



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.

(Signature)

2. **Cool Places:-** means a place having temperature between 10⁰C to 25⁰C. 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 2⁰C to 8⁰C.
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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2. Cool Places:- Temperature control between 10 °C to 25 °C be maintained at these places.

Following steps be taken for maintaining proper conditions in this area

1. ACs are provided to DDWs which are to be exclusively used for maintaining the cool place temperature between 10 °C to 25 °C for storing the drugs which are recommended to be stored at cool place.
2. A totally separate room must be identified for this, which should not be used for any other purpose.
3. A room which can have effective temperature control between 10 °C to 25 °C be dedicated for this purpose.
4. Air tight doors with proper door-closures should be provided in this room and doors should be kept locked and should be opened only for inward or outward shifting of the medicines from this area.
5. Provide temperature reading devices, thermometers etc. in this cool room and temperature log book be maintained.

General-

1. To put blue curtains over the windows of DDWs, Hospital Sub-Stores, DDCs to avoid direct exposure of drugs to sunlight.
2. Doors of DDWs and stores should be kept closed and be opened only for transfer of medicines.
3. Temperature can be regulated by using ceiling fans, exhaust fans and plantation of trees outside the stores.
4. Wall mounted thermometer shall be put in the general store and in the room of Pharmacist in-charge so that they are aware of the prevailing temperature, and can initiate appropriate measures if temperature become very high.

As the summer has already approached and the environmental temperature is gradually on the rise hence it is enjoined upon to all the OIC DDWs, Superintendents of medical college attached hospitals, PMOs of District and Satellite Hospitals and In-charges of CHC and PHCs to ensure & follow the above guidelines in maintaining proper conditions at the time of storage, transportation and supply medicines as per the norms for which orders have already been issued.


(Dr. Samit Sharma)
Managing Director
RMSC

Copy for information & necessary action please:

1. PS to Principal Secretary, Medical & Health, GOR
2. All District Collectors
3. Director (PH/RCH/HA), Medical & Health Services, DM&HS
4. ED, Quality Control, RMSC
5. Office Copy


Adat Drug Controller (QC)

Cold Place Drug List- RMSC drugs which are required to stored in COLD PLACE at temperature 2⁰C to 8⁰C in ILRs, Refrigerators, WIC etc

- 1 Recombinant Human Erythropoitin Alpha Injection
- 2 Recombinant Streptokinase For Injection
- 3 Rabies Vaccines IP
- 4 Snake Venom Antiserum IP
- 5 Biphasic Isophane Insulin Injection IP
- 6 Insulin Injection IP Soluble Soluble Insulin, Neutral
- 7 Rho(D) Immune Globulin (Human) Preservative Free Prefilled Anti-D Injection
- 8 Anti-D (Rho) Immunoglobulin (Monoclonal)
- 9 Anti -A Monoclonal Serum IP
- 10 Anti -B Monoclonal Serum IP
11. Anti -D Monoclonal Serum IP
- 12 RPR Slide Kit
- 13 Tetanus Vaccines (Adsorbed)
- 14 Tetanus Immunoglobulin BP (Human)
- 15 Bleomycin Injection IP
- 16 Vincristine Sulphate Injection USP
- 17 Carboprost Tromethamine Injection IP
- 18 Atracurium Besylate Injection USP
- 19 Dinoprostone Gel

Cool Place Drug List - Drugs which are required to stored in COOL PLACE at temperature 10⁰C to 25⁰C in Air-Conditioned Room

All heat sensitive & thermolabile drugs viz. Vitamins, Antibiotics Tablets, Capsules, dry powder injectables should be stored in cool place.

Room Temperature Drug List – Drugs on the labels of which ‘store in cold place or cool place’ are not mentioned may be stored at room temperature.

Note:- Copy of Schedule-P of Drugs & Cosmetics Rules 1945 are also enclosed herewith for ready reference.

