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A Review on Climatic Change and Medicine Stability

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Abstract:
The stability ofmedicinal dosage preparation a critical component in testingdrug security, effectiveness, characteristics throughout the products shelf life. The issue is especially common in specific areawith increased temperature, relative humidity accelerate physical, chemical and microbiological degradation processes. Shelf life prediction essential consideration during development of pharmaceutical products in all dosage forms. Therefore, throughout pharmaceutical formulation, packaging, stability testing, storage and distribution, climatic zone is a key factor for impact on stability of drugs.
The goal of this studies for determining the relationship between changing weather and medications stabilityincluding change in temperature,relativehumidity along with additional environmental conditions. Solubility, drug potency, appearance, effectiveness, moisture content that all may impacted by climatic change which could harm therapeutic efficacy. Standardized conditions and methodsforcarryingoutstabilitytestsareprovidedbyICHandotherregulatoryguidelines.Inaddition to facilitating regulatory approval and global pharmaceutical products harmonization, proper use of ICH stability criteria encourages consistent product quality. Overall, climate change can affect reliability, shelf life of medicine.

Keywords: Stabilitystudies, Climatevariations, Productsshelflife, Drug Degradation, Pharmaceuticalquality

I. Introduction:

The stability assessment of therapeutic formulation maintain organoleptic, analytical, drug disposition featuresandpropertiesduringcourseofshelflifefromthetimeofmanufacture **[1].**Influenceof environmental stressors onconsistency, efficacy of medicine become primary concern for industry, which like other industrial sector, faces growing risk from a changing climate**[2].**

Stability studies were created to observe and evaluate the quality of Active Pharmaceutical Ingredients (API) and Finished Pharmaceutical Product (FPP) governed by multiple environmental parameters involving thermal conditions,atmospheric moisture,light, interaction between APIs and excipients, packaging of components, shelf life of drug or container closure system throughoutspecific time period **[3].**

According to United Nations Framework Convention on Climate Change (UNFCCC), long term changes in ambient conditions in the Earth's climate caused associated with human activities, which change the composition of atmosphere and occur in addition to natural variations in climate **[4].**

The key steps during drug discovery process includechemical characterization,stability profiling of medicinal products,which required for evaluating and ensuring the quality, desired effect,storage stability of drug products.Uniformity of medicinal product influenced by microbiological factors, including the multiplicationofmicroorganismsinnon-sterileproductsand alterationsinpreservativeeffectiveness.
Environmental variations altering global ecosystems and causing serious risk to medicinal plants, geographical distribution,andtherapeuticeffectiveness.
Variationsintemperature,rainfallpatterns, CO2level significantly influence the growth, survival, and phytochemical composition of medicinal plants**. [5]**

Climatic changeaffecting healthcare workers ahealth infrastructure, which limits their capacity to deliver universal health coverage (UHC).Sixth Assessment Report (AR6) of Intergovernmental Panel on Climate Change (IPCC) concluded that climate-related risks are emerging more rapidly and are expected to intensify sooner than previously predicted, while increasing global temperatures will make adaptation increasingly difficult. Climate alteration

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isassociatedwithprematuredeaths,increased diseaseburden,and worseningof existing health conditions, influencing various physiological systems, including circulatory, pulmonary , nephrological,and dermatological systems etc **[6].**

Pharmaceutical stability is the capacity of a drug substance or pharmaceutical product to retain its required quality, safety, efficacy, and mechanical, biochemical, sterility related properties throughout its intended shelf life. As outlined in ICH Q1A(R2), stability studies assess changes in the quality of drug products over time by examine how medicine respond to changes in temperature, air humidity, and light, thereby helping to determine their shelf life and recommended storage conditions. Excessive heat mayspeed up chemical decomposition and physical changes in pharmaceutical products. Increased humidity lead to moisture absorption, hydrolysis, changes in drug dissolution, and deterioration of moisture-sensitive formulations. Temperature fluctuations during storage and transportation can expose medicines to conditions beyond their recommended storage limits.**[7].**

Stability studies are conducted to assess changes in the quality of API or finished dosage forms over duration under various climatic conditions todeterminesuitablestorageconditionsandshelflife.
ICH stability guidelines recognize temperature and humidity is mainaffect the integrity,reliability of pharmaceutical products **[8].**

