



Government of Rajasthan  
**Medical & Health Department**

Rajasthan Medical Services Corporation, Swasthaya Bhawan, C-Scheme, Jaipur  
 Phone No: 0141-2228975 Fax No: 0141-2228065 E\_mail :- rpsc.hqtrs.qc@gmail.com

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All Principals & Controllers, Govt. Medical Colleges,  
 All Superintends of Medical College attached Hospitals  
 All JDs, CMHOs/PMOs, OIC DDWs

**Sub: RMSC Guidelines for maintenance of proper storage conditions for drugs at DDWs, Hospital Sub-Stores and DDCs.**

It is very important that Drugs maintain their quality, potency and efficacy throughout their shelf life when stored under specified storage conditions. Special conditions of storage vis-à-vis shelf life of many drugs are given under Schedule-P of Drugs & Cosmetics Rules 1945 and drugs which are not included in Schedule-P they are required to be stored at room temperature. Storage conditions for drug formulation are also described in their individual monographs in respective pharmacopeia as well as in respective schedules of Drugs & Cosmetics Rules 1945 in which they are classified. These storage conditions necessarily appear on the labels of the formulations and all concerned personnel's responsible for storage of drugs and distribution thereof are required to follow these storage norms in strict terms so as to ensure availability of quality drugs with desired potency, safety, bioavailability & efficacy.

For the purpose of clarity shelf life of drug means that it can be used till its Expiry Date which necessarily appears on labels of each drug formulation and often written in terms of month & year and legally it implies that it can be used till last date of that month of the particular year. The potency of the drug should be maintained throughout its shelf life.

Further the general requirements of keeping the drugs in dark place, away from direct sun light etc. are often met out in warehouses, stores and centers but maintenance of proper storage temperature requires special attention for which storage places can be broadly classified into three categories: (1.) Cold Place (2.) Cool Place & (3.) Normal Room Temperature. These are defined in Schedule-P of Drugs & Cosmetics Rules 1945 and relevant portion is reproduced below:-

1. **Cold Places:-** means a place having temperature not exceeding 8 °C. Label direction on such drugs normally appears reading as "To be stored in cold places at 2 °C to 8 °C". List of RMSC supply drugs falling in this category is enclosed.

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2. **Cool Places:-** means a place having temperature between 10<sup>0</sup>C to 25<sup>0</sup>C. Label direction on such drugs normally appears reading as "To be stored in cool places". List of RMSC supply drugs recommended to be stored at cool places is enclosed.
3. **Normal Room Temperature:-** Wherever conditions of storage are not specified they may be stored at Normal Room Temperature.

The following guidelines are hereby issued in respect of proper storage conditions for drugs at DDWs, Hospital Sub-Store and DDCs:-

**1. Cold Places:-** Drugs falling under this category are required to be stored maintaining cold chain all throughout their shelf-life. This can be achieved with following measures:-

1. Ensure that the supplies of such transported drugs are received from supplier through cold-chain vehicles or in cold-chain containers. Check if there are in built temperature monitoring device on label (Just like Vaccine Vial Monitor (VVM) in Oral Polio Vaccine)
2. Shift these drugs immediately in cold places i.e. ILRs, refrigerators etc. which are having proper temperature of 2<sup>0</sup>C to 8<sup>0</sup>C.
3. Put temperature reading devices, thermometers etc. at all such places & equipment. Temperature log book should also be maintained for each such place or equipments.
4. Temperature recording be done at least thrice a day, once preferably during high temperature peak hours of 12 PM to 2 PM.
5. Take suitable measures whenever there is any rise of temperature towards upper permissible limit by adjusting thermostat knob or replacing ice-bags.
6. Transportation of medicines from DDW to institution should also be done following the principles of cold chain maintenance using ice-packs, thermacol boxes & vaccine carriers. In the event of any shortage of vaccine carriers, RCHO at the district level may be requested to provide these for transportation of these drugs. Sufficient number of Ice Packs should always be kept ready for this purpose.
7. Dedicated auto-cut generator set is to be installed at DDWs and regular maintenance is necessary to avoid electricity problems in case of electricity failure.
8. In addition to the existing Cold Storage facilities at DDW Walk-in-Coolers are also to be installed shortly for which Tender Process has already been initiated, however following steps may be taken wherever necessary for providing additional cold space in DDWs, till such time where there is any shortage of adequate cold space-
  - (a) Adequate number of ILRs may be arranged from the office of RCHO. If required, necessary directions may be issued by District Level Monitoring Committee, which is chaired by District Collector, to CMHOs/RCHOs to ensure availability of ILRs.
  - (b) Other alternative source of storage, like cold storage of State Warehouse Corporation, spare cold storage units of pharmaceutical companies or their suppliers may be explored. These facilities may be explored and hired on rent; for which money will be reimbursed by RMSC.
  - (c) Further DPCs are directed to identify the space for Walk-in Coolers (WIC).
9. At Sub-stores such drugs be kept in ILRs and at DDCs such drugs should be stored in refrigerators.

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