24/1/2016

52 [SCHEDULE P

[See Rule 96]

LIFE PERIOD OF DRUGS

Sl. No.	Name of the drug	Period in months (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified in Column No. 4	Conditions of storage
1	2	3	4
ANTIBIOTICS			
1.	Adramycin	30	In a cool place
2.	Ampicillin	36	In a cool place
3.	Ampicillin Capsules	24	
4.	Ampicillin Dry Syrup	24	
5.	Ampicillin Injection	24	
6.	Ampicillin Sodium	36	In a cool place
7.	Ampicillin Trihydrate	30	In a cool place
8.	Amoxycillin Trihydrate	36	In a cool place
9.	Amoxycillin Trihydrate Capsules	24	
10.	Amoxycillin Trihydrate Dry Syrup	18	
11.	Bacitracin	18	In a cool place
12.	Bacitracin or Zinc Bacitracin tablets	12	
13.	Bacitracin Lozenges	12	
14.	Carbenicillin Sodium Injection	24	At temperature not exceeding 5°C.
15.	Carbenicillin Sodium Powder	24	At temperature not exceeding 5°C.
16.	Cephalexin	24	In a cool place
17.	Chloramphenicol	60	In a cool place
18.	Chloramphenicol capsules and tablets	48	
19.	Chloramphenicol Palmitate	48	
20.	Chloramphenicol Palmitate Oral suspension	36	

52. Subs. by GSR 17(E), dt. 7-1-1986 (w.e.f. 7-1-1986) as corrected by GSR 1059(E), dt. 5-9-1986.

1	2	3	4
21.	Chloramphenicol Eye drops	24	
22.	Chloramphenicol Sodium Succinate powder	48	In a cool place
23.	Chloramphenicol Sodium Succinate Injection	36	In a cool place
24.	Chlortetracycline Hydrochloride	60	In a cool place
25.	Chlortetracycline Hydrochloride capsules	60	
26.	Chlortetracycline Hydrochloride tablets	24	
27.	Chloritetracycline Hydrochloride Ointment	24	
28.	Cloxacillin (Oral)	36	In a cool place
29.	Cloxacillin Sodium (Injection Grade)	36	In a cool place
30.	Colistin Sulphate	60	Protected from light
31.	D-Cycloserine	48	In a cool place
32.	Dimethyl chlortetracycline Hydrochloride	48	
33.	Dimethyl Chlortetracycline Hydrochloride Capsules	36	
34.	Daunoblastin Injection	36	
35.	Doxycycline Hydrochloride	48	In a cool place
36.	Doxycycline Monohydrate	36	In a cool place
37.	Doxycycline Monohydrate for Oral Suspension	24	
38.	Doxycycline Monohydrate capsules	36	
39.	Erythromycin Estolate	36	In a cool place
40.	Erythromycin Ethylsuccinate	60	In a cool place
41.	Erythromycin Oral Suspension	36	
42.	Erythromycin Estolate for Oral Suspension	36	
43.	Erythromycin Ethyl Succinate tablet	24	
44.	Erythromycin Estolate tablets	24	
45.	Erythromycin Stearate	36	In a cool place
46.	Framycetin Sulphate	48	In a well closed container with temperature not exceeding 30°C.
47.	Framycetin Sulphate Eye drops	24	In a well closed container with temperature not exceeding 30°C.
48.	Framycetin Sulphate Ointment	24	In a well closed container with temperature not exceeding 30°C.

