

Moisture-Induced Degradation in Pharmaceuticals: Mechanisms, Excipient Selection, and Strategies for Stability Enhancement

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ABSTRACT

Background: Moisture induced degradation significantly influences the physicochemical stability of pharmaceutical formulations leading to reduced potency, and therapeutic efficacy. **Objectives:** This study methodologically examines the degradation mechanisms resulting from exposure to moisture, as well as the stability of formulation under various relative humidity conditions, also, the study considers advanced stabilization methods. **Materials and Methods:** Griseofulvin based formulations were stored at different temperature and relative humidity as per ICH and WHO guideline for accelerated stability, moisture sorption and microbiological studies. Karl Fischer titration, Thermogravimetric Analysis (TGA) and Near-Infrared (NIR) spectroscopy were used to determine the moisture content. **Results:** The physicochemical properties of the formulations were affected by moisture and showed reduced tensile strength and rate of dissolution ($p < 0.05$). Microbial growth increased the disintegration time and reduced hardness. After six months of packaging tests, cyclic olefin and HDPE blisters showed a high degree of moisture protection, with less than 2.9% of moisture uptake and more than 97% of drug activity retention. **Conclusion:** The findings demonstrate the significance of moisture-resistant excipients, hydrophobic coatings, and higher quality packaging in maintaining formulation stability. Future development should focus on novel packaging materials, nanocoatings and process analytical technologies for the real-time humidity control.

Keywords: Excipient compatibility, Stability study, Moisture sorption, Moisture degradation, Nanocoating, Pharmaceutical packaging.

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INTRODUCTION

Pharmaceutical dosage forms are affected by undesirable changes when exposed to a humid atmosphere before they are administered. These changes are caused by molecular changes, like hydrolysis, oxidation or reactivity with other components of the formulation or the environment. Active Pharmaceutical Ingredients (APIs) and formulations are extremely sensitive to moisture and this can produce physical and chemical changes that affect the pharmacokinetic and pharmacodynamic properties, which can affect therapeutic efficacy and safety. Humidity, an unavoidable issue of the environment, plays a major role in the stability, quality and efficiency of pharmaceuticals. Moisture has two effects on drugs: physical and chemical. Physically, it may alter the crystallinity and porosity, hence affecting the

rate of dissolution and bioavailability (Chaudhari & Patil, 2012). Chemically, moisture can act as a catalyst for hydrolysis processes, resulting in the interruption of active pharmaceutical ingredients and excipients. Such chemical modifications not only challenge the drug's therapeutic performance, but may also result in the creation of toxic contaminants, posing potential concerns to patient safety (Malamataris *et al.*, 1991). According to ICH recommendations, when relative humidity levels reach 60% or more, viruses, bacteria, mould, fungi, and mites may grow, further affecting the quality and safety of the drugs (Arundel *et al.*, 1986). Excess moisture may disrupt the pharmaceutical manufacture process by making the pharmaceutical products clump, stick, or clog their machinery thus leading to disruption of the production process. On the other hand, intense low humidity may cause the amount of static and over-drying and consequently lowering the solvent performance during the manufacturing process. Physical and chemical instability can be caused by moist exposure in semisolid dosage forms, which include creams, ointments, gels, and pastes. It can physically cause the phase separation in emulsions by interfering with the oil-water balance. Moisture can chemically promote hydrolysis of APIs that are sensitive,



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especially esters and amides and reduce medicinal activity. Drugs that are hygroscopic are the most sensitive because they can readily pick up the water in the atmosphere as shown in Figure 1 (Durig & Fassihi, 1991).

A novel aspect of this paper is its cross-sectional analysis of different dosage forms, excipients, and polymer systems under various humidity conditions, including detailed description of commonly used drugs and their specific degradation mechanisms (Table 1). Furthermore, the article distinguishes itself by aligning analytical methods (e.g., Karl Fischer titration, TGA, NIR spectroscopy) with regulatory frameworks like those from United States Food and Drug Administration (USFDA), European Medicines Agency (EMA) and International Council for Harmonisation (ICH), highlighting the role of stability testing and Good Manufacturing Practice (GMP) in moisture control. The emerging strategies such as co-crystallization, encapsulation and innovative packaging technologies, that are rarely covered in one united review. This paper serves as a novel reference point for researchers, formulation scientists, and regulatory professionals seeking to design and evaluate moisture-resistant drug products with prolonged shelf-life and optimized therapeutic outcome. This review presents a distinctive and integrative perspective on moisture-induced degradation of pharmaceutical formulations that sets it apart from earlier works, which often addressed moisture as a secondary factor in broader stability discussions. Unlike previous literature that mainly focused on hydrolytic degradation or packaging aspects in isolation, this review widely unpacks both chemical (hydrolysis, oxidation, polymorphic transitions) and physical (agglomeration, crystallization, microbial contamination) effects of moisture exposure across a range of dosage forms, including tablets, capsules, and semisolids. It uniquely correlates these degradation mechanisms to their pharmacokinetic and pharmacodynamic impacts, openly linking moisture interaction with loss of drug potency, efficacy, and patient safety (Frank *et al.*, 2014).

