

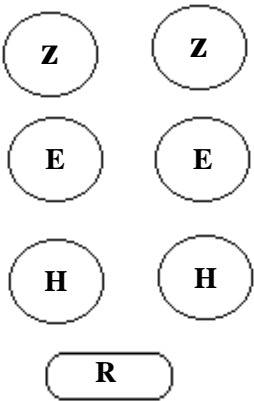
Product Code 4


A. Specific requirements

Item:

Product Code 4 (PC4) consists of combipacks of Schedule 1 (for prolongation of Intensive Phase) in laminated pouches. The drugs 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 drugs contained in the product shall also be currently registered in India and shall meet all the requirements of the licensing authority in India.

Serial no.		Schedule 1								
01	Description:	<p>Schedule 1 is a multi blister combipack consisting of 01 capsule of Rifampicin; 02 tablets of Isoniazid; 02 tablets of Ethambutol Hydrochloride and 02 tablets of Pyrazinamide. The individual component of the combipack shall conform to the general requirements of Capsules (if in capsule form) and Tablets (if in tablet form) and the requirements under individual monograph given in IP.</p> <p>Rifampicin Capsules contain Rifampicin and each capsule shall contain –</p> <table><tr><td>Rifampicin IP</td><td>450 mg</td></tr></table> <p>Isoniazid Tablets contain Isoniazid and each tablet shall contain -</p> <table><tr><td>Isoniazid IP</td><td>300 mg</td></tr></table> <p>Ethambutol Tablets contain Ethambutol Hydrochloride and each tablet shall contain –</p> <table><tr><td>Ethambutol Hydrochloride IP</td><td>600 mg</td></tr></table> <p>Pyrazinamide Tablets contain Pyrazinamide and each tablet shall contain –</p> <table><tr><td>Pyrazinamide IP</td><td>750 mg</td></tr></table> <p>The qualities of Rifampicin, Isoniazid, Ethambutol Hydrochloride and Pyrazinamide should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.</p>	Rifampicin IP	450 mg	Isoniazid IP	300 mg	Ethambutol Hydrochloride IP	600 mg	Pyrazinamide IP	750 mg
Rifampicin IP	450 mg									
Isoniazid IP	300 mg									
Ethambutol Hydrochloride IP	600 mg									
Pyrazinamide IP	750 mg									
02	Protocol Testing and	<p><u>For International manufacturers:</u> Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.</p> <p><u>For local manufacturers:</u> Complete Test Protocol and samples are taken and sent to the Testing Laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.</p>								

		<p>Protocols of tests should include the requirements given for Capsules or Tablets as the case may be and those included under individual monograph given in IP, besides the following tests</p> <p>Package Integrity Test: Check 10 strips (combipacks). Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration</p> <p>Microbial Count: When the test is conducted as per IP -Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram -Absence of Escherichia coli</p> <p>The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.</p> <p>Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.</p>
03	Labelling (Strip of blisters)	<p>The label for each pharmaceutical product shall meet the WHO GMP standards. The label RED in color on each combipack shall identify each individual drug as follows:</p> <div style="text-align: center;">  </div> <p>“RNTCP Central Government Supply NOT FOR SALE”</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin-top: 10px;"> <p>SCHEDULE H DRUGS</p> </div> <p>The label shall indicate the content of Rifampicin IP in each capsule identified as ‘R’; content of Isoniazid IP in each</p>