1	2	3	4
49.	Gentamycin Sulphate	60	In a cool place
50.	Gentamycin Sulphate Injection	36	
51.	Gramicidin	60	In a cool place
52.	Griseofulvin	48	In a cool place
53.	Griseofulvin Tablets	36	
54.	Kanamycin Sulphate Injection	24	
55.	Kanamycin Acid Sulphate Powder	48	In a cool place
56.	Mitomycin C	48	In a cool place
57.	Neomycin Sulphate	48	In a cool place
58.	Nystatin	36	At temperature not exceeding 5°C.
59.	Oleandomycin Phosphate sterile	24	In a cool place
60.	Oleandomycin Phosphate non sterile	36	In a cool place
61.	Oxytetracycline Hydrochloride	48*	In a cool place
62.	Oxytetracycline Hydrochloride capsules	36	
63.	Oxytetracycline Hydrochloride tablets	24	
64.	Oxytetracycline Hydrochloride Injection	24	
65.	Oxytetracycline Hydrochloride Ointment	36	
66.	Penicillin Crystalline	36	In a cool place
67.	Penicillin Tablets	18	In a cool place
68.	Procaine Penicillin G	36	In a cool place
69.	Benzathin Penicillin G	48	In a cool place
70.	Potassium Phenoxo Methyl Penicillin	48	In a cool place
71.	Potassium Phenoxo Methyl Penicillin tablets	24	
72.	Polymixin B Sulphate	48	In a cool place
73.	Polymixin B Sulphate Ointment or powder	24	In a cool place
74.	Rifampicin	36	In a cool place
75.	Rifampicin Capsules	53[36]	
76.	Spiramycin Base	24	In a cool place
77.	Streptomycin Injection	36	
78.	Streptomycin Ointment	24	
79.	Streptomycin tablets	24	

* *Vide* Hindi version.

53. *Subs.* for "24" by GSR 250(E), dt. 4-4-2002 (w.e.f. 4-4-2002).

1	2	3	4
80.	Streptomycin Sulphate	48	At temperature not exceeding 20°C.
81.	Tetracycline Base	24	In a cool place
82.	Tetracycline Hydrochloride	36	In a cool place
83.	Tetracycline Hydrochloride Capsules	36	
84.	Tetracycline Tablets	24	
85.	Tyrothricin	60	In a cool place
<i>VITAMINS</i>			
1.	Vitamin A Injection	24	
2.	Vitamin B ₁ Injection	24	
3.	Thiamine Mononitrate tablets	36	
4.	Thiamine Hydrochloride	48	In a well-closed container, protected from light, in a cool place.
5.	Thiamine Mononitrate	48	In a well-closed container, protected from light, in a cool place.
6.	Riboflavin	60	In a well-closed container, protected from light, in a cool place.
7.	Riboflavin 5 Phosphate	24	In a well-closed container, protected from light, in a cool place.
8.	Riboflavin Tablets	36	
9.	Vitamin B ₂ Injection	24	
10.	Vitamin B ₆	60	In a well-closed container, protected from light, in a cool place.
11.	Vitamin B ₆ tablets	36	
12.	Cyanacobalamin	48	In a well-closed container, protected from light, in a cool place.
13.	Hydroxycobalamin	48	In a well-closed container, protected from light, in a cool place.
14.	Vitamin B ₁₂ Injection	36	
15.	Calcium Pantothenate	36	In a well-closed container, protected from light, in a cool place.
16.	Vitamin C injection	24	
17.	Calcium Pantothenate tablets	36	
18.	Vitamin C	48	In a well-closed container, protected from light, in a cool place.
19.	Vitamin D ₂ D ₃	36	In a well-closed container, protected from light, in a cool place.

1	2	3	4
20.	Vitamin E or E-Acetate	60	In a well-closed container, protected from light, in a cool place.
21.	Folic Acid	60	In a well-closed container, protected from light, in a cool place.
22.	Folic Acid tablets	36	
23.	Vitamin K	60	In a well-closed container, protected from light, in a cool place.
24.	Vitamin K Injection	36	
25.	Niacinamide	60	In a well-closed container, protected from light, in a cool place.
26.	Niacinamide tablets	36	
27.	D-Panthenol	60	In a well-closed container, protected from light, in a cool place.
<i>INSULIN PREPARATIONS</i>			
1.	Golbuline Zinc Insulin Injection	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
2.	Insulin Injection	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
3.	Insulin Zinc suspension	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
4.	Insphane Insulin Injection	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
⁵⁴ [5.	Human Insulin Injection	30	At temperature between 2°C and 8°C, must not be allowed to freeze.]
<i>NORMAL HUMAN PLASMA</i>			
1.	Anti-Haemophillic Human Globulin	12	In a cool place.
2.	Dried Plasma	60	At temperature not exceeding 25°C.
3.	Dried Normal Human Serum Albumin	60	At temperature not exceeding 25°C.
4.	Frozen Plasma	60	In deep freeze.
5.	Liquid Plasma	24	In cold place.
6.	Liquid Normal Human Serum Albumin	60	In cold place.