THE EFFECT OF MOISTURE ON FORMULATION STABILITY

The stability of pharmaceuticals formulations is extremely related to its potency, purity, effectiveness, and safety across its entire shelf life. Stability indicating methods are essential for determining potency and stability. The therapeutic efficacy of a formulation is determined by its potency, with greater accuracy, resulting in enhanced patient compliance. Stability of pharmaceutical formulations, safeguards a drug's chemical composition and efficacy over time and environmental conditions. The implementation of strict drug potency analysis along with stability tests forms one of the fundamental requirements, regulatory compliance and quality assurance in pharmaceutical manufacturing as shown in Figure 2 (Veronica *et al.*, 2021).

Experimental Methodologies

Accelerated Stability Studies

Stability study is one of the significant parameters for the development of new drugs formulations and dosage form. Most of the researches must be carried out the stability study according to the guidelines issued by ICH and WHO. In this review, griseofulvin had been prepared using microcrystalline cellulose, mannitol, lactose or dibasic calcium phosphate. Samples were stored on up to four weeks in five humidity levels and accelerating temperatures. Tensile strength, porosity, contact angle, disintegration and dissolution tests showed that increased humidity inhibited dissolution and the importance of moisture in drug release. This research focused on the significance of stability tests in determining the safety, efficacy and the factors that affect the performance of tablet (Maclean *et al.*, 2023).

Microbiological Studies

The growth of microorganisms on various levels of moisture may have an impact on drug safety and stability. Tablets and capsules are the primary examples of solid dosage forms, which are not thoroughly monitored in terms of microbial contamination. Common excipients like lactose and starch have been found to contain *Geotrichium*, *Aspergillus* spp. and *Staphylococcus aureus*. In tablets with 5% starch binder, microbial activity increased disintegration time and decreased hardness, highlighting that excipient contamination can significantly affect physical properties and bioavailability.

Moisture Sorption Studies

Moisture analysers, such as Dynamic Vapour Sorption (DVS) and gravimetric techniques, measure drug moisture adsorption by exposing formulations to variable humidity while monitoring stability and physicochemical changes. In furosemide tablets stored under high temperature and humidity for 20 days, moisture absorption reduced hardness and disintegration time, particularly on the first day, then stabilized. While hardness decreased, melting parameters remained mainly unchanged except under dangerous conditions, the changes correlating with amount of absorbed water (Akbuga & Gürsoy, 1987).

Physical and Chemical Characterization

Analytical technique such as Fourier Transform Infrared spectroscopy (FTIR), Differential Scanning Calorimetry (DSC) and Thermogravimetric Analysis (TGA) or moisture-specific analytical balances to determine moisture-induced degradation caused changes in the physical properties of drugs. These methods are used to evaluate changes in thermal behavior, weight loss during drying or moisture changes in pharmaceuticals (Dos Santos Silva *et al.*, 2018).

EFFECTIVE CONCENTRATION 50% (EC_{50}) OR EFFECTIVE DOSE 50% (ED_{50})

These terms refer to the amount or concentration of a drug needed to have half of its maximum effect in a biological system.

EC_{50} is commonly used for measuring the potency of drug in *in vitro* studies, while ED_{50} is used for *in vivo* studies (in living organisms) (Singh *et al.*, 2020).

Toxic Dose 50% (TD_{50})

TD_{50} represents a drug dose that is toxic to 50% of the test population. It is often used in toxicology studies to assess the relative toxicity of different compounds (Sills & Brodie, 2009).

Lethal Dose 50% (LD_{50})

Lethal Dose 50% is the amount of a drug that kills half of the people who take it. It is a way to measure how toxic something is usually evaluated in animal studies (Chinedu *et al.*, 2013).