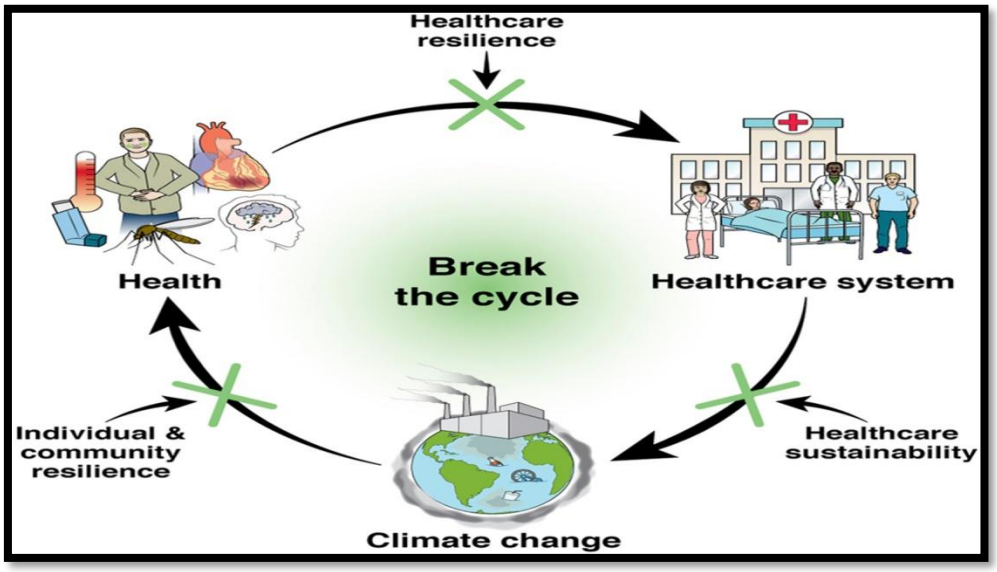


Figure 1: Climate alteration and its effect

Importance of stabilitytesting[9]

1. **Underdosing:** Instabilityof APIreduces the amount of drug present medicinal preparations over time.
2. **Patient safety:** Degradation of pharmaceutical product produce toxic or harmful effect ,influence patient safety.
3. **Determination of shelf life:** Stability studies generate scientific evidence that helps establish the shelf life and expiry date of pharmaceutical products.
4. **Selection of suitable packaging:** Stability testing help to determine whether the packaging system adequately protects the pharmaceutical productwhile storing and transportation.
5. **Regulatory compliance:** Stability result is important to regulatory approval and submissions, as they demonstratethatapharmaceuticalproductto maintain required standards of quality until it's expiry date.

Variousfactorsaffectingondrugstability[10]

1. **Temperature:** Increased speed of chemical transformation that are responsive to drugs degradation, possibly resulting in a reduction, and alteration in physical characteristics of pharmaceutical manipulators.As per Arrhenius equation, an increase in temperature accelerates extent of drug decomposition , such as hydrolysis and oxidation.
2. **Humidity/Moisture:** Exposure to moisture may accelerate degradation processes such as

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

hydrolysis and can adversely affect the physical properties of moisture-sensitive dosage forms, including changes in hardness, dissolution, appearance, and integrity

3. **Light:** Prolonged exposure to light, particularly ultraviolet radiation, may initiate photochemical reactions in light-sensitive drugs, resulting in degradation of API and a subsequent reduction in its therapeutic potency.

4. **pH:**The pHofa medicinal preparations isimportant factor inmaintaining drug stability. Inappropriate pH conditions may accelerate degradation reactions including hydrolysis and other pH-dependent chemical processes.

5. **Oxygen/Oxidation:** Exposure to atmospheric oxygen can initiate or accelerate oxidative reactions in susceptible drug substances and excipients, resulting in the production of breakdown compoundsand a possible reduction in purity,performance of the formulation.

6. **Physical Factors:** Various physical conditions, including agitation, particle size, crystal or polymorphic form, and physical changes in dosage form, can influence drug stability by affecting processes such as dissolution, diffusion, crystallization, and degradation.

7. **Packaging and Container-Closure System:** The selection and design of container closure materials are main for maintaining drug stability because an appropriate container-closure system can minimize the product's exposure to environmental factors which is moisture, oxygen, and light while keeping transportation.

8. **Microbial Contamination:** Microbial contamination can compromise grade, shelf life of pharmaceutical products, particularly aqueous and non-sterile formulations. Microbial growth may cause changes in product and also reduce the efficacy of antimicrobial preservatives.

