Essentials of Drug Storage

Is Storage Important?

Storage of medicine vs Quality of Medicine
- Temperature
- Light & Humidity
- Reduced shelf life
- Loss of potency
- Degradation of drugs

Consideration of storage requirements

Proper Medication Storage
- Controlled drug substances
- Expensive medications vulnerable to theft

Secure Medication Storage
- Adequate Temperature
- Adequate Light
- Adequate Humidity
- Stable product
- Physical location
- Determines the correct storage place for a drug

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Safe Medication Storage

Dosage form wise storage

Company wise storage

Therapeutic area wise storage

Result of Improper storage: Drug Degradation

Drug Degradation

Partial / complete loss of clinical effect or May produce toxic effects

Therapeutic Failure Leading to patient harm

Processes leading to drug degradation

Exposure to air (oxidation)

- Many medicines undergo oxidation when they come in contact with oxygen present in the environment in which they are stored.
- Ascorbic acid (Vit. C.), Epinephrine, Chlorpromazine, Isoproterenol, Morphine & preparations containing fats and oils. Most of the above products are oxidized to a less active chemical forms.

Exposure to heat

- The heat sensitive drugs like Vitamins, insulins, Oxytocin, Heparins, Dutasteride, dry Syrups like Ampicillin, are inactivated when exposed to high temperatures. They are either converted to a less active or in case of most of the vaccines they may be converted to a complete inactive or even harmful toxic form.

Exposure to light

Access to moisture

Exposure to heat

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Processes leading to drug degradation contd...

**Access to moisture (hydrolysis, microbial growth)**

- Many medicines undergo hydrolysis when they come in direct or indirect contact with water through the humidity in the environment in which they are stored.
- The growth of micro-organisms like fungus is facilitated in presence of moisture.
- Examples: Antibiotics like Penicillins and amoxicillin are hydrolyzed to Penicillinic Acid, the less potent/active chemical form. The preparations containing proteins, carbohydrates like glucose are easily contaminated with microbes in presence of moisture.

**Exposure to light (Oxidation or photochemical degradation)**

- Some medicines and their preparations are sensitive to light and lose their action when exposed to light.
- Example, in ciprofloxacin the fluorine present in chemical structure of ciprofloxacin is liberated in presence of ultraviolet light and it is converted to a toxic form.
- Most of the water soluble Vitamins like Riboflavin, Cyanocobalamin are inactivated in presence of light.
- More importantly, all the chemical reactions mentioned above Hydrolysis, oxidation are facilitated in presence of light.

Visible Signs of Instability

<table>
<thead>
<tr>
<th>Liquids</th>
<th>Tablets</th>
<th>Capsules</th>
<th>Creams &amp; Ointment</th>
<th>Injectables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uneven Redispersability</td>
<td>Change in normal size shape, weight, and coating.</td>
<td>Excessive softness</td>
<td>Bleeding</td>
<td>Presence of particulate matter, microbial growth in clear solutions</td>
</tr>
<tr>
<td>Pourability</td>
<td>Excessive powdering</td>
<td>Sticking together</td>
<td>Too soft so that it becomes messy to apply.</td>
<td>Presence of precipitation, crystallization in clear solutions</td>
</tr>
<tr>
<td>Microbial Growth</td>
<td>Cracks, chips on the face of the tablets</td>
<td>Hardness and cracks under slight application of pressure</td>
<td>Too hard</td>
<td>Discoloration of the solution</td>
</tr>
<tr>
<td>Cake formation</td>
<td>Mortling</td>
<td>Growth of fungus on the surface of soft gelatin capsules</td>
<td>Other common changes like change in colour, odour, viscosity, consistency, particle size distribution &amp; microbial growth etc</td>
<td>Any type of leakages.</td>
</tr>
<tr>
<td>Breakage of the Emulsions</td>
<td></td>
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</tr>
</tbody>
</table>

Visible Signs of Instability

Check your stock regularly to identify any degradation.
Schedule “P” under Drugs & Cosmetic Act provides a list of all such drugs and their formulations for which specific storage conditions are specified.

Storage Conditions as per Indian Pharmacopoeia

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Indian Standards As Per IP-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold</td>
<td>Temperature Not Exceeding 8°C (Between 2°C-8°C)</td>
</tr>
<tr>
<td>Cool</td>
<td>Any Temperature Between 8°C – 25°C</td>
</tr>
<tr>
<td>Warm</td>
<td>Any Temperature Between 30°C–40°C</td>
</tr>
<tr>
<td>Excessive Heat</td>
<td>Any Temperature Above 40°C</td>
</tr>
<tr>
<td>Freezer</td>
<td>Temperature Between -25°C To -10°C</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Temperature prevailing At Working Area</td>
</tr>
<tr>
<td>Dry Place</td>
<td>Average Relative Humidity Not Exceeding 40%</td>
</tr>
</tbody>
</table>

If no specific storage directions are given then conditions include protection from moisture, freezing and excessive heat.

Special Storage Requirements

- Products to be stored at a certain temperature
- Products sensitive to heat & requiring refrigeration
- Flammable products
- Vaccines and sera
- Insulin
- Elixirs and alcohol based products
- Products that have reduced shelf life at uncontrolled room temperature
- Products prone to theft or misuse
- Nitroglycerine
- Expensive & habit forming drugs
- Storage of Antibiotics should be as per the manufacturer’s instructions
- Storage of Insulin
- Storage of Levothyroxine

Keep insulin at 2°C-8°C. Do Not freeze me.

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Actions To Be Taken At Retailer Level

- Any suspected stability problem should be immediately acted upon by:
  - Looking for similar changes in other containers of same batch of the same product.
  - Inquiring with other retailer, distributor and manufacturer regarding such changes, spoilage and defects.
  - Inform to the representative of the manufacturer or local F.D.A. office about the defect in the product.

Expire Date…..vital for safe and effective use of medicines

Epinephrine injection used in life threatening situations like anaphylaxis, should not be used past their expiry dates as it has been shown to lose its potency.

Focus on Storage of medicine whilst Patient Counseling

Give written instructions
Conclusion

Pharmacist
the ultimate
care taker of
the medicines

"If you take care of
your medicine
Your medicine will take
care of you"

Thank you