Mediterranean Journal of Pharmacy & Pharmaceutical Sciences
ISSN: 2789-1895 online
www.medjpps.com
doi: 10.5281/zenodo.18928651
ISSN: 2958-3101

REVIEW Article

Drugs' stability in tropical climates: Formulation challenges, degradation pathways, and mitigation strategies

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Received: 06-01-2026, **Accepted**: 03-03-2026, **Published online:** 10-03-2026

HOW TO CITE THIS
Yasmin et al. Drugs' stability in tropical climates: Formulation challenges, degradation pathways, and mitigation strategies. Mediterr J Pharm Pharm Sci. 2026; 6(1): 83-92. [Article number: 245]. https://doi.org/10.5281/zenodo.18928651

Keywords: Drug degradation, ICH climatic zones, pharmaceutical stability, tropical areas

Abstract: Throughout a product's shelf life, the stability of pharmaceuticals (drugs) is a crucial factor in determining drug safety, efficacy, and quality. In tropical areas, where high relative humidity and high temperatures speed up chemical, physical, and microbiological degradation processes, the problem is more prevalent. Several countries in Asia, Africa, and Latin America are located in climatic zones III and IV of the International Council for Harmonization, where traditional packaging systems and formulations designed for temperate climates frequently fall short of stability standards. This review offers a comprehensive discussion of how tropical weather affects pharmaceutical dosage forms, with a focus on formulation-related issues, drug degradation pathways, and workable mitigation techniques. This article will serve as a practical reference for formulation scientists, and quality professionals working in tropical markets.

Introduction

Pharmaceutical items are designed to maintain their identity, strength, quality, and purity during the shelf life. As a result, stability is an essential need for regulatory approval and medicine development. If a drug product's physical, chemical, microbiological, or therapeutic properties alter while it is being kept, patient safety and treatment outcomes might be at risk. Stability problems exist worldwide, but they are more severe in tropical and subtropical areas because of the extreme climatic conditions [1, 2]. High relative humidity (>65%) and high ambient temperatures (>30°C) are characteristics of tropical climates. Pharmaceutical product physical instability and degradation reactions can be greatly accelerated by these circumstances. Formulations that were developed and optimized in temperate regions may operate effectively under moderate settings but fail when exposed to tropical environments during shipment, storage, or use [3-5]. The expiration date of pharmaceutical dosage form is influenced by some environmental elements, including temperature, humidity, light, radiation, physical and chemical active ingredients in the formulation, and the kind of container employed and storage conditions. Adequate analytical techniques are available together with literature data on the degradability and breakdown process of active compounds [6]. Pharmaceutical analysis and stability studies, which are necessary to ascertain and guarantee the identity, potency, and purity of ingredients, and those of the manufactured products, are the crucial phases during the developing stages [7, 8]. Pharmaceutical products are marketed across several climate zones due to the growing globalization of drug production and distribution. This has led to an increasing need to comprehend and deal with stability issues. Drug stability in tropical regions is the main topic of this review, which highlights formulation difficulties, degradation mechanisms, regulatory issues, and mitigation techniques that can enhance product performance and patient safety.

Tropical climatic conditions: The International Council for Harmonization (ICH) has divided the world into various climate zones according to the average temperature and humidity levels to standardize stability testing regulations. Chiefly, accelerated and long-term (real-time) stability testing is performed in most cases (**Figure 1**). Long-term and accelerated stability studies are designed using these zones as a reference.