		<p>tablet identified as ‘H’; content of Ethambutol Hydrochloride IP in each tablet identified as ‘E’; and content of Pyrazinamide IP in each tablet identified as ‘Z’.</p> <p>All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the individual drug and storage requirements alongwith a common (Master) Batch no. with its Date of Expiry (DOE).</p> <p>The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.</p>
04	Labelling for Laminated Pouches	<p>The individual drug of the same batch should form part of the combipack and the pouch in the schedule.</p> <p style="text-align: center;">ANTI TB DRUGS</p> <p style="text-align: center;">PRODUCT CODE - 4</p> <p style="text-align: center;">12 Blister Combipacks of one dose each Intensive Phase (Schedule I)</p> <p style="text-align: center;">Z E H R</p> <p>Batch Nos: Mfg Date: Expiry Date</p> <p style="text-align: center;">“RNTCP Central Government Supply NOT FOR SALE”</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: fit-content;">SCHEDULE H DRUGS</div> <p style="text-align: right;">  </p> <p>The label shall indicate the content of Rifampicin IP in each capsule identified as ‘R’; content of Isoniazid IP in each tablet identified as ‘H’; content of Ethambutol Hydrochloride IP in each tablet identified as ‘E’; and content of Pyrazinamide IP in each tablet identified as ‘Z’.</p> <p>The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the individual drug and storage requirements along with the number of the combipacks alongwith a common (Master) Batch no. with its Date of Expiry (DOE).</p> <p>The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.</p>
05	Quality Assurance - Compliance	<p>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) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials, and (f) have been pre-qualified by WHO.</p>
06	Quality Assurance	<p>The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of</p>

	- Evidence	<p>this document for which no specific inspection has been mentioned.</p> <p>The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.</p> <p>The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.</p> <p>The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.</p> <p>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.</p> <p>The Supplier shall provide evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.</p> <p>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.</p> <p>Details of samples lifted for testing (such as quantity of Millboard/greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.</p>
07	Inspection	<p>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.</p> <p>The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.</p>
08	Testing	<p>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.</p>
09	Primary Packaging (Combipack):	<p>A combipack consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all packaging material. Colour coded BCP's.</p> <p>Aluminium-PVC Blister:</p> <p>PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200 microns, PE coating: 25 microns, PVdC coating: 60gsm.</p> <p>Aluminium foil: Hard tempered Blister foil, VMCH coated RED coloured. Thickness: 0.025mm.</p> <p>Strip size: Schedule – 1 Approx. 80 mm X 62 mm +_ 10%</p> <p>Spacing between tablets should be enough so as to allow removal by patients with finger deformities.</p> <p style="text-align: center;">Complex Constructions with PVC Films*</p>

		<div>TECHNICAL DATA FOR THE STANDARD COMPLEXES</div> <div><div><div>Complex:</div><div><div>Rigid PVC film gauge (microns)200</div><div>PE coating (microns)25</div><div>PVdC coating (gsm)60</div><div>Total weight (gsm)356</div><div>Complex gauge (mm)0.280</div></div><div><div>Water Vapour Transmission Rate (W V T R):</div><table><tr><th>Temperature</th><th>Relative Humidity</th><th>gsm/24h</th><th colspan="2">Vapour Transmission rate</th></tr><tr><th></th><th></th><th></th><th>Thermoformed</th><th>Not thermoformed</th></tr><tr><th>(°C)</th><th>% RH</th><th></th><th></th><th></th></tr><tr><td>20</td><td>85</td><td>gsm/24 h</td><td>0.15</td><td>0.06</td></tr><tr><td>38</td><td>90</td><td>gsm/24 h</td><td>0.7</td><td>0.4</td></tr></table></div><div><div>Shrinkage longitudinally</div><div>T = 140°C, t = 20 min. (%) 5 – 6</div><div>Application temperature (°C)68 – 74</div><div>* Complex Constructions with PVC Films</div></div></div></div>				Temperature	Relative Humidity	gsm/24h	Vapour Transmission rate					Thermoformed	Not thermoformed	(°C)	% RH				20	85	gsm/24 h	0.15	0.06	38	90	gsm/24 h	0.7	0.4																											
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10	Laminated Pouches	Separate for each Schedule. 12 blister combipacks (strips) should be packed in laminated pouches duly Gusseted and																																																							

	in WHITE colour. These are fabricated from Glassine paper (40 gm)/ Aluminium (9 mcm)/ PVC (150 gauge).
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Storage:

Store protected from light and moisture at room temperature.

Shelf-life:

Shelf life of various Drugs would be as follows :-

- **Rifampicin:** 36 months
- **INH (Isoniazid):** 60 months
- **Ethambutol hydrochloride:** 60 months
- **Pyrazinamide:** 60 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 (combipack). Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions at 30⁰ C and 65% r.h. (relative humidity).

