy handling, transport and distribution. Each box shall contain 80 syringes and 80 needles. It shall be fabricated from at least 3 mm corrugated card board, surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of box shall be Top and bottom tuck-in-flip type.

B. Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

C. Testing:

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

D. Labelling on 5 Ply Shipper:

The external surface of insulated packages should be either white or in the natural color of corrugated carton. The labels on 5 Ply Shipper must be affixed at least on two sides of the shipper. The label should include the name of the product, the quantity of Millboard Boxes of Injection Kanamycin; Sterile water for Injections and Disposable Syringes plus Disposable Needles, the name of the manufacturer, Master batch number, date of manufacture, date of expiry and storage handling instructions. The label on 5-Ply Shipper should be at least of A-4 paper size with date of manufacture, date of expiry, batch no. etc. mentioned in font size 18 so as to be readable from a distance. Details of samples lifted for testing (such as quantity of vials/ampoules/syringes/needles, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

MDR-TREATMENT DRUG Product Code 17

10 Millboard / Greyboard Boxes each of Injection Kanamycin (500mg), 10 Millboard / Greyboard Boxes of Sterile Water for Injection(5ml) and 10 Millboard / Greyboard Boxes of Disposable Syringes(5ml) & Disposable Needles (22 gauge size)

SCHEDULE H DRUG

RNTCP
CENTRAL GOVERNMENT SUPPLY
NOT FOR SALE



Store in a cool, dry place.

SHAKE WELL BEFORE USE.

Dosage: As prescribed by the physician.

FOR INTRAMUSCULAR USE ONLY.

Manufactured by:

Mfg. Lic. No.:

Inj. Kanamycin, Water for Injections, Syringe and Needle

Batch No.:

Mfg. Date:

Expiry Date:

Master Batch No.

Expiry Date:

Numbering of shipper packaging:

All 5 Ply shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

E. Packing for 5 Ply Shipper:

Each shipper contains 10 Millboard/Greyboard Boxes of Inj. Kanamycin (500 mg.), 10 Millboard/Greyboard Boxes of sterile water for Injection and 10 Millboard/Greyboard Boxes of Disposable syringes (5 ml) & Disposable needles (22 gauge). The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimensions of the carton should be such that its contents do not get damaged during transportation and storage.

F. Shelf Life of the Product Code 17

The expiry date of the 5 Ply Shipper of Product Code 17 shall be the same as that of its constituent with the shortest shelf life.

G. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. In case of drugs, the manufacturing facility must conform to WHO-GMP standards for the product quoted by them. In case of Medical devices, the manufacturing facility must conform to the standards given in ISO 13485 and WHO pre qualified.

H. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

I. Colour Coding:

The labels on vials, Millboard/Greyboard Boxes and 5 ply shipper packages shall be identified by WHITE background.

J. Bar Coding:

Bar code shall be used for better inventory management. It shall be printed on the labels of Millboard/Greyboard Boxes and 5 Ply Shippers containing

- 1) Product identification(GTIN 14) using application identifier (01)
- 2) Expiry Date in YYMMDD format & using application identifier (17)
- 3) Batch number using application identifier (10)

The labels on the Millboard/Greyboard Boxes should contain information about point nos. 1, 2 & 3 above whereas the labels on the 5 Ply-Shippers should contain information about point nos. 1, 2 above & Master Batch No., numbered consecutively using application identifier (21).

Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

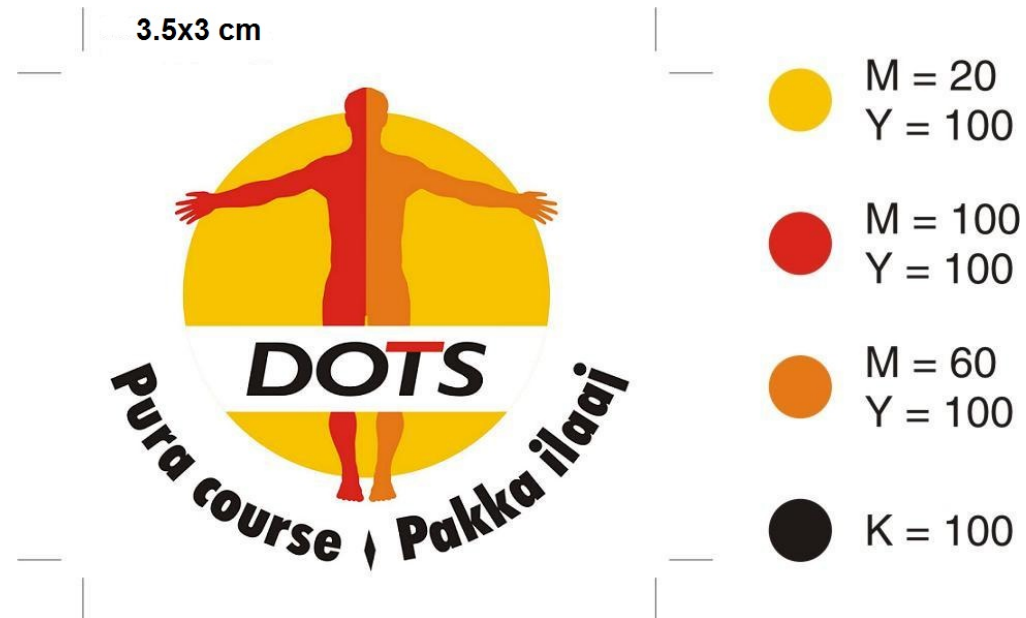
- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX



5 – Ply Shipper

