

Guidelines for Storage of 2nd Line Anti-TB Drugs for Revised National TB Control Programme (RNTCP).

(I) State Drug Store

1. Storage Space:-

- i. Requirements of space for various levels of drug stores should be based on the estimated number of MDR TB patients likely to be placed on treatment in the concerned State for whom the maximum quantity of drug stocks are to be maintained at the concerned stocking unit. As per the current guidelines of RNTCP, number of MDR TB patients who are to be placed on 2nd Line treatment are estimated as follows:-
 - i. 3% of new cases of TB.
 - ii. 12-17% of re-treatment cases.
- ii. Based on above, storage space will need to be worked out separately for each State Drug store.

2. Specifications for drug stores:-

- i. The Drug Store should preferably comprise one large room. Where multiple rooms already exist, they should be contiguous or proximate to each other
- ii. Preferably separate space for storage, handling and re-packing into IP/CP Boxes.
- iii. Ceiling to have a height of at least 3 metres.
- iv. A lockable door.
- v. At least one window with grill.
- vi. Proper lighting.
- vii. An even-level, 'pukka' floor.
- viii. Plastered walls and ceiling with whitewash without any kind of seepage in the room.
- ix. In case of a situation where separate room for storing 2nd line drugs is not possible, an attempt to demarcate and enclose a specified area for storing 2nd line drugs should be made within the larger store to ensure required temperature control for 2nd line drugs.
- x. Architects should be consulted for suitable modifications in the existing drug store/construction of a new drug store for the same.
- xi. A signage board with instructions in local language should to be put near the entrance of the store to remind the concerned officials regarding good storage practices.
- xii. Ideally, Vacuum de watered flooring (VDF) should be used for the Drug Stores. However depending on the feasibility, such flooring may be done at the State Drug Store level.
- xiii. In case it is feasible at the State Drug Store level, separate areas should be demarcated for receiving and dispatching the drugs.

3. Shelves, Racks & Storage Arrangements:-

- i. If sufficient space is available on the existing storage shelves in the State Drug Store (SDS), these shelves made of 40 mm. bore medium quality (external diameter - 48.3 mm.) mild steel pipes should continue to be used as per the existing RNTCP guidelines. New shelves, if required, are to be made from pre-fabricated slotted angles ensuring sufficient 'gap' between cartons from the ceiling, floor and walls, facilitating ventilation and the free movement of air.
- ii. Shelves to be positioned so that there is no possibility of seepage into cartons.
- iii. Typically, five rows of shelves to be fabricated, one on top of the other into racks. A single rack to usually be long enough to accommodate three cartons on each shelf. Accordingly, a rack would typically accommodate fifteen cartons.
- iv. In the case of a broad room, there shall be multiple rows of racks, all parallel to one another. There should be sufficient space between parallel blocks of racks and the walls, to facilitate free movement of men and trolleys for the smooth stacking and removal of cartons. In case of a long and narrow room, racks to be positioned such that there is sufficient space between them and the walls.
- v. Drug cartons to rest on shelves and not on each other, to prevent eventual sagging of the cartons in the bottom row.
- vi. Rows & Columns, where drugs are stored should be defined and locations to be assigned a unique identification number.
- vii. In future, if the State Drug Store of a particular state has to handle large volume of drugs and occupies larger space, Isle space (between the two racks across the storeroom) can be of 3 metres. In such situation, material handling equipments shall be required.

4. Stacking Arrangements:-

- i. Name of the Drugs alongwith their expiry dates be indicated on stickers pasted on the face of cartons/ drug boxes and should be written again by hand, in large easily visible characters using a colored, permanent marker pen.
- ii. Insofar as possible, the same drug should be stored at a single location within the store.
- iii. Additionally, drugs of the same expiry should be stored together at the same location.
- i. Recognizing the above rules, drugs expiring earliest should be so stored that they are issued first. For example, in case IP (< than 45 Kgs) boxes are placed on multiple shelves in a single part of the store, boxes expiring earlier should be stored at ground level and fresher boxes (which shall expire later) on elevated shelves. This method of stacking shall ensure that drugs that shall expire first shall automatically be issued first, based on the principle of FEFO (First Expiry First out).
- iv. Expired drugs should be segregated, sealed and stored in a separate part of the store eliminating the possibility of their issue to patients. Expiry dates should be highlighted in these cases.
- v. Bin cards at State Drug Store level be displayed which would provide details of Receipts, Issues, Closing balance (quantity) and expiry dates of drugs.

- vi. Only Na-PAS is slow moving drug and should be stored at higher level shelves. Rest all other 2nd Line Drugs are fast moving, therefore, should be stored on lower level shelves.