The expiry date of the combipack shall be the same as that of Rifampicin Capsules being the constituent of combipack with the shortest shelf life.

B. Labelling:**Requirements applicable to all Labels :**

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **RNTCP Central Government Supply – NOT FOR SALE** to be imprinted on the strips, Pouches, Mill board / Grey Board and 5-Ply Shipper.
- RNTCP TB logo to be imprinted on the laminated Pouch, Millboard/Greyboard Box and 5-Ply Shipper
- The labels on the laminated pouches, Millboard/Greyboard and 5 – Ply Shipper should be readable from a distance. The label of 5 – Ply Shipper should be of at least A-4 paper size with date of manufacture, date of Expiry, batch no. etc; of the individual component as well as Master Batch no. and Date of Expiry of the Boxes to be mentioned in bold Arial font size 18 so as to be readable from a distance.

Labeling for Millboard/ Grey board Box:




<p>PRODUCT CODE 4 ANTI-TB DRUG REGIMEN POUCH CONTAINS DRUGS FOR PROLONGATION OF INTENSIVE PHASE OF CATEGORY I & II PATIENTS</p>
<p>5 pouches each containing 12 Blisters of one dose Combipacks of Rifampicin (R), INH (H), Ethambutol (E) & Pyrazinamide (Z)</p> <p style="text-align: center;">Z E H R</p> <p>Batch Nos: Mfg. Date: Exp. Date:</p>
<p style="text-align: center;">SCHEDULE H DRUGS “RNTCP Central Government Supply NOT FOR SALE”</p> <p>Manufacturer's Name Manufacturing Lic. No. Master Batch No. Expiry Date</p>



The labels on Millboard/Grey board Box must be attached to at least two sides and **WHITE** in colour. The label should include the name of the product, the number of pouches of Schedule 1, the name of the manufacturer, batch number/Mfg. date/Expiry date of the individual drug within the schedule. The label shall also include storage instruction as well as the Master Batch No. of the Box along with Date of Expiry of Box. 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.

Labeling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER	
ANTI-TB DRUGS PRODUCT CODE - 4	
20 Millboard/Greyboard Boxes	
Z E H R	
	Batch Nos:
	Mfg. Date:
	Exp. Date:
	SCHEDULE H DRUGS
	“RNTCP Central Government Supply
NOT FOR SALE”	
Manufacturer’s Name	
Manufacturing Lic. No.	
Master Batch No.	
Expiry Date	

The labels on shipper package must be attached to at least two sides and **White** in colour. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the name of the manufacturer, Master batch number/Mfg. date/Expiry date of the individual drug within the schedules. The label shall also include storage/handling instructions as well as the Master Batch No. of the Boxes along with Date of Expiry of Boxes. 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.

Numbering of shipper packaging:

All 5 Ply Shippers boxes should be numbered consecutively. Shipping documents should be included in the Shipper numbered first (consignee wise).

C. 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. The manufacturing facility must conform to WHO-GMP standards.

D. 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.

E. Colour Coding:

The labels on laminated pouches, Millboard/Greyboard Box and 5 Ply Shipper shall be identified by **WHITE** background.

F. Bar Coding

Bar code shall be used for better inventory management. It shall be printed on the label of Millboard/Grey board Boxes and 5 – Ply shipper containing

- 1) Product identification(GTIN 14) using application identifier (01)
- 2) Expiry Date in YYMMDD format & using application identifier (17)
- 3) Master 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 & 3 above and also be 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

G. Packing

The drugs are initially packed in Blister Combipacks and 12 such blisters thereafter would be packed in laminated pouches for prolongation of Intensive phase. 5 such pouches would be further packed in white coloured Millboard/Grey board boxes. 20 such Boxes would be ultimately packed in 5-Ply Shipper. Laminated Pouch, Millboard/Greyboard Box & 5- Ply Shipper should contain drugs of the same batch number. No case should contain drugs from more than one batch.

