

Product Code DSTB- IP (Adult Patients)

A. Specific requirements

Item:

Product Code **DSTB-IP(A)** (Drug Sensitive Anti Tuberculosis Drugs for Intensive Phase-Adult Patients) consists of 24 blister packs of Schedule 13 for Intensive Phase. The drugs contained in the product shall have valid registration 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 have valid registration in India and shall meet all the requirements of the licensing authority in India.

Serial no.	Description	
01	Item : Schedule 13	<p>Schedule 13 is a blister pack of 28 tablets, each tablet consisting of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in fixed dose combination (HRZE–Fixed Dose Combination).</p> <p>The FDCs in blister pack shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</p> <p>Each FDC tablet shall contain -</p> <p>Isoniazid *Selected Pharmacopeia (IP/ BP/USP/Other International <u>pharmacopeia</u> 75 mg</p> <p>Rifampicin *Selected Pharmacopeia (IP/ BP/USP/Other International <u>pharmacopeia</u> 150 mg</p> <p>Pyrazinamide *Selected Pharmacopeia (IP/ BP/USP/Other International <u>pharmacopeia</u> 400 mg</p> <p>Ethambutol Hydrochloride *Selected Pharmacopeia (IP/ BP/USP/Other <u>International pharmacopeia</u> 275 mg</p> <p>The quality of Isoniazid, Rifampicin, Ethambutol Hydrochloride and Pyrazinamide shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</p>

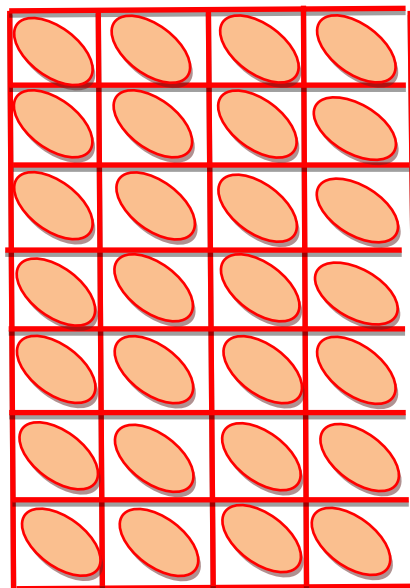
*Only one of the selected pharmacopeia to be indicated.

02	Protocol Testing and	<p><u>For manufacturer outside India:</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 Indian manufacturer:</u> Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative. 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 I IP or any other International Pharmacopoeia, 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. Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.</p>
----	----------------------	--

03

Blister pack design
and Labelling
(blisters)

Design & alignment of the tablets should be strictly as per figure given below.



The label shall indicate the content of Isoniazid identified as 'H'; content of Rifampicin identified as 'R'; content of Ethambutol Hydrochloride identified as 'E'; and content of Pyrazinamide identified as 'Z' in each tablet.

All labeling 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 drugs, Schedule H1 drug warning and storage requirements.

Information pertaining to date of manufacturing, date of expiry & batch no. of a blister should be imprinted on atleast 2 edges of the blister. Remaining requisite information i.e. manufacturing license no., Schedule H1 drug warning and storage requirements etc. may be printed once on reverse side of the blister. All the requisite information printed on blisters should be displayed clearly & prominently.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made there under and as amended from time to time.

Each blister strip will contain 28 tablets of HRZE –Fixed Dosed Combination, in the packaging designed and aligned as given above.

05	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) 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) the product has been manufactured as per WHO GMP requirements.
06	Quality Assurance - Evidence	<p>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.</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 at the time of bid submission.</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	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.
09	Primary Packaging (Blister):	<p>A blister consisting of 28 tablets 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 shall be according to ISO 9001 for all packaging material.</p> <p>Aluminium-PVC Blister: PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm. Aluminium foil: Hard tempered Blister foil, VMCH coated Red coloured, Thickness: 0.025mm.</p>

Blister Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips.

[illegible]

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Temperature	Relative Humidity	gsm/24h
-------------	-------------------	---------

Temperature (°C)	Relative Humidity % RH	gsm/24h	Vapour Transmission rate	
			Thermoformed	Not thermoformed
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

T = 140°C, t = 20 min. (%)	5 – 6
Application temperature (°C)	68 – 74

A. Storage & Shelf-life

Storage: Store protected from light and moisture at room temperature.