5. Control of Humidity and Temperature:-

i. Monitoring of Humidity & Temperature:-

Hydrothermometers are to be installed upto TU drug store levels to monitor humidity and temperature regularly. The record of both these variables should be maintained in charts properly and checked on a daily basis by the concerned Store Incharge. This should be reviewed by STO / Officer in-charge of SDS and necessary corrective measures be taken immediately.

ii. Control of Humidity:- In order to keep humidity levels below the maximum 60% recommended for storage of drugs, following measures may be taken:-

- a. **Ventilation:** Open the windows or air vents of the store to allow air circulation. Ensure all windows have screens / wiremesh to keep out insects and birds and also should have metallic grills / iron bars. Drug Boxes/Cartons should be placed on shelves ensuring that there is sufficient space between shelves and walls of the store room.
- b. **Packaging:** The cartons/drug boxes should not be opened unless necessary.
- c. **Circulation:-** Use fans to circulate fresh air from outside.

iii. Protection from Sunlight:- To protect the drugs from sunlight, following measures may be taken:-

- a. Shade the windows or use curtains if they are in direct sunlight.
- b. Keep products in cartons/drug boxes.
- c. Do not store or pack products in sunlight.
- d. Maintain trees around the premises of the drug store to help provide shade and cooling. Check their condition regularly to prevent any untoward incident.

iv. Control of temperature:- The 2nd Line Anti-TB Drugs should preferably be stored below 25⁰ C. In the area specified for storing 2nd Line Drugs, temperature of about 20⁰ C should be maintained with the help of Air-Conditioners (Tonnage would depend on size of the room).

v. Power Supply:- Regular power supply should be available for Air Conditioning in the State Drug Store. Arrangements for backup power supply should also be made through solar panels / fuel based power generators.

The purpose of information provided in the above sub-paras is to emphasise that the drugs should be stored in cool & dark place for proper efficacy. Experimental data/literature review also reveals that these drugs lose their efficacy beyond 6 months if exposed to stressful storage conditions of 40⁰ ± 2⁰ C temperature and humidity of 75% ± 5 % RH.

6. Packing Instructions:-

- i. Packaging of loose drugs into three monthly Intensive Phase (IP) / Continuation Phase (CP) Boxes should be done under guidance of the STO/Medical Officer/Drug logistics In-charge at the State level.
- ii. Three monthly IP / CP drug Box should have 3 divisions for one monthly boxes/pouches – so as to contain all the drugs required for treatment for one month under IP / CP.
- iii. One monthly pouch of Cap. Cycloserine & Tab. Ethambutol each should be made from plastic bag with zip lock facility in which 1 gm. pouch of silica gel dessicant should be kept. In each IP/CP Box, one pouch of silica gel dessicant of 4 gm. weight should also be kept.
- iv. Durable cardboard boxes with defined thickness, size, material to be used for 3 monthly IP & CP drug boxes. The IP/CP boxes shall be made from weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 4-ply Shippers, each ply having strength of minimum 150gsm. These should be fabricated from virgin quality 'A' grade kraft paper.
- v. Each IP / CP Box should be numbered consecutively at the SDS. The record of the serial no. of the Box should be maintained at the State, District & Sub-district (TU) Drug Stores and it would be of help while tracking a particular IP / CP Box.
- vi. Instructions should be issued to the DOT provider that IP/CP Box should be closed properly everytime after withdrawal of drugs from the Box.
- vii. Label on IP/CP Boxes to clearly mention the following:-
 - i. Item-wise name of drugs with quantity of each drug in the Box.
 - ii. Batch No. & DOE of individual drugs.
 - iii. DOE of IP/CP box – would be the expiry date of the drug having shortest expiry.
 - iv. Date of Issue of the Box from SDS.
 - v. IP/CP Box serial number.
 - vi. Storage instructions on the IP / CP Box in English/ Hindi/ local regional language for ensuring adequate precautions in storage of the drugs, specially at the DOT provider level. Some suggested messages are:-
 - Store in a cool and dark place.
 - Do not expose to direct sunlight.
 - Keep away from children/unauthorized persons.
 - Box to be closed properly everytime after withdrawal of drugs.

7. Quality Assurance of Drugs:-

As per the protocol developed by Central TB Division (CTD), samples of 2nd Line Anti TB Drugs should be picked up on random basis from various levels in the field and sent for testing by an independent drug testing laboratory contracted by CTD to find out any change in the quality of these drugs. This should be done based on communication sent by CTD to the concerned states.