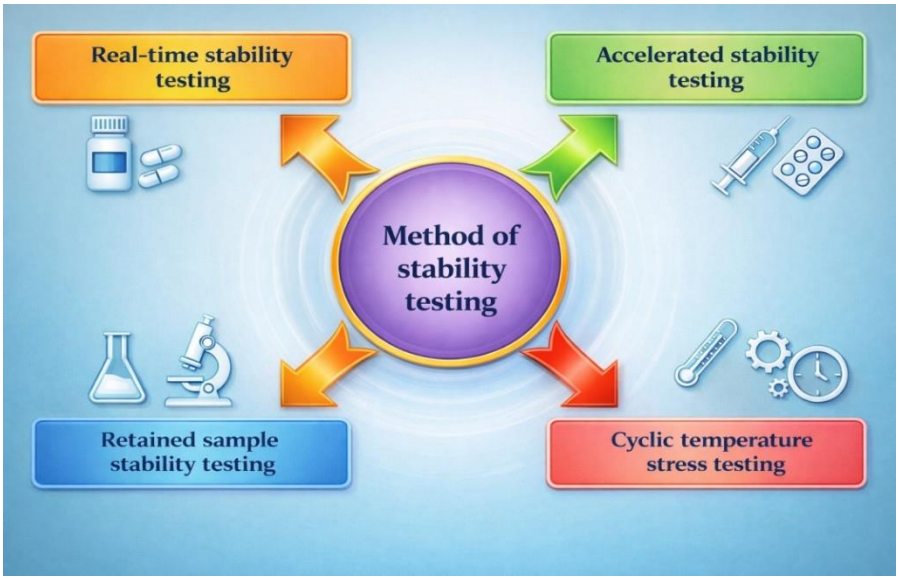

Figure 1: Different methods used to examine drug stability

Four climatic zones were defined: Zone I: Temperate climate, Zone II: Subtropical and Mediterranean climate, Zone III: Hot and dry climate, and Zone IV: Hot and humid climate. Later, Zone IV was split into Zone IVb (hot and extremely humid, 30°C/75% relative humidity) and Zone IVa (30°C/65%). Zone IVb includes the majority of tropical countries, such as Bangladesh, India, Sri Lanka, Thailand, Indonesia and several African countries. Pharmaceutical stability is hampered by the circumstances in Zones III and IV, for medications that are thermolabile and moisture-sensitive. High humidity encourages microbiological growth, hydrolytic breakdown, and physical alterations such as caking, swelling, and altered dissolving rate. Higher temperatures speed up chemical reactions and diffusion processes by increasing molecular mobility.

Stability testing conditions: New revisions have been made to the ICH guideline Q1A (R2) for stability tests, which was finalized in 2003 and amended in 2005 (withdrawing chapter Q1F, which describes additional stress testing conditions in Zones III and IV). Following the removal of chapter Q1F, the Association of South East Asian Nations (ASEAN) members have presented their own technical dossier according to the ICH rules and modified the testing circumstances to accommodate their respective climates. The ASEAN ICH norms are being enforced throughout the ASEAN nations [9]. The ASEAN nations provide as a clear illustration of how the testing standards will grow progressively stricter and more detailed. There is talk of individual breakthroughs from different nations to investigate testing procedures under different climatic conditions or more stringent testing circumstances. The pharmaceutical sector establishes new benchmarks for the stability testing of medicinal products. Being ready for the needs of the future is a problem for pharmaceutical businesses and testing equipment vendors [10]. The real conditions are governed by chapter Q1A (R2) for climatic stability testing and chapter Q1B for light stability testing, following the most recent revision and implementation for ICH stability testing. New regional testing circumstances were established for the long-term stability tests to be conducted in the ASEAN countries with the establishment of the ICH rules for ASEAN, which are classified as Zone IVb [9, 11]. Pharmaceutical product stability testing under ambient, refrigerated, and frozen storage settings is governed by Chapter Q1A (R2), **Table 1**. The ICH rules mandate accelerated testing settings for all storage conditions (frozen, refrigerated, and ambient) in addition to long-term stability testing of various storage conditions. If the rapid testing reveals unacceptable degradation, intermediate testing is required (**Table 2**).

Table 1: Long-term testing conditions

Climate zone	Temperature	Humidity (r=Relative)	Minimum duration
Zone I	21°C±2°C	45% rH±5% rH	12 months
Zone II	25°C±2°C	60% rH±5% rH	12 months
Zone III	30°C±2°C	35% rH±5% rH	12 months
Zone Iva; **Zone IVb**	30°C±2°C; 30°C±2°C	65%rH±5% rH; 75% rH±5% rH	12 months
Refrigerated	5°C±3°C	No humidity	12 months
Frozen	- 15°C±5°C	No humidity	12 months

Table 2: Accelerated testing conditions

Climate zone	**Temperature**	**Humidity (r=Relative)**	**Minimum duration**
Accelerated ambient	40°C±2°C	75% rH±5% rH	6 months
Accelerated refrigerated	25°C±2°C	60% rH±5% rH	6 months
Accelerated frozen	5°C±3°C	No humidity	6 months
Intermediate	30°C±2°C	65% rH±5% rH	6 months