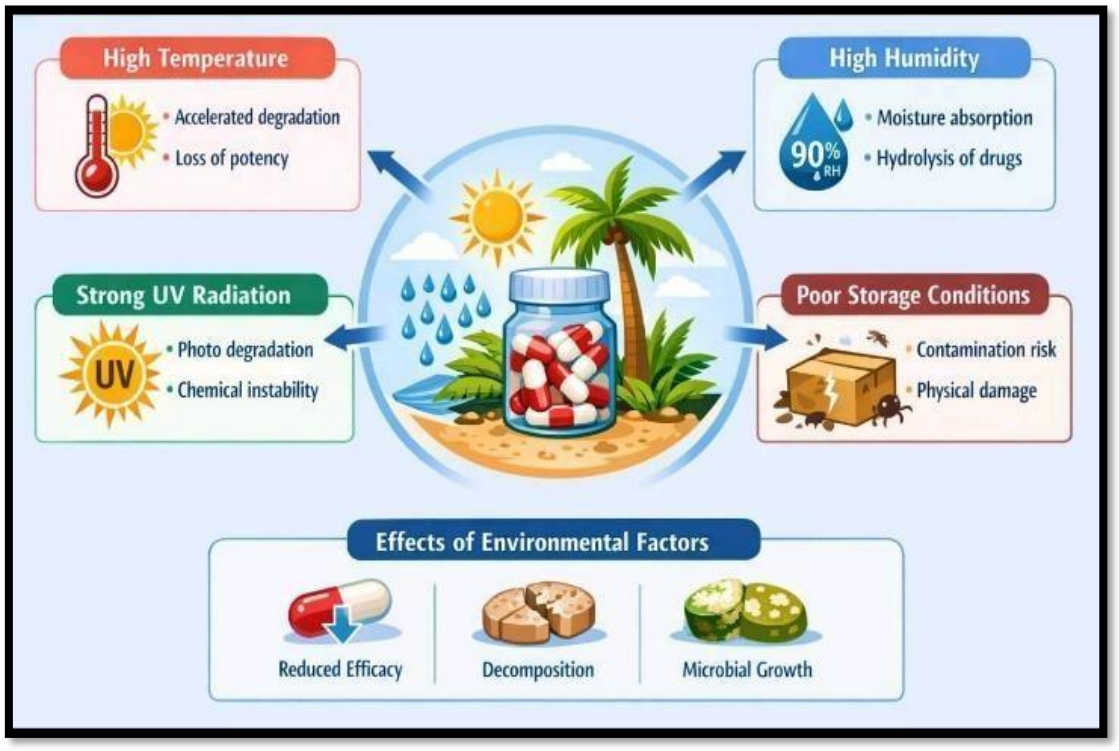


Figure 2:Variousfactorsaffectingondrugstability

Impact of climaticchangeonpharmaceuticaldosageform[11] [12]

1. SolidDosageForms(TabletsandCapsules)

Accelerated Disintegration and Dose Dumping: Increased ambient humidity can adversely affect hygroscopicand moisture-sensitive tablets, causing excessivemoistureuptake and premature disintegration or dissolution. In extended-release formulations, this cause dose dumping, from which drug is released rapidly instead of gradually, potentially increasing hazard toxic or adverse

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

effects.

Physical Alterations:

Elevated temperatures may cause gelatin capsules to soften, become sticky, and adhere to one another. These physical variations can alter their dissolution characteristics and may make the capsules unsuitable for use.

2. LiquidandSemi-SolidDosageForms(Solutions,Creams,andOintments)

PhaseSeparation:

Creams,ointments, andemulsionscanbesignificantlyaffectedby changes intemperature. Exposure to excessive heat may destabilize the emulsion, causing the oil and water phases to separate and resulting in non-uniform drug distribution.

Precipitation:

In liquid formulations, fluctuations in temperature can change the solubility of the drug substances. This may cause API to separate from the solution and form crystals, potentially affecting the product's quality and effectiveness.

3. BiologicsandSterileForms(Vaccines,Insulin,andInjections)

Thermal Degradation: Biological medicines, including vaccines, insulin, and blood-derived products are often sensitive to temperature changes and require proper cold-chain storage. Increased temperatures and prolonged heatexposurecanacceleratetheirdegradation,reducing orcompletelycompromisingtheirtherapeuticactivity.

Power Grid Failures: Unusualenvironmental events resulting with climate variations,particularly storms, floods, and wildfires, can disrupt electricity supplies and interrupt cold-chain systems in pharmacies, healthcare facilities, and homes. Such interruptions may cause temperature-sensitive sterile injectable medicines to deteriorate or become unsuitable for use.

4. PackagingandChemicalStability

Chemical API Degradation: Elevated temperature and humidity can faster chemical processes such as hydrolysis and oxidation, resulting in rapid deterioration of active pharmaceutical ingredients (APIs). This can shorten the product's shelf life and may cause the production of potentially harmful degradation products.

CompromisedPackagingBarriers:

Fluctuationsinhumidity canadverselyaffectthe integrityandprotective properties of blister packs and plastic containers. Damage or failure of these packaging barriers may allow moisture to enter and come into contact with the drug formulation, thereby promoting its degradation.