Minimum Effective Dose

The minimum effective dose is the least amount of a drug that works for a certain percentage of people. It is an important consideration in clinical practice for determining the optimal dosing regimen (Kang & Lee, 2009).

METHODS FOR ASSESSING MOISTURE-INDUCED DEGRADATION

Karl Fischer Titration

Widely considered as the gold standard for moisture analysis, evaluates moisture content directly by reaction with water. It

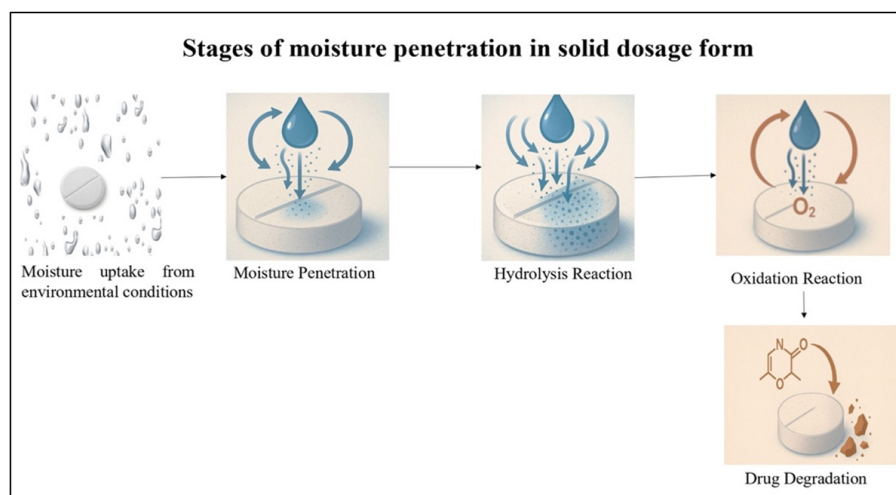


Figure 1: Moisture induced degradation in pharmaceutical solid dosage form.

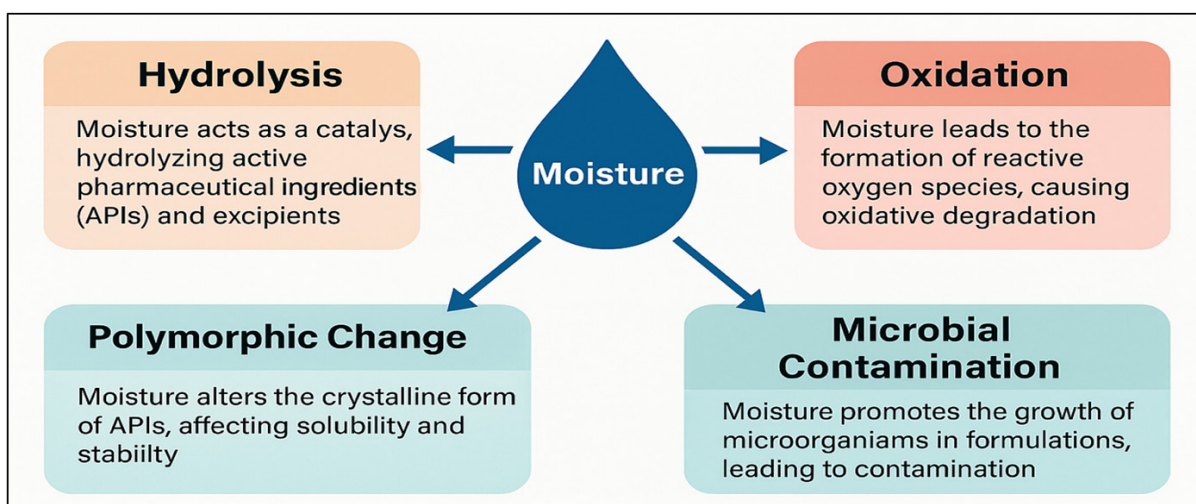
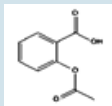
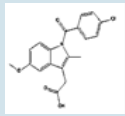
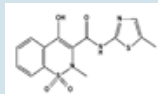
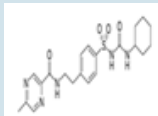


Figure 2: Effect of Moisture on Drug Stability and Relation to Chemical Interactions. Moisture influences drug degradation through multiple chemical pathways including hydrolysis, oxidation, polymorphic transitions, and microbial growth, ultimately compromising the stability, efficacy, and safety of pharmaceutical formulations.

