



GOVERNMENT OF INDIA

**MINISTRY OF HEALTH AND FAMILY
WELFARE**

(Department of Health)

**THE DRUGS AND COSMETICS ACT
AND RULES**

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

¹[SCHEDULE P

[See Rule 96]

LIFE PERIOD OF DRUGS

<i>Sl. No.</i>	<i>Name of the drug</i>	<i>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</i>	<i>Condition of storage</i>
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 & Tablets	48	
19.	Chloramphenicol Palmitate	48	
20.	Chloramphenicol Palmitate Oral Suspension	36	
21.	Chloramphenicol Eye drops	24	
22.	Chloramphenicol Sodium Succinate Powder	48	In a cool palace
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.	Chlortetracycline Hydrochloride Ointment	24	
28.	Cloxacillin (Oral)	36	In a cool place
29.	Cloxacillin Sodium (Injection Grade)	36	In a cool place

1. Subs. by G.S.R. 17(E) , dt. 7.1.1986 (w.e.f. 7.1.1986).

Drugs and Cosmetics Rules 1945

1	2	3	4
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
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.	Oxytetracine Hydrochloride	36	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

1	2	3	4
69.	Benzathin Penicillin G	48	
70.	Potassium Phenoxy Methyl Penicillin	48	In a cool place
71.	Potassium Phenoxy 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
¹ [75]	Rifampicin Capsules	36]	
76.	Spramycin Base	24	In a cool place
77.	Streptomycin Injection.	36	
78.	Streptomycin Ointment	24	
79.	Streptomycin Tablets	24	
80.	Streptomycin Sulphate	48	At temperature not exceeding 20oC
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.

VITAMINS

1.	Vitamin A Injection	24	
2.	Vitamin B1 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 B2 Injection	24	
10.	Vitamin B6	60	In a well closed container, protected from light, in a cool place.
11.	Vitamin B6 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 B12 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	
² 18.	Vitamin C	48	In a well closed container, protected from light, in a cool place.

1. Subs. by G.S.R. 250(E), dt. 4.4.2002

2. Subs. by G.S.R. 626(E), dt. 14.10.1991

1	2	3	4
19.	Vitamin D ₂ D ₃	36	In a well closed container, protected from light, in a cool place.
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.
INSULIN PREPARATIONS			
1.	Globuline 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.	Isophane Insulin Injection.	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
¹ [5.	Human Insulin Injection	30	At temperature between 2°C and 8°C, must not be allowed to freeze.

NORMAL HUMAN PLASMA

1.	Anti-Haemophilic Human Globulin	12	In a cool place
2.	Dried Plasma	60	At a temperature not exceeding 25°C
3.	Dried Normal Human Serum Albumin	60	At a 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.
² [7.	Whole Human Blood-		
	(a) Collected in ACD solution	21days	At temperature between 4°C and 6°C
	(b) Collection in CPDA solution.	35days	At temperature between 4°C and 6°C]

1. Subs. by G.S.R. 626(E), dt. 14.10.1991.

2. Subs. by G.S.R. 626(E), dt. 14.10.1991.

SERA TOXIN AND TOXOID

1.	Alum Precipitated Diphtheria Toxoid	24	In cold place.
2.	Alum Precipitated Diphtheria and Tetanus toxoid and Pertusis vaccine combined	18	In cold place
3.	Alum Precipitated Tetanus Toxoid	24	In a cold place
4.	Aluminium Hydroxide Absorbed Diphtheria Toxoid	24	In a cold place.
5.	Aluminium Hydroxide Absorbed Diphtheria Tetanus Toxoid and Pertussis Vaccine combined.	18	In a cold place
6.	Aluminium Phosphate Absorbed Diphtheria Toxoid.	24	In a cold place.
7.	Aluminium Phosphate absorbed Diphtheria and Tetanus Toxoid	24	In a 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.
18.	Tetanus Toxoid	36	In cold place]
19.	uberculin PPD	60	In cold place

OTHER VACCINES

1.	Alum precipitated pertussis Vaccine.	18	In cold place
² [2.	BCG Vaccine	24	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

1. Subs. by G.S.R. 26(E), dt. 19.01.2006.

2. Subs. by G.S.R. 174(E), dt. 16.03.2005.

1	2	3	4
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
¹ [16.	Anti-Rabies Vaccine (Cell Culture)	24	In cold place.]

ANTITOXIN

(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

MISCELLANEOUS DRUGS

² [1. Adrenaline for Injection	12	[As prescribed in Indian Pharmacopoeia]
2. Chorionic Gonadotrophin for Injection (Lyophilised)	36	At temperature not exceeding 20°C
3. Corticotrophin	24	In cold place
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.]

1. Ins. by G.S.R. 215(E), dt. 19. 3. 1999.

2. Subs. by G.S.R. 174(E), dt. 16. 3. 2005.