

- **Important note**
- **Storage of Drug**

Importance

- **Decomposition of a drug may result on one hand in efficacy decrease and**
- **on other in the possible presence of toxic degradation products.**

Relevance

- **Pharmacists are committed to the safety of patients and the public as their highest priority**

General requirements

- Medications should be stored in accordance with regulatory requirements and manufacturer recommendations
- Internal medicines must be stored separately from medicines for external use.
- Flammable liquids and gasses need to be kept in a cupboard suitable for storage of such products.

Separate Storage area

- **Medicines for Internal use**
- **Medicines for External use**
- **Controlled drugs**
- **Medicines requiring cool storage**
- **Diagnostic Reagents**
- **Large volume intravenous fluids**
- **Inflamables**

Storage Accommodation Standards

- **Drug storage rooms must feature:**
- **a lockable room**
- **security screens on all windows**
- **adequate lighting (240 lx illuminance or more)**
- **a temperature of 25°C or below, with air conditioning units that operate 24 hours per day and are connected to an emergency power supply**
- **a purpose built vaccine refrigerator for storage of vaccines, anti-venom and point-of-care equipment consumables.**
- **a nominated refrigerator for cold storage of pharmaceutical products requiring refrigeration, in addition to the vaccine refrigerator**
- **a dangerous drugs cupboard**
- **adequate shelving for appropriate storage of the different categories of drugs used**

Contd..

- a workbench with an impervious top
- an adjustable swivel chair on castors, if the workbench is low
- a stainless steel sink with impervious surrounds, preferably with elbow controlled taps
- two RUM containers as per Return of Unwanted Medicines
- a soap dispenser and paper towel holder
- a portable, non-slip step or a sturdy two rung ladder, if shelving is above shoulder height

Indian Pharmacopoeia

- Effect of atmosphere, moisture, heat and light
- Store in a
 - dry, well ventilated place at a temp NE 30°
 - Refrigerator (2° to 8°). Do not freeze
 - Freezer (- 2° to -18°).
 - Deep freezer (below -18°).
- *Not related to temperature
 - Protected from light
 - Protected from moisture

Product storage I.P.

- Capsule – temperature not exceeding 30°
- Creams – < 25° unless specific. Do not freeze
- Eye Oint - < 30° unless specific. Do not freeze
- Gel - < 30° unless specific. Do not freeze
- Ointment- < 30° unless specific. Do not freeze
- Inhalation – avoid extremes of temp & wide fluctuation of temperature.
- Insulin prepn - unless specific, protected from light, 2° - 8°. Should not be frozen.

Contd...

- Nasal powder—protected from light & moisture
- Oral liquid-Well closed contained, NE 30°
- Oral powder – protected from moisture
- Pessaries – in well closed container
- Suppositories – in well closed container

B.P.2009

- **To be stored under conditions that prevent contamination and as far as possible deterioration.**
- **Unless otherwise stated in the monograph, keep in a well closed container & store at temperature not exceeding 25°.**
- **Atmosphere, moisture, heat & light precautions**

Common terms

- ***Store frozen:*** Some products, such as certain vaccines, need to be transported within a cold chain and stored at -20°C . Frozen storage is normally for longer-term storage at higher-level facilities.
- ***Store at 2° – 8°C :*** Some products are very heat sensitive but must not be frozen. These are usually kept in the first and second part of the refrigerator (never the freezer). This temperature is appropriate for storing vaccines for a short period of time.
- ***Keep cool:*** Store between 8° – 15°C (45° – 59°F).
- ***Store at room temperature:*** Store at 15° – 25°C

Contd..

- ***Store at ambient temperature:*** Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means “room temperature” or normal storage conditions, which means storage in a dry, clean, well ventilated area at room temperatures between 15° to 25°C or up to 30°C, depending on climatic conditions.

Medicines with stability problems under tropical conditions

- Oral solids (tablets) - acetylsalicylic acid, amoxicillin, ampicillin, penicillin V, retinol
- Oral liquids (syrups) - paracetamol
- Injections- ergometrine, methylergometrine, adrenaline, reconstituted antibiotics, oxytocin¹
- Source: Quick, J. S., J. R. Rankin, R. O. Laing, R. W. O'Connor, H. V. Hogerzeil, M. N. Dukes, and A. Garnett, (editors). 1997. *Managing Drug Supply, 2nd ed.* West Hartford, CT: Kumarian Press.
- ¹ Reynolds, J. E. F. (editor). 1996. *Martindale: The Extra Pharmacopoeia, 31st ed.* London: Royal Pharmaceutical Society.

SCHEDULE P

- In a cool place
- At temperature not exceeding 5°C. (Nystatin)
- Protected from light
- In a well closed container with temperature not exceeding 30°C
- At temperature not exceeding 20°C (Streptomycin Sulphate)
- In a well closed container, protected from light, in a cool place.
- At temperature between 2°C and 8°C, must not be allowed to freeze.
At a temperature not exceeding 25°C
At temperature between 4°C and 6°C

Schedule P contd..

- In deep freeze(Frozen Plasma)
- In cold place (Liquid Plasma)
- Between 2°C and 5°C protected from light.(Cobra venom in solution)
- Between 2°C and 10°C preferable at the lower limit.
- Polio Vaccine 24 months When stored at -20°C
- 6 months When stored at 0°C
- 3 months When stored at 4°C

(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.

Refrigerator Storage

- “Store between 2°C and 8°C”.
- Refrigerators:
 - Must be routinely maintained and cleaned and defrosted regularly (included in the manual).
 - Fridge temperatures and room temperature should be monitored daily.
 - During periods of exceptionally hot or cold weather the frequency of monitoring should be increased.
 - Must not be kept at temperatures below 2°C as freezing can cause deterioration of the product and breakage of the container.
- Products should be stored to allow air to circulate around the packages.
- not stored in the storage compartments of the door.
- Must have an electrical supply that cannot be accidentally interrupted e.g. by using a switches socket or by placing cautionary notices on plugs and sockets.

Multi-dose Vials

- Multi-dose vials present unique challenges to patient safety
- All multi-dose vials should be labeled with date opened, expiration date (30 days after opening unless otherwise specified by manufacturer), and any applicable warnings.
- Multi dose vials stored according to manufacturer recommendations should be discarded if :
- Suspected or visible contamination occurs
- 30 days lapse after opening unless otherwise noted by manufacturer
- Found opened and without a revised expiration date based on date opened

■ Thanks to Dr.R.S.THAKUR