Climatic zones: Northern Europe, Canada, and the Northern areas of the United States are examples of regions with temperate (Zone I) climates. Products kept in cold environments are subjected to stability testing under Zone I conditions. The temperatures and humidity in these regions are moderate. Zone II includes countries in Southern Europe, portions of Japan, and the central United States. Products evaluated in these regions should be stable in environments that are fairly warm and humid (**Figure 2**). High temperatures and low humidity can have an impact on pharmaceutical items' volatile components, coatings, and packaging materials. Stability studies under Zone III ensure product robustness against heat stress. This climatic group includes sections of Africa, the Middle East, and some areas of India. Climate Zone IVa includes nations including southern India, Thailand, and Indonesia (**Table 3**). Because of the high humidity in these places, the product may absorb moisture and develop microorganisms. These parameters are met by testing at 30°C and 65% humidity. Later, Zone IVb was added to represent tropical areas like Singapore, Malaysia, and the Philippines. The most difficult stability conditions are found in this zone. Many studies assured that the product is stable in high humidity at 75% RH.

Table 3: List of countries with tropical climatic zones

Country	Climatic zone	Assigned to zone
Bangladesh	IVa	IVa
Barbados	IVb	IVb
Belize	IVa	IVa
Bolivia	II, IVb	IVb
Zimbabwe	IVb	IVb
Tonga	II, IVa	IVa
United Arab Emirates	IVa	IVa
Tanzania	II, IVb	IVb
Thailand	IVb	IVb
Uganda	IVa	IVa
Saudi Arabia	II, III, IVa	IVa
Qatar	IVa	IVa
Nicaragua	IVa	IVa
Gabon	IVa	IVa
Columbia	IVb	IVb
Congo	II, IVa	IVa
Fiji	IVa	IVa
Hong Kong	IVa	IVa
India	III, IVa	IVa
Indonesia	IVb	IVb
Kenya	II, IVa	IVa
Malaysia	II, IVb	IVb
Maldives Islands	IVa	IVa

Myanmar	IVb	IVb
Niger	II, IVa	IVa
Pakistan	II, III, IVa	IVa
Philippines	IVb	IVb
Senegal	IVa	IVa
Somalia	IVa	IVa
Singapore	IVb	IVb
Sri Lanka	IVa	IVa
Vietnam	IVb	IVb
Yemen	II, IVa	IVa
Venezuela	II, IVb	IVb
Peru	IVb	IVb
Paraguay	IVa	IVa
Oman	IVa	IVa
Nigeria	IVb	IVb
Kuwait	IVa	IVa
Jamaica	IVa	IVa
Ghana	IVb	IVb
Ivory Coast	IVa	IVa
Laos	IVb	IVb
Liberia	IVa	IVa
Madagascar	II, IVa	IVa
Mali	III, IVa	IVa
Panama	IVb	IVb
Togo	IVb	IVb
Benin	IVa	IVa
Bahrain	III, IVa	IVa
Brazil	II, IVb	IVb
Cuba	IVb	IVb
Central African Republic	IVb	IVb
Cameron	IVb	IVb
Ethiopia	II, IVa	IVa
Ecuador	I, II, IVa	IVa
El Salvador	IVa	IVa
Guyana	IVb	IVb

