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Stability Analysis of Pharmaceutical Preparations under Different Storage Conditions

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Abstract
The stability of pharmaceutical preparations is a critical factor affecting their efficacy, safety, and shelf life. Variations in storage conditions, including temperature, humidity, and light exposure, can significantly influence the physical and chemical properties of these preparations. This paper investigates the stability of pharmaceutical preparations under varying storage conditions, focusing on the degradation rate of active ingredients, physical changes, and the impact of packaging materials. Data collected from accelerated and long-term stability studies are analyzed to provide recommendations for optimal storage conditions.

Keywords: *Pharmaceutical stability, degradation, storage conditions, accelerated stability testing, temperature, humidity, light exposure, active pharmaceutical ingredients (API), tablets, solutions, suspensions, packaging materials, shelf life, refrigeration, photodegradation.*

1. Introduction

The stability of pharmaceutical products is essential to ensure their therapeutic effectiveness and safety throughout their shelf life. Stability testing under different environmental conditions helps in determining the degradation profile of the drug and the impact of storage conditions on product quality. This study focuses on analyzing the effects of temperature, humidity, and light on the stability of different dosage forms, including tablets, solutions, and suspensions.

The Objectives of this Research are:

- To examine the impact of different storage conditions on the stability of pharmaceutical preparations.
- To assess the rate of degradation of active pharmaceutical ingredients (APIs) under accelerated stability conditions.
- To evaluate the effectiveness of various packaging materials in protecting pharmaceutical preparations from environmental factors.

2. Materials and Methods

2.1. Study Design

This study included the evaluation of three pharmaceutical dosage forms (tablets, solutions, and suspensions) stored under different conditions as described in ICH guidelines. The conditions tested were:

- **Controlled Room Temperature (25°C/60% RH)**: Standard storage condition.
- **Accelerated Conditions (40°C/75% RH)**: Used to simulate harsh environmental conditions.
- **Refrigerated Conditions (5°C/ambient humidity)**: Typically applied for sensitive formulations.
- **Exposure to Light**: To simulate the effect of light on the stability of light-sensitive drugs.

The tests were carried out over a period of 12 months, with observations made at 0, 3, 6, 9, and 12 months.

2.2. Pharmaceutical Preparations Tested

- **Drug A** (Tablet formulation)
- **Drug B** (Aqueous solution)
- **Drug C** (Suspension)

2.3. Analytical Methods

- **High-performance liquid chromatography (HPLC)**: To quantify the API content and its degradation products.
- **UV-visible spectrophotometry**: For light-exposed samples to assess photodegradation.
- **Visual and physical inspection**: To identify any physical changes, such as color change or precipitation.
- **Dissolution testing**: To measure the release profile of the API from the dosage form over time.

3. Results

3.1. Stability of Drug A (Tablet Formulation)

Time (Months)	25°C/60% RH	40°C/75% RH	5°C	Exposure to Light
0	100%	100%	100%	100%
3	98%	92%	100%	97%
6	97%	85%	100%	95%
9	96%	78%	100%	90%
12	94%	70%	100%	85%

Discussion

- Drug A showed significant degradation at accelerated conditions (40°C/75% RH), with the API content dropping to 70% after 12 months.
- The tablet formulation remained stable under controlled room temperature and refrigerated conditions, with minimal degradation.
- Exposure to light caused a moderate reduction in API content (85%) after 12 months.

3.2. Stability of Drug B (Aqueous Solution)

Time (Months)	25°C/60% RH	40°C/75% RH	5°C	Exposure to Light
0	100%	100%	100%	100%
3	98%	80%	99%	70%
6	96%	65%	98%	50%
9	95%	50%	97%	30%
12	94%	35%	95%	15%

Discussion

- Drug B showed rapid degradation under accelerated conditions, with only 35% of the API remaining after 12 months.
- The solution formulation was relatively stable at controlled room temperature and refrigeration, with less than 6% degradation over 12 months.
- Exposure to light caused significant degradation, with API content dropping to 15% at the end of the study.

3.3. Stability of Drug C (Suspension)

Time (Months)	25°C/60% RH	40°C/75% RH	5°C	Exposure to Light
0	100%	100%	100%	100%
3	97%	88%	98%	95%
6	95%	80%	97%	90%
9	92%	72%	96%	85%
12	90%	65%	95%	80%

Discussion

- Drug C (suspension) exhibited moderate degradation under accelerated conditions, retaining 65% of its API content after 12 months.
- Refrigeration provided the best stability for this suspension, with only 5% degradation observed at 12 months.
- Exposure to light caused a moderate reduction in API content, dropping to 80% after 12 months.

4. Discussion

The data presented demonstrate that different dosage forms have varying levels of stability depending on the storage conditions. As expected, accelerated conditions (40°C/75% RH) led to faster degradation of all three drugs, with Drug B (aqueous solution) being the most affected. In contrast, refrigeration (5°C) helped maintain stability, particularly for suspensions and tablets. Exposure to light was a critical factor for solution and suspension forms, highlighting the need for light-protective packaging.

These results suggest that specific storage recommendations should be tailored to each dosage form, with refrigeration and light protection being particularly important for sensitive formulations.

5. Conclusion

The stability of pharmaceutical preparations is significantly impacted by storage conditions, with temperature, humidity, and light exposure playing critical roles. Accelerated conditions led to increased degradation of active pharmaceutical

ingredients, particularly for solutions, while refrigeration offered better stability for most formulations. Light protection is essential, especially for solutions and suspensions. Pharmaceutical manufacturers should consider these factors when recommending storage conditions and designing packaging materials to ensure product stability throughout its shelf life.

6. References

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