5. DirectFormulationandEnvironmentalImpact Summary

The following table illustrates the relationship between climatic stressors, affected pharmaceutical formulations, changes in product quality, and potential clinical consequences:

Environmental Stressor	Affected Formulations	Immediate Physical/Chemical Changes	Potential Clinical Consequences
Prolongedhigh humidity(>75% RH)	Extended-release tabletsand hygroscopicpowders	Increased moisture uptake, softening of the dosage form, and acceleratedhydrolytic degradation	Altered drug-release rate, possible dose dumping, or reduced therapeutic efficacy.
Extreme heat (>40°C)	Emulsions, creams, and suppositories	Phaseseparation,melting or softening of the formulation base, and changesinphysical stability	Non-uniform dosing, reduced product performance, and possible skin irritation
Cold-chain interruption	Vaccines, insulin, monoclonalantibodies,andother biologics	Protein denaturation, aggregation, or loss of biological activity	Reduced or complete loss of therapeutic effectiveness
Increased UV/solar exposure	Photosensitive pharmaceutical solutions and other light-sensitive formulations	Photochemical degradation, photo-oxidation, andformation of degradation products	Reduced drug potency and possible exposure to potentially harmful degradation products

Table 1: DirectFormulationandEnvironmentalImpact

International Journal of Pharmaceutical research and Applications
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Stability Study Types:

A comprehensivepharmacopoeial approach,as describedin USP standards,evaluates pharmaceuticalstability based on physical, chemical, microbiological, therapeutic, and toxicological characteristics to assure product remains safe, effective, and of acceptable quality throughout its intended shelf life.

1. PhysicalStability[13]

Physical stability refers to the ability of a pharmaceutical product to maintain its original physical characteristics, such as appearance, dissolution properties, palatability, and suspendability. Changes in these properties may influence the uniformity and drug-release characteristics of the formulation, thereby affecting its quality, safety, and therapeutic effectiveness.

2. ChemicalStability[14]

Chemicalstability istheabilityof adrug substance or product toresistchemical degradation ordecomposition when exposed to environmental conditions, including air, atmospheric conditions, temperature, moisture, and light. Maintaining chemical stability is essential for preserving the drug's potency and preventing the formation of undesirable degradation products.

3. MicrobiologicalStability

Microbiologicalstabilityrefersto the abilityof apharmaceuticalproducttoresistmicrobialcontamination and growth during its specified storage period. For formulations containing antimicrobial preservatives, these agents should retain their intended antimicrobial effectiveness throughout the product's shelf life.

4. TherapeuticStability

Therapeutic stability refers to the ability of a pharmaceutical product to maintain its intended pharmacological or therapeutic effect throughout its specified shelf life, without significant loss of drug action.

5. ToxicologicalStability

Toxicological stability refers to the ability of a pharmaceutical product to remain free from significant increases in toxicity during storage, ensuring that degradation products or other changes do not pose additional safety risks.

Stability testing conducted to evaluate howexcellence, therapeutic effectiveness of drug product changewhenitismaintainedunderdifferenttemperatur eandrelativehumidity (RH) conditions. These studies are mainly important when medicines are intended to be transported ormarketed indifferent geographical regions,where climatic conditions may vary considerably. In long-term stability studies, drug samples kept with suitable preservation conditions and tested at predetermined time intervals. The results help determine how the product changes over time and are mainly used to establish its shelf life and appropriate storage conditions.

Stability studies are commonly grouped into long-term, intermediate, accelerated, and in-use stabilitystudies.Thecommonlyusedconditionsforthe majorstabilitystudiesaresummarized below.

Typesofstabilitystudy	Storageconditions	Minimumstudyperiod
Long-term	25±2°C/60±5%RHor 30±2°C/65±5%RH	12months
Intermediate	30±2°C/65±5%RH	6months
Accelerated	40±2°C/75±5%RH	6months

Table 2: Typesofstabilitystudy

Stability Study Methods:

Every pharmaceutical product undergoes stability testing at different phases of its development. Early on, stability testing is carried out through stability assessment at high temperatures and high humidity.The drug is primarily tested at long-term storage in accelerated stability studies. The product's shelf life is determined during this time by using high temperatures. The primary goal of stability testing is to determine the acceptable degree of quality and fitness for the duration, they are provided for patience and should be suitable for the patient's acceptance of the medication. This facilitates the patient's easy recovery. The medication would be easily accepted, and the pharmaceutical's known therapeutic potential ofmanufactured goods.

Depending on the goal, the procedures taken, and the stability analysis four types of procedures have been identified, and they are

1. Real-timestabilitytesting
2. Acceleratedstabilitytesting
3. Retainedsamplestabilitytesting

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

4. Cyclictemperaturestresstesting
5. Photostability testing