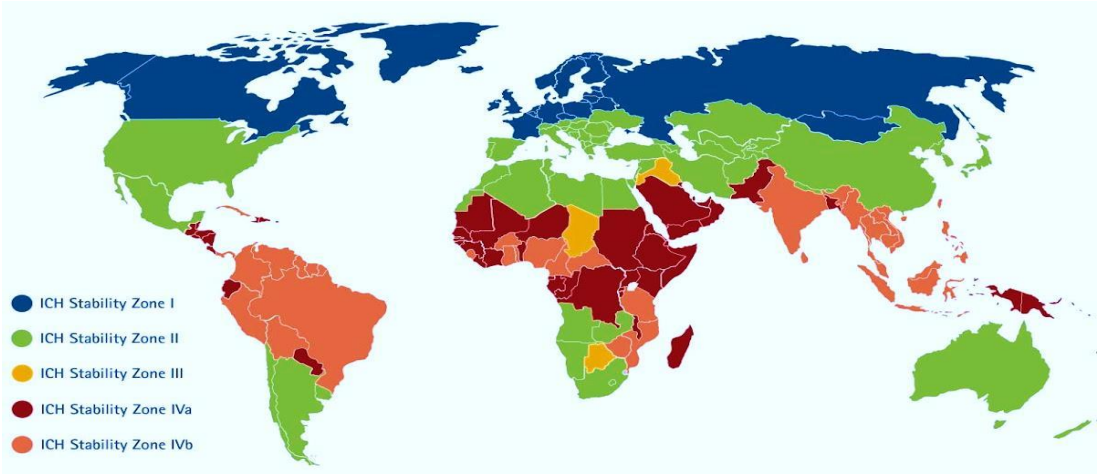

Figure 2: Different stability zones (ICH) across the world [12]

Environmental factors affecting stability in tropical regions: Temperature is one of the most significant factors influencing the stability of medications. According to the Arrhenius equation, the rate of chemical reactions increases exponentially with temperature. If excipients and active pharmaceutical ingredients (APIs) are exposed to temperatures above the recommended storage, temperature may quickly deteriorate in tropical regions [13, 14]. Thermolabile medications that are particularly vulnerable include hormones, antibiotics, and some biological products. Even solid dosage forms, which are usually more stable than liquids, may undergo polymorphic changes, excipient melting, or gelatin capsule softening at high temperatures [15].

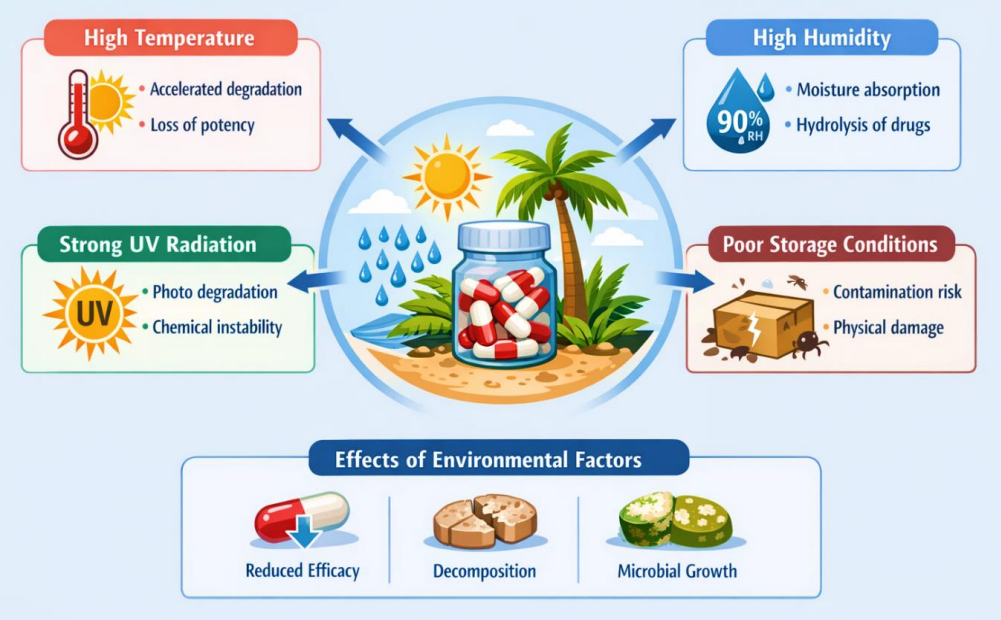

Figure 3: Environmental factors possibly affecting drug stability in a tropical climate

Tropical climates are characterized by high relative humidity, which plays an integral part in pharmaceutical instability (**Figure 3**). APIs and excipients can be chemically degraded by moisture acting as a reactant or catalyst in hydrolytic reactions. Materials that are hygroscopic easily absorb moisture from their surroundings, changing their hardness, friability, and disintegration time [16, 17, 18]. Moisture absorption can result in tablet swelling, cracking, or sticking in solid dosage forms and shell deformation or brittleness in capsules. Liquid and semi-solid formulations are also affected since increased water activity might promote microbial development [19]. Tropical areas frequently have high levels of sunlight exposure, which raises the possibility of photodegradation. Photosensitive medications may undergo chemical changes brought on by ultraviolet and visible light, which could lead to a potency reduction or the formation of hazardous products. This problem is made worse by inadequate packaging and unsuitable storage conditions [20, 21]. Drug molecules may react with oxygen, resulting in oxidation and deterioration. Drug instability is frequently caused by oxidation, which is frequently increased by temperature, light, and the presence of metal ions [22, 23, 24, 25]. Drug stability can be impacted by the environment or the pH in the drug formulation. Certain medications are sensitive to pH shifts and can break down quickly in acidic or alkaline environments.