Mill board/ Grey board Box:

Each box shall contain five individual laminated pouches separately of Schedule 1. The boxes shall be labeled in **WHITE** and fabricated from atleast 3 mm corrugated white cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom tuck-in-flap type. The dimensions of the box shall be 22 ± 1 cm (Length) x 17 ± 1 cm (Breadth) x 11 ± 1 cm (Height)

Self adhesive patient label should also be present on the Millboard Box.

5 – Ply Shipper Package:

Each shipper shall contain 20 millboard/greyboard boxes labeled in **WHITE**. 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.

Each shipping carton when packed should weigh not more than 50 kg.

H. Markings

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

Millboard/Grey board Box:

The Boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Manufacturer's name and registered address.
- Manufacturer's License number.
- Batch number of individual drugs.
- Master Batch number and Date of Expiry of Box.
- Number of pouches contained in the box.
- Date of manufacture (month and year) of individual drugs.
- Expiration date (month and year) of individual drugs.
- Instructions for storage and handling.
- Logo of DOTS.
- Place of manufacture (Made in_____)

5 – Ply Shipper:

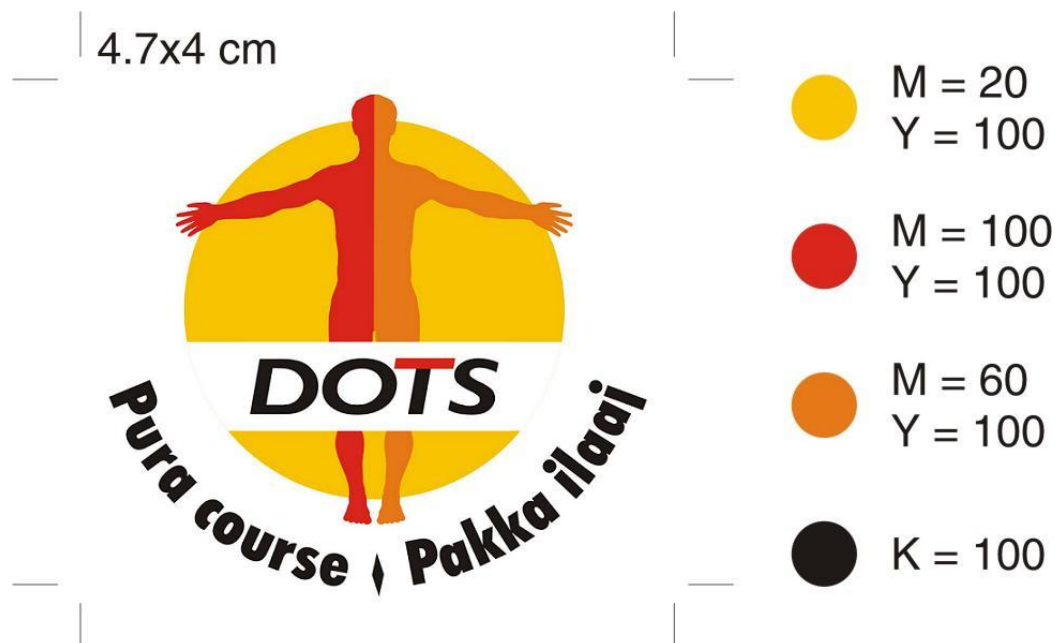
The following information shall be stenciled or labeled on the 5 – Ply Shipper on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product.
- Batch number of the individual drugs.
- Master Batch number and Date of Expiry of Box
- Date of manufacture of the individual drugs (month and year).
- Expiration date of the individual drugs as well as that of the product (month and year).
- Manufacturer's name and registered address.
- Manufacturer's national registration number.
- Logo of DOTS.
- Destination country license or registration number.
- Consignee's address and emergency phone number including mobile number.
- Destination airport (if any).
- Contract number.
- Number of boxes contained in the carton (5 Ply Shipper).
- Gross weight of each carton (in kg).
- Instructions for storage and handling.
- Place of manufacture (Made in_____).

I. Documentation

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

Laminated Pouch



MILLBOARD/GREYBOARD BOX



5 – Ply Shipper