8. Training:-

Training / sensitization programme for staff at all levels (State / District / TU Drug Stores, PHCs, DOT Centres) regarding drug logistics management of 2nd Line Anti TB Drugs under RNTCP to be conducted as per Annual Action Plan by the states.

9. Waste Disposal Guidelines:-

If any drug expires due to reasons beyond control, it should be disposed off as per the procedures laid down in the Rules under Drugs & Cosmetics Act and Bio-medical Waste (Management and Handling) Rules of Govt. of India.

10. Guidelines for Recording, Reporting, Transportation of Drugs and Fire Safety measures remain the same as given in the SOP Manual for State Drug stores for 1st Line Anti TB Drugs and the guidelines of RNTCP.

(II) District Drug Store and (III) Sub District (TU) Drug Store

1. Storage Space:-

- ii. Requirements of space for various levels of drug stores should be based on the estimated number of MDR TB patients likely to be placed on treatment in the concerned District / Sub-district (TU) for whom the maximum quantity of drug stocks are to be maintained at the concerned stocking unit. As per the current guidelines of RNTCP, number of MDR TB patients who are to be placed on 2nd Line treatment are estimated as follows:-
 - i. 3% of new cases of TB.
 - ii. 12-17% of re-treatment cases.
- iii. Based on above, storage space will need to be worked out separately for each District / Sub-district (TU) Drug store.

2. Specifications for drug stores:-

- ii. The Drug Store should preferably comprise one large room. Where multiple rooms already exist, they should be contiguous or proximate to each other
- iii. Preferably separate space for storage and handling of IP/CP Boxes.
- iv. Ceiling to have a height of at least 3 metres.
- v. A lockable door.
- vi. At least one window with grill.
- vii. Proper lighting.
- viii. An even-level, 'pukka' floor.
- ix. Plastered walls and ceiling with whitewash without any kind of seepage in the room.
- x. In case of a situation where separate room for storing 2nd line drugs is not possible, an attempt to demarcate and enclose a specified area for storing 2nd line drugs should be made within the larger store to ensure required temperature control for 2nd line drugs.
- xi. Architects should be consulted for suitable modifications in the existing drug store/construction of a new drug store for the same.
- xii. A signage board with instructions in local language should to be put near the entrance of the store to remind the concerned officials regarding good storage practices.

3. Shelves, Racks & Storage Arrangements:-

- i. If sufficient space is available on the existing storage shelves in the DTC / TU Drug stores, these shelves made of 40 mm. bore medium quality (external diameter - 48.3 mm.) mild steel pipes should continue to be used as per the existing RNTCP guidelines. New shelves, if required, are to be made from pre-fabricated slotted angles ensuring sufficient 'gap' between cartons from the ceiling, floor and walls, facilitating ventilation and the free movement of air.
- ii. Shelves to be positioned so that there is no possibility of seepage into cartons.

- iii. Typically, five rows of shelves to be fabricated, one on top of the other into racks. A single rack to usually be long enough to accommodate three cartons on each shelf. Accordingly, a rack would typically accommodate fifteen cartons.
- iv. In the case of a broad room, there shall be multiple rows of racks, all parallel to one another. There should be sufficient space between parallel blocks of racks and the walls, to facilitate free movement of men and trolleys for the smooth stacking and removal of cartons. In case of a long and narrow room, racks to be positioned such that there is sufficient space between them and the walls.
- v. IP/CP Drug Boxes to rest on shelves and not on each other, to prevent eventual sagging of the Boxes in the bottom row.

4. Stacking Arrangements:-

- i. Insofar as possible, similar Boxes should be stored adjacent to each other at a single location within the store.
- ii. Additionally, drugs of the same expiry should be stored together at the same location.
- iii. Recognizing the above rules, drugs expiring earliest should be so stored that they are issued first. For example, in case IP (< than 45 Kgs) boxes are placed on multiple shelves in a single part of the store, boxes expiring earlier should be stored at ground level and fresher boxes (which shall expire later) on elevated shelves. This method of stacking shall ensure that drugs that shall expire first shall automatically be issued first, based on the principle of FEFO (First Expiry First out).
- iv. IP/CP Boxes at DTC Drug store should have remaining shelf life of at least 9 months and at TU Drug Store should have remaining shelf life of at least 6 months.
- v. Expired drugs should be segregated, sealed and stored in a separate part of the store eliminating the possibility of their issue to patients. Expiry dates should be highlighted in these cases.
- vi. If the volume of 2nd Line Drugs stores being handled at a District Drug Store is high, Bin cards at the District Drug Store may be displayed which would provide details of Receipts, Issues, Closing balance (quantity) and expiry dates of drugs.
- vii. Only Na-PAS is slow moving drug and should be stored at higher level shelves. Rest all other 2nd Line Drugs are fast moving, therefore, should be stored on lower level shelves.