Drug degradation pathways under tropical conditions: Pharmaceutical items are especially susceptible to deterioration in tropical environments, which are characterized by high temperatures, high humidity, and excessive sun exposure (**Figure 4**). Hydrolysis, oxidation, photo-degradation, and thermal degradation are common processes that result in potency loss and the creation of degradation products (**Table 4**).

Hydrolysis: One of the most prevalent degradation processes in tropical regions is hydrolysis. Functional groups such as esters, amides, lactams, and imides are especially vulnerable to hydrolytic cleavage. Because hydrolysis is greatly accelerated by high temperatures and humidity, moisture control is an essential step for formulation and packaging design [26, 27].

Oxidation: Drug molecules react with oxygen or reactive oxygen species during oxidative degradation. Light, heat, or trace metal contaminants can start or speed up this process. Discoloration, potency loss, and the formation of dangerous contaminants are all possible consequences of oxidation [22, 28].

Photo-degradation: A chemical process called photo-degradation occurs when drug molecules absorb light energy. One well-known adverse effect of drugs like riboflavin, nifedipine, and several corticosteroids is photosensitivity. In tropical regions, degradation can happen fast if there is not enough protection from the sun [29].

Physical instability: Tropical climates can lead to physical instability in addition to chemical deterioration. These include variations in viscosity in suspensions and gels, phase separation in emulsions, crystallization in amorphous systems, and polymorphic transitions. Drug release, bioavailability, and patient acceptability may all be affected by such modifications [3, 30].

Table 4: Drug degradation pathways and their impact

Degradation pathway	Tropical stress factor	Chemical mechanism	Susceptible drug moieties	Impact on drug quality
Hydrolysis	High humidity, elevated temperature	Cleavage of labile bonds by water (acid- or base-catalyzed)	Esters, amides, lactams, carbamates	Loss of potency, formation of inactive or toxic degradants
Oxidation	Heat, oxygen, light, trace metals	Electron loss via free radical or peroxide formation	Phenols, thiols, amines, unsaturated bonds	Reduced efficacy, discoloration
Photo-degradation	Intense sunlight, UV exposure	Photon-induced bond cleavage or rearrangement	Aromatic rings, conjugated systems	Rapid potency loss
Thermal degradation	Sustained high temperatures	Heat-induced bond breakage or rearrangement	Thermolabile functional groups	Denaturation, reduced bioactivity
Humidity-induced solid-state degradation	High relative humidity (>65%)	Increased molecular mobility and phase transformation	Hygroscopic solids, amorphous powder	Reduced stability, altered dissolution
Polymerization/ Aggregation	Heat, light, oxidative stress	Molecular cross-linking or aggregation	Peptides, proteins	Loss of biological activity, immunogenicity