54. *Ins.* by GSR 215(E), dt. 19-3-1999 (w.e.f. 19-3-1999).

1	2	3	4
⁵⁵ [7.	Whole Human Blood— (a) Collected in ACD solution (b) Collection in CPDA solution	21 days 35 days	At temperature between 4°C and 6°C. At temperature between 4°C and 6°C.]
<i>SERA TOXIN AND TOXOID</i>			
1.	Alum Precipitated Diphtheria Toxoid	24	In cold place.
2.	Alum Precipitated Diphtheria and Tetanus toxoid and Pertussis vaccine combined	18	In cold place.
3.	Alum Precipitated Tetanus Toxoid	24	In cold place.
4.	Aluminium Hydroxide Absorbed Diphtheria Toxoid	24	In cold place.
5.	Aluminium hydroxide Absorbed Diphtheria Tetanus Toxoid and Pertussis Vaccine combined	18	In cold place.
6.	Aluminium Phosphate Absorbed Diphtheria Toxoid	24	In cold place.
7.	Aluminium Phosphate absorbed Diphtheria and Tetanus Toxoid	24	In cold place.
8.	Aluminium phosphate absorbed Diphtheria Toxoid Tetanus Toxoid and Pertussis vaccine combined	18	In cold place.
9.	Diagnostic Diphtheria Toxin (Schick Test)	12	In cold place.
10.	Cobra venom in solution	3	Between 2°C and 5°C protected from light.
11.	Diphtheria Toxoid	24	In cold place.
12.	Inactivated Diagnostic Diphtheria Toxin	12	In cold place.
13.	Liquid serum	12	Between 2°C and 10°C preferable at the lower limit.
14.	Lyophilised anti-snake venom serum	60	
15.	Lyophilised Schick test Toxin and control	60	
16.	Old Tuberculin	60	In cold place.
17.	Thrombin (Bovine origin)	36	In cold place.
⁵⁶ [18.	Tetanus toxoid	36	In cold place.]
19.	Tuberculin PPD	60	In cold place.

55. Subs. by GSR 626(E), dt. 14-10-1991 (w.e.f. 14-10-1991).

56. Subs. by GSR 26(E), dt. 19-1-2006 (w.e.f. 19-1-2006).

1	2	3	4
<i>OTHER VACCINES</i>			
1.	Alum precipitated pertussis Vaccine	18	In cold place.
2.	BCG Vaccine	⁵⁷ [24] days	In cold place.
3.	Cholera Vaccine	18	In cold place.
4.	DHL Vaccine (for dog)	12	In cold place.
5.	Measles Vaccine	24	In cold place.
6.	Plague Vaccine	36	In cold place.
7.	Polio Vaccine	24	When stored at minus 20°C.
		6	when stored at Zero °C.
		3	when stored at 4°C.
8.	Rabies Vaccine	6	In cold place.
9.	Typhoid Vaccine	18	In cold place.
10.	Typhoid and Para Typhoid Vaccine	18	In cold place.
11.	Typhoid Para Typhoid A and B Vaccine	18	In cold place.
12.	Typhoid Para Typhoid A, B & C Vaccine	18	In cold place.
13.	Typhoid Para Typhoid A, B & C and Tetanus Vaccine	18	In cold place.
14.	Typhus Vaccine	12	In cold place.
15.	Yellow Fever Vaccine	12	In cold place.
⁵⁸ [16.	Anti-Rabies Vaccine (Cell Culture)	24	In cold place.]
<i>ANTITOXIN</i>			
	(For serum extracted preparations)		
	20% Excess potency	12	In cold place.
	30% Excess potency	24	In cold place.
	40% Excess potency	36	In cold place.
	50% Excess potency (for enzyme preparations)	48	In cold place.
	5% Excess potency	12	In cold place.
	10% Excess potency	24	In cold place.
	15% Excess potency	36	In cold place.
	20% Excess potency	48	In cold place.
<i>MISCELLANEOUS DRUGS</i>			
1.	Adrenaline for Injection	12	⁵⁹ [As prescribed in Indian Pharmacopoeia]
2.	Chorionic Gonadotrophin for injection (Lyophilised)	36	At temperature not exceeding 20°C.
3.	Corticotrophin	24	In cold place.