Table 1: Different Drugs Susceptibility to Moisture-Induced Degradation.

Drugs Category	Drugs Example	Chemical Structure	Susceptibility to Moisture-Induced Degradation
Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	Aspirin		Aspirin is highly susceptible to moisture-induced hydrolysis of its ester group, forming salicylic and acetic acids. Humidity accelerates degradation and may promote oxidation and impurity formation. High moisture can also cause agglomeration and crystallization, affecting dissolution and bioavailability (Abd-El-aziz <i>et al.</i> , 2021).
	Indomethacin		Indomethacin is prone to moisture-induced degradation. Its carboxylic acid group (RCOOH) reacts with water, initiating hydrolysis that produces inactive metabolites. Hydrolysis can also cause ring-opening, forming cyclic hemiacetals with altered pharmacological properties (García <i>et al.</i> , 2006).
	Meloxicam		Meloxicam, which belongs to the oxicam class, is likely to break down when it comes into with moisture. Water molecules can easily attack its carboxylic acid group, which breaks bonds and breaks down molecules. Other functional groups, including the amide bond and the aromatic ring, also break down when they come into contact with water through hydrolysis or other chemical reactions (Xu <i>et al.</i> , 2014).
Anti-diabetics Drugs	Glipizide		Glipizide is an oral sulfonylurea that is used to treat type 2 diabetes. Its Sulfonamide (-SO ₂ NH ₂) and Carbonyl (-C=O) groups make it very sensitive to damage caused by moisture. When these functional groups get into contact with water, they are likely to undergo hydrolytic processes, which break bonds and create degradation products. Water weakens the bonds between sulphur and oxygen atoms, which makes molecules break down (Ranasinghe <i>et al.</i> , 2022).

incorporates titration of the sample with reagent that has iodine and sulphur dioxide which reacts selectively with water to give an electrical signal that is proportional to its concentration. This specific and sensitive technique can be used in a large variety of drug preparations like tablets, powder and capsules and it gives very precise moisture measurements (Patel *et al.*, 2023).

Loss on Drying (LOD)

This is a gravimetric method of identifying the amount of moisture available in the form of weight loss of a sample under heat. The substance is subjected to heating states so that moisture is eliminated. The variation in weights prior to heating and after heating is the one that represents the content of moisture.

Near-Infrared Spectroscopy (NIR)

Moisture is measured indirectly using NIR spectroscopy by analysing the sample's absorption of near-infrared light. A calibration model correlates the absorption spectrum with known moisture levels. NIR is non-destructive, fast, and appropriate for in-line or at-line monitoring in manufacturing processes (Marin & Moore, 2024).

Moisture-Specific Analytical Balances

Specialised moisture analysers or balances use the loss-on-drying principle but have accurate temperature and humidity control. These instruments heat the sample and constantly measure weight variations until a stable weight is obtained, indicating moisture removal. These techniques are required to maintain the quality and stability of drugs, as accurate determination of moisture content is critical in maintaining the desired properties of the finished formulations (Dhondale *et al.*, 2023).

STUDIES TO OVERCOME MOISTURE-RELATED POTENCY LOSS

Four formulation strategies have been developed to address the hygroscopicity of oral solid dosage forms: film coating, spray drying (encapsulation), co-processing and co-crystal engineering. Film coating and encapsulation act as protective barriers between the hygroscopic core and the environment, while co-processing introduces moisture-repelling excipients to reduce water uptake. Co-crystallization modifies crystal packing with stabilizing co-formers to enhance stability. Among these, coating and co-crystallization are the most commonly used approaches for hygroscopic pharmaceuticals (Ng *et al.*, 2022).

This study aimed to develop and evaluate a moisture-resistant film coating using HPMC–Avicel (microcrystalline cellulose) and compare it with Sepifilm, a commercial coating for moisture-sensitive tablets. HPMC films were prepared by solvent evaporation with 10–40 wt% Avicel and 5 wt% stearic acid as a plasticizer. The optimal formulation was applied to aspirin tablets via spin-casting and fluidized bed coating. Coated tablets were stored at 40°C/75% RH for two months and analyzed after 30 and 60 days for drug release, disintegration, hardness, and aspirin content. Stearic acid enhanced the mechanical strength, as well as flexibility, and avicel reduced water permeability. HPMC film with 30 wt. Avicel and 5 wt. stearic acid were used that showed the same performance as Sepifilm, which had good moisture protection and stability (Abbaspour *et al.*, 2010).