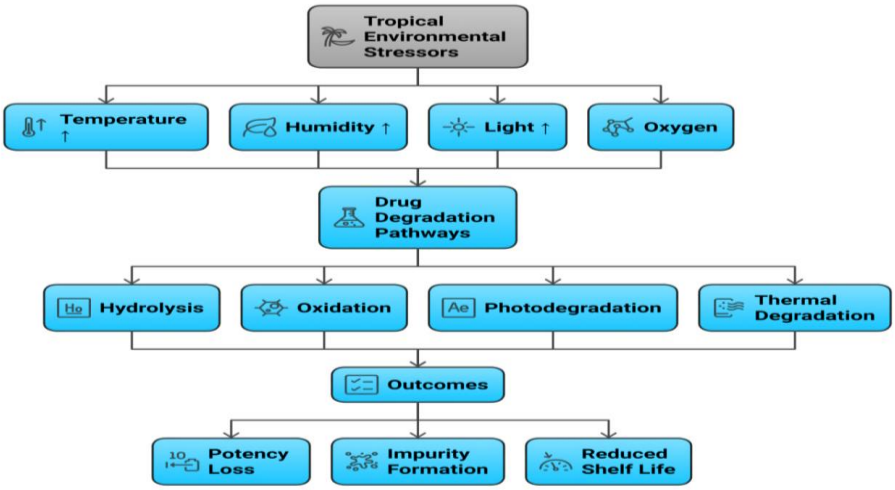

Figure 4: Causes of drug degradation with potential consequences

Solid dosage form: The most stable pharmacological formulations are typically thought to be solid dosage forms, such as tablets and capsules. However, high humidity can cause moisture absorption in tropical areas. This may alter dissolving profiles, enhance friability, and decrease hardness. Because gelatin capsules are susceptible to moisture, the environment can cause the shell to become either soft or brittle [15, 31].

Liquid dosage form: In tropical regions, liquid formulations-such as syrups, solutions, and suspensions-are more likely to have stability issues. Chemical structure breakdown is accelerated by high temperatures. High humidity promotes the growth of microorganisms. Preservatives may become less effective, increasing the possibility of contamination [32, 33].

Semi-solid dosage form: Under tropical circumstances, creams, ointments, and gels may experience contamination by microbes, phase separation, or viscosity changes. The dispersed phase may become unstable because emulsions are especially sensitive to temperature changes [34].

Challenges in stability-focused formulation: It is extremely challenging to develop formulations that need higher stability when they are subjected to oxidative, light, wet, or temperature stress. In addition to meeting

bioavailability, acceptability, and regulatory requirements, formulations must be stable in terms of both API chemical stability and dosage form physical stability. Apart from the incompatibility of the excipient, the formulation may be negatively impacted by changes in solid state and the contact between the closure system and container during storage, particularly in tropical or rapid storage circumstances [5, 35-38]. APIs that are prone to hydrolysis, like β-lactam antibiotics, necessitate strict moisture control by incorporating less water in formulations, packaging based on desiccants, and careful pH optimization. Rapid potency loss and the creation of inactive degradation products might result from improper management of residual moisture [39, 40]. Due to their vulnerability to heat-induced denaturation and aggregation, thermolabile biologics, such as proteins and vaccines, cause formulation problems. To maintain structural integrity and therapeutic efficacy, stabilization techniques such as buffer tuning, the use of cryoprotectants or cytoprotectants, and cold-chain storage maintenance are crucial [41].

Packaging and storage challenges: The pharmaceutical product's packaging acts as a primary barrier against the external environment. Standard packaging technology might not be an effective barrier against light, oxygen, and moisture in tropical regions. Despite its lack of good moisture protection, PVC blister packing has been used. Aluminum-Aluminum blister packaging has been considered superior and recommended increasingly in the tropics [42-44]. Containers made of high-density polyethylene, desiccants, or light-sensitive packaging may improve this issue. However, costs associated with packaging may play an important role, especially when considering generic drug manufacturers operating in developing nations [42, 45].

Formulation and packaging strategies for tropical climates: To overcome stability issues in tropical climatic conditions, several formulation and packaging strategies might be adopted (**Table 5**, **Figure 5**). These approaches involve using coatings that protect from moisture, using antioxidants and stabilizers, choosing less hygroscopic excipients, and using high-barrier packaging materials [46]. Reformulation of products to improve intrinsic stability may be necessary for particularly sensitive drugs. A combination of rational composition, suitable packaging, and regulated storage conditions can improve drug stability [47, 48].

pH adjustment: Changes in pH can affect the stability of a drug solution. Raising the pH can improve stability in some situations, while reducing the pH could be necessary in other situations.

Antioxidant: Antioxidants can help to stop the deterioration of drugs by scavenging free radicals and reactive oxygen species that could cause oxidation.

Suitable packaging: Appropriate packaging can improve the stability of a medication. For example, storing a medication in a sealed container with a desiccant inside can help prevent moisture from entering and causing degradation.

Chemical changes: In certain circumstances, altering a drug's chemical makeup can improve its stability. This could mean adding functional groups that can prevent deterioration or changing the formulation to a more stable one.