57. *Subs.* for "14" by GSR 174(E), dt. 16-3-2005 (w.e.f. 16-3-2005).58. *Ins.* by GSR 215(E), dt. 19-3-1999 (w.e.f. 19-3-1999).59. *Subs.* for "In cold place" by GSR 174(E), dt. 16-3-2005 (w.e.f. 16-3-2005).

1	2	3	4
4.	Corticotrophin Lyophilised	36	In cold place.
5.	Heparin Injection	36	In a cool place.
6.	Liquid Extract of Ergot	12	In cold place.
7.	Liver Extract Crude Injection	24	In a cool place.
8.	Oxytocin Injection	24	In cold place.
9.	Paraldehyde Injection	6	In cool place protected from light.
10.	Pituitary Injection	24	In cold place.
11.	Vasopressin Injection	24	In cold place.

Note.—(1) The term “cool place” means ‘place having a temperature between 10°C and 25°C’.

(2) The term “cold place” means a place having a temperature not exceeding 8°C.

(3) Capsules should be kept in a well-closed container at temperature not exceeding 30°C.

(4) Wherever condition of storage is not specified in Column 4, it may be stored under normal room temperature.]

Status of Cold Chain Equipments in DDWs (31.03.2012)

DISTRICT	DEEP FREEZER(SM ALL)	DEEP FREEZER(BIG)	Total	ILR(SMALL)	ILR(BIG)	Total
	Available	Available		Available	Available	
Ajmer	5	0	5	0	10	10
Alwar	2	1	3	0	6	6
Barmer	2	1	3	4	3	7
Banswara	2	1	3	2	4	6
Baran	3	0	3	6	0	6
Bharatpur	3	0	3	2	4	6
Bhilwara	3	0	3	3	3	6
Bikaner	5	0	5	3	7	10
Bundi	3	0	3	4	2	6
Chittorgarh	3	0	3	4	2	6
Churu	3	0	3	2	4	6
Dausa	3	0	3	6	0	6
Dholpur	3	0	3	4	2	6
Dungarpur	3	0	3	5	3	8
Ganganagar	3	0	3	6	2	8
Hanumangarh	3	0	3	4	2	6
Jaisalmer	3	0	3	4	4	8
Jalore	2	1	3	4	2	6
Jhalawar	3	0	3	4	2	6
Jhunjhunu	3	0	3	3	3	6
Jodhpur	5	0	5	2	8	10
Karauli	2	1	3	10	3	13
Kota	5	0	5	4	6	10
Nagaur	3	0	3	5	3	8
Pali	1	2	3	2	4	6
Pratapgarh	4	0	4	0	10	10
Rajsamand	2	1	3	2	4	6
Sawai madhopur	2	1	3	1	5	6
Sikar	3	0	3	3	3	6
Sirohi	3	0	3	2	4	6
Tonk	3	0	3	4	2	6
Udaipur	5	0	5	3	7	10
Jaipur (I & II)	2	0	2	0	35	35
Total	100	9	109	108	159	267