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 supplier will provide manufacturer's test data substantiating the claimed shelf life in the proposed package (blister pack). 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 as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

Shelf life would be as follows: -

- **Rifampicin:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Isoniazid:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Ethambutol hydrochloride:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Pyrazinamide:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Shelf-life** of the drugs in Fixed Dose Combination should not be less than Minimum 24 months from the date of manufacturing.



B. Labelling:

Requirements applicable to all Labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- NTEP Central Government Supply – NOT FOR SALE to be imprinted on the blister strips, Mill board / Grey Board and 5-Ply Shipper.
- NTEP TB logo to be imprinted on the Millboard/Greyboard Box and 5-Ply Shipper

The labels on the 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., to be mentioned in bold Arial font size 18 so as to be readable from a distance. It should be seen clearly by naked eyes.

Labeling for Millboard/ Grey board Box:

National Tuberculosis Elimination Programme (NTEP) ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (A) DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE (Adult Patients)		
	24 Blister packs for Intensive Phase (Schedule 13) H E R Z Batch Nos: Mfg. Date: Exp. Date:	
<div style="border: 1px solid red; padding: 5px; margin: 10px auto; width: 80%;"><p>SCHEDULE H1 PRESCRIPTION DRUG – CAUTION It is dangerous to take this preparation except in accordance with the medical advice. Not to be sold by retail without the prescription of a Registered Medical Practitioner.</p></div> <p style="text-align: center; color: red;">“NTEP Central Government Supply NOT FOR SALE”</p> <p>Manufacturer's Name Manufacturing Lic. No.</p>		

The labels on Millboard/Grey board Box must be attached to at least two sides and shall be **red** in colour. The label should include the name of the product, name of the manufacturer, batch number/Mfg. date/Expiry date of the drug. The label shall also include storage instruction. 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 / Hand held device (Tablet computer / Smartphone).

Labeling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER		
	<div>National Tuberculosis Elimination Programme (NTEP) ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (A) DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE (Adult Patients) 20 Millboard/Greyboard Boxes H E R Z Batch Nos: Mfg. Date: Exp. Date: <div>SCHEDULE H1 PRESCRIPTION DRUG – CAUTION It is dangerous to take this preparation except in accordance with the medical advice. Not to be sold by retail without the prescription of a Registered Medical Practitioner.</div> “NTEP Central Government Supply NOT FOR SALE” Manufacturer’s Name Manufacturing Lic. No.</div>	

The labels on shipper package must be attached to at least two sides and shall be **Red** in colour. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the name of the manufacturer, batch number/Mfg. date/Expiry date of the drug within the schedule. The label shall also include storage/handling instructions as well as the 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 / Hand held device (Tablet computer / Smartphone).

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 Millboard/Greyboard Box and 5 Ply Shipper shall be identified as indicated below:-

Drug Name	Blister	Millboard (Label)	5 – PLY SHIPPER (Label)
PC- DSTB- IPA)	Red	Red	Red

B. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

- 1) Product Name/content
- 2) Product Strength
- 3) Batch Number
- 4) Date of Manufacturing
- 5) Date of Expiry
- 6) Manufacturer Address
- 7) Manufacturer License number
- 8) Storage conditions requirement
- 9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

F. Packing

The drug is initially packed in a Blister Strip each containing 28 Tablets. 24 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

G. Mill board/ Grey board Box:

Each box shall contain 24 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of the box shall be top and bottom tuck-in-flap type. The standardized box size of Millboard / Greyboard is to be confirmed by the supplier with programme at the time of approval of art work. Self-adhesive patient label should also be present on the Millboard Box.

H. 5 – Ply Shipper Package:

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

I. 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.
- Date of manufacture (month and year) of drugs.
- Expiration date (month and year) of 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.
- Date of manufacture of the drugs (month and year).
- Expiration date of the drugs (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_____).

J. Documentation

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

K. Dimensions of the logos

MILLBOARD/GREYBOARD BOX



5 – Ply Shipper