Using stabilizers: Stabilizers can be added to pharmaceutical formulations to help prevent degradation. These could include components like proteins, carbohydrates, or amino acids that help stabilize the drug molecule.

Freeze-drying: During the freeze-drying process, a pharmaceutical solution is frozen and then vacuum-dried. Eliminating water can help to stabilize the medication by lowering the chance of deterioration.

Conclusion: Pharmaceutical product stability studies are a crucial step in the development of new drugs and formulations. Departure from the defined stability profile may have an impact on its efficacy, safety, and quality. Pharmaceutical stability in tropical climates presents substantial challenges that require careful consideration during formulation, packaging, and regulatory submission. All dosage forms' physical stability and degradation mechanisms are greatly impacted by high temperatures and humidity. Pharmaceutical

scientists can increase product robustness, improve patient safety, and boost therapeutic effects in tropical settings by comprehending these difficulties and putting suitable mitigation techniques into practice.

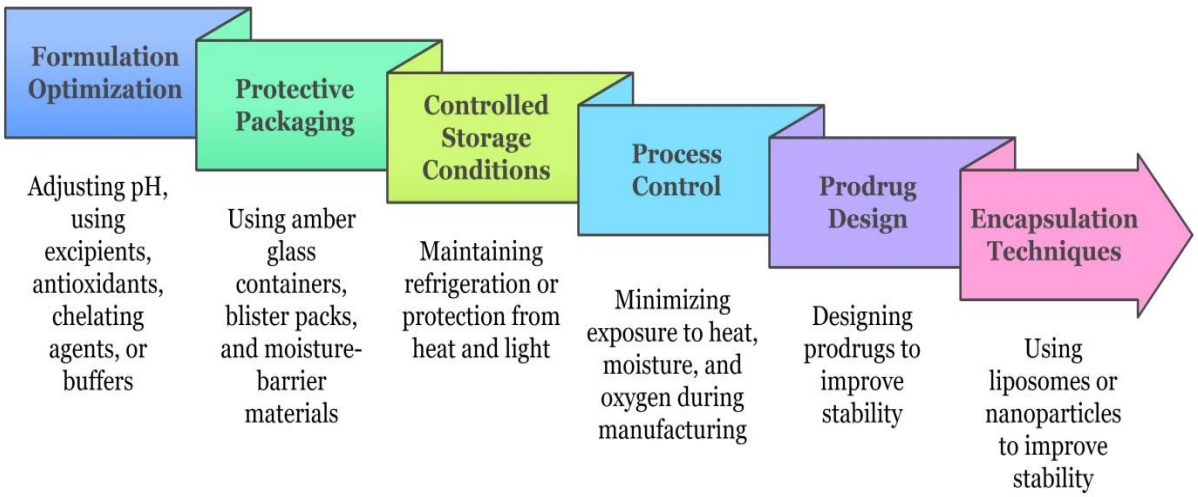

Figure 5: Drug degradation and mitigation strategies

Table 5: Formulation and packaging strategies to improve stability in tropical climates

Stability issue	Mitigation strategy	Examples
Moisture sensitivity	Use of desiccants, moisture-resistant blisters	Alu-Alu blister packs
Oxidative degradation	Antioxidants, inert excipients	Ascorbic acid, nitrogen flushing
Photo-degradation	Light-resistant packaging	Amber vials
Thermal instability	Cold-chain optimization and using stabilizers	Buffers, cryoprotectants
Excipient incompatibility	Compatibility screening is needed	Appropriate container–closure systems to minimize interactions
Physical instability	Optimization of particle size, surfactants, and stabilizing agents	Protection from temperature and humidity fluctuations, during storage
High temperature	Selection of thermally stable APIs, incorporation of stabilizers, optimization of formulation pH	Proper regulation of drug depot and cold storage

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Author's contribution: MFY & MH contributed to data analysis and all authors contributed equally, and approved the final version of the manuscript and agreed to be accountable for its contents.
Conflict of interest: The authors declare the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.
Ethical issues: The authors completely observed ethical issues, including plagiarism, informed consent, data fabrication or falsification, and double publication or submission.
Data availability statement: The raw data that support the findings of this article are available from the corresponding author upon reasonable request.
Generative AI disclosure: No Generative AI was used in the preparation of this manuscript.