5. Control of Humidity and Temperature:-

- i. **Monitoring of Humidity & Temperature:-**
Hydrothermometers are to be installed upto TU drug store levels to monitor humidity and temperature regularly. The record of both these variables should be maintained in charts properly and checked on a daily basis by the concerned Store Incharge. This should be reviewed by DTO /MO-TC for DTC/TU Drug Stores respectively and necessary corrective measures be taken immediately.

- ii. **Control of Humidity:-** In order to keep humidity levels below the maximum 60% recommended for storage of drugs, following measures may be taken:-
 - a. **Ventilation:** Open the windows or air vents of the store to allow air circulation. Ensure all windows have screens / wiremesh to keep out insects and birds and also should have metallic grills / iron bars. Drug Boxes/Cartons should be placed on shelves ensuring that there is sufficient space between shelves and walls of the store room.
 - b. **Packaging:** The cartons/drug boxes should not be opened unless necessary.
 - c. **Circulation:-** Use fans to circulate fresh air from outside.
 - d. Installation of appropriate **dehumidifiers** may be considered at DTC/TU Drug Store levels, in case of high humidity prone areas.

- iii. **Protection from Sunlight:-** To protect the drugs from sunlight, following measures may be taken:-
 - a. Shade the windows or use curtains if they are in direct sunlight.
 - b. Keep products in cartons/drug boxes.
 - c. Do not store or pack products in sunlight.
 - d. Maintain trees around the premises of the drug store to help provide shade and cooling. Check their condition regularly to prevent any untoward incident.

- iv. **Control of temperature:-** For District / Sub-district (TU) Drug Store, cooling facilities such as room coolers (of appropriate size), ceiling fans etc. are to be provided in the drug storage area.

- v. **Power Supply:-** Regular power supply should be available for cooling facilities and dehumidifiers (if installed) in the drug stores at various levels.

The purpose of information provided in the above sub-paras is to emphasise that the drugs should be stored in cool & dark place for proper efficacy. Experimental data/literature review also reveals that these drugs lose their efficacy beyond 6 months if exposed to stressful storage conditions of $40^{\circ} \pm 2^{\circ}$ C temperature and humidity of $75\% \pm 5\%$ RH.

6. Packing Instructions:-

- i. The record of the serial no. of the Box should also be maintained at the District & Sub-district (TU) drug stores since it would be of help while tracking a particular IP / CP Box.
- ii. Instructions should be issued to the DOT provider that IP/CP Box should be closed properly everytime after withdrawal of drugs from the Box.
- iii. The concerned Drug Store Incharge should ensure that the label on IP/CP Boxes stored there do clearly mention the following:-
 - a. Item-wise name of drugs with quantity of each drug in the Box.
 - b. Batch No. & DOE of individual drugs.
 - c. DOE of IP/CP box – would be the expiry date of the drug containing shortest expiry.

- d. Date of Issue of the Box from SDS.
- e. IP/CP Box serial number.
- f. Storage instructions on the IP / CP Box in English/ Hindi/ local regional language for ensuring adequate precautions in storage of the drugs, specially at the DOT provider level. Some suggested messages are:-
 - Store in a cool and dark place.
 - Do not expose to direct sunlight.
 - Keep away from children/unauthorized persons.
 - Box to be closed properly everytime after withdrawal of drugs.

7. Quality Assurance of Drugs:-

As per the protocol developed by Central TB Division (CTD), samples of 2nd Line Anti TB Drugs should be picked up on random basis from various levels in the field and sent for testing by an independent drug testing laboratory contracted by CTD to find out any change in the quality of these drugs. This should be done based on communication sent by CTD to the concerned states.

8. Training:-

Training / sensitization programme for staff at District / TU Drug Stores, PHCs, DOT Centres regarding drug logistics management of 2nd Line Anti TB Drugs under RNTCP to be conducted as per Annual Action Plan by the states.

9. Waste Disposal Guidelines:-

If any drug expires due to reasons beyond control, it should be disposed off as per the procedures laid down in the Rules under Drugs & Cosmetics Act and Bio-medical Waste (Management and Handling) Rules of Govt. of India.

10. Guidelines for Recording, Reporting, Transportation of Drugs and Fire Safety measures remain the same as given in the SOP Manual for District Drug stores for 1st Line Anti TB Drugs and the guidelines of RNTCP.