

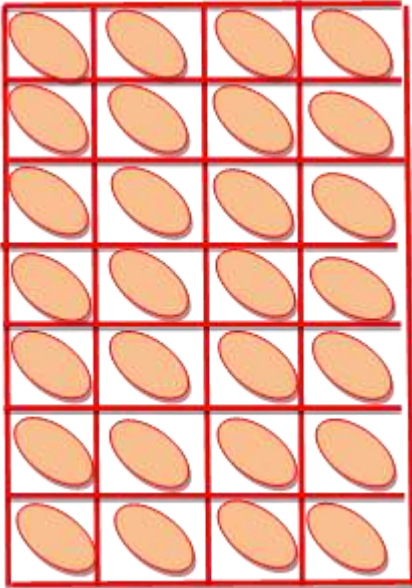
DSTB-IP (Pediatric Patients) / 3 FDC(P)

A. Specific requirements

Item:

Product Code DSTB-IP(P) consist of Drug Sensitive Anti Tuberculosis Drugs for the Pediatric patients and used for Intensive Phase regimen. The Product Code DSTB-IP(P) consists of drugs as per the Schedule 15 . 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.

S no.		Schedule 15
01	Description:	<p>Schedule 15 is a blister/strip pack having 28 dispersible tablets of Fixed Dose combination of Isoniazid, Rifampicin and Pyrazinamide.</p> <p>The drugs in the blister/strip 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 blister pack shall contain the below mentioned drugs in Fixed Dose combination and in the Dispersible form :</p> <p style="padding-left: 40px;">Tab Isoniazid IP 50 mg Tab Rifampicin IP 75 mg Tab Pyrazinamide IP 150mg</p> <p>The quality of Isoniazid, Rifampicin and Pyrazinamide shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</p> <p>Each blister pack should have enough spacing between tablets to allow easier removal by patients with finger deformities and easier separation of individual tablets within the strips.</p>
02	Blister pack design and Labelling (blisters)	<p>Design & alignment of the tablets should be strictly as per figure given below.</p> <p>The label shall indicate the content of Isoniazid IP identified as 'H'; content of Rifampicin IP identified as 'R' and content of Pyrazinamide IP identified as 'Z' in each tablet. Each aluminum foil</p>

		<p>strip shall have 28 dispersible tablets of HRZ–Fixed Dosed Combination in the packaging designed and aligned as given below:</p>  <p>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.</p> <p>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.</p> <p>The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made there under and as amended from time to time.</p>
03	Protocol and Testing	<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 IP, besides the following tests</p> <p>Package Integrity Test: Check 10 strips. 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>
04	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) the product has been manufactured as per WHO GMP requirements.</p>
05	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. 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 shall provide evidence of basis for expiration dating and other stability data</p>

		<u>TECHNICAL DATA FOR THE STANDARD COMPLEXES</u>			
Technical Data for the Standard Complexes	<u>Complex:</u>				
	Rigid PVC film gauge (microns)	200			
	PE coating (microns)	25			
	PVdC coating (gsm)	60			
	Total weight (gsm)	356			
	Complex gauge (mm)	0.280			
	<u>Water Vapour Transmission Rate (W V T R):</u>				
	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	
	<u>Shrinkage longitudinally</u>				
	T = 140°C, t = 20 min. (%)	5 – 6			
	Application temperature (°C)	68 – 74			

A Storage:

Store protected from light and moisture.

B. Shelf life:

- **RIFAMPICIN:** shelf life should be minimum 24 months from the date of manufacture.
- **ISONIAZID:** shelf life should be minimum 24 months from the date of manufacture.
- **PYRAZINAMIDE:** shelf life should be 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.

Stipulated Shelf-life upon arrival at Consignee warehouse:

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. 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

C. 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. 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.
- **“Schedule H1 Drug”** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.


D. Packaging

a) Packaging of Schedule 15 / Millboard/Grey board Box

The drug is initially packed in a Blister / Strip each containing 28 Tablets. Three such strips would be further re-packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper. The labels on Schedule 15 must be attached to atleast two sides. Further, Schedule 15 should be labeled in Orange colour.

The label on each box of Schedule 15 should include the name of the product, storage instructions, flavour used in dispersible formulations, name of the manufacturer, batch number, Mfg. date, Expiry date. 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 Millboard/Grey board Box

<p>National Tuberculosis Elimination Programme (NTEP) ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (P) / 3FDC (P)</p>	
<p>DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE (PEDIATRIC PATIENTS)</p>	
<p>3 x 28 Blister Packs each of Schedule 15 for Intensive Phase</p>	
	<p>H R Z</p>
<p>Batch Nos: Mfg. Date: Exp. Date:</p>	
<div style="border: 1px solid red; padding: 5px;"> <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;">“NTEP Central Government Supply NOT FOR SALE”</p>	
<p>Manufacturer's Name Manufacturing Lic. No.</p>	

b) 5 – Ply Shipper Package:

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

The labels on shipper package must be attached to at least two sides and **Orange** in colour. The label should include the name of the product, number of Millboard/Greyboard Boxes, name of the manufacturer, flavour used in dispersible formulations, storage instruction, batch number, Mfg. date, Expiry date. 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).

Labelling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER



National Tuberculosis Elimination Programme (NTEP)

ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (P) / 3 FDC(P)

DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE
(PEDIATRIC PATIENTS)

20 Millboard/Greyboard Boxes each of Schedule 15 for

H R Z

Batch Nos:

Mfg. Date:

Exp. Date:

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.

**“NTEP Central Government Supply
NOT FOR SALE”**

**Manufacturer's Name
Manufacturing Lic. No.**



c) Markings

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

E. 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

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 Co-blisters contained in the box.
- Date of manufacture (month and year) of individual drugs.
- Flavour used in dispersible formulations
- 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).
- Flavour used in dispersible formulations
- 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_____).

d) Documentation

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

Dimensions of the logos

MILLBOARD/GREYBOARD BOX



5 – Ply Shipper

5.5x4.7 cm



● M = 20
Y = 100

● M = 100
Y = 100

● M = 60
Y = 100

● K = 100