Stable packaging (<10% strength loss) was achieved for a moisture-sensitive tablet formulation stored under accelerated conditions for six months. Moisture content measured 2.3% at 25°C/60% RH, 2.4% at 30°C/60% RH, and 2.9% at 40°C/75% RH. Product stability was predicted using equilibrium moisture content, decomposition rate of unpackaged tablets, and packaging barrier properties. Physical and chemical stability were evaluated by HPLC at intervals up to 24 weeks under ICH conditions. Moisture permeability values for polyvinyl chloride, cyclic olefin, Aclar, and cold-formed aluminium blisters were 0.259, 0.040, 0.008, and 0.001 mg/blister/day, respectively. After six months, remaining drug activity was 84% for PVC, 91% for cyclic olefin, and 97% for clear blisters, while high-density polyethylene bottles with induction-sealed membranes maintained 99–100% activity, demonstrating superior moisture protection (Allinson *et al.*, 2001).

GUIDELINES FOR GOOD MANUFACTURING PRACTICES (GMP)

Process Validation of Finished Drug Products

The FDA has issued requirements about finished drug product process validation requirements, which has incorporated Performance Attribution Testing (PAT) as a structure or new way of developing pharmaceuticals, producing regulatory evaluation (Iacocca *et al.*, 2010).

21 CFR Part 211 Current Good Manufacturing Practice for Finished Products

21 Regulations of FDA CFR Part 211 provides briefs of the minimum current good manufacturing practices in drug product preparation that takes into account the control of the components and container and closures of drug products.

INNOVATIVE ASPECTS AND FUTURE DIRECTIONS

An emerging development in pharmaceutical manufacturing focuses on implementing advanced manufacturing technologies and innovative approaches to minimize the impact of moisture on drug formulations. Future research will focus on developing moisture-resistant excipients, including novel polymers and co-crystals, that limit water uptake by Active Pharmaceutical Ingredients (APIs). In addition, coatings and encapsulation techniques based on nanotechnology provide more effective barriers against humidity, which minimize hydrolysis and other related degradation mechanisms. Smart packaging with innovative materials will enhance integrity of products by adding in-time humidity sensors and built in desiccants. The recent development of analytic technologies, including moisture specific sensors, real-time monitoring equipment and Process Analytical Technology (PAT) equipment like near-infrared spectroscopy enables continuous moisture regulation in production. Compression coating and hot melt coating methods of dry coating are promising aqueous coating alternatives to the moisture sensitive drugs. The further evolution is dedicated to the development of particular effective approaches that would help to avoid degradation processes of pharmaceutical formulations under the influence of moisture and provide more stability, potency and extended shelf life (Heidemann & Jarosz, 1991).

CONCLUSION

Moisture is a major problem in pharmaceutical industry, which affects the stability, potency and performance of pharmaceutical formulations during the self life. Hydrolysis, oxidation, polymorphic transitions and microbial contamination that leads to poor bioavailability, loss of efficacy and potential toxicity are some of the degradation processes that can be initiated by exposure to moisture during manufacturing, storage and other processes. Formulation, processing, and packaging are also important to control because of the sensitivity of Active Pharmaceutical Ingredients (API). Semi solid and liquid moisture forms can cause destabilization of emulsions as well as altering viscosity and facilitating microbial growth. The stability testing that is based on humidity is mandatory in Good Manufacturing Practice (GMP) and Quality by Design (QbD) in many regulatory agencies such as FDA, EMA, and ICH to regulate moisture. There are analytical procedures like Karl Fischer titration, Loss on Drying (LOD), Thermogravimetric Analysis (TGA) and Near Infrared Spectroscopy (NIR) to determine precisely the content of moisture in the product to determine stability. The protection of solid dosage forms is enhanced with the help of modern methods, such as co-crystallization, hydrophobic coating, moisture barrier films. Furthermore, there are new packaging materials like blister packed with cold-formed aluminium, polyethylene containers with high density and cyclic olefin polymers, which were found

to be very resistant to moisture ingress. These are scientific, technological and regulatory methods that assure stability, safety and efficacy of moisture sensitive pharmaceutical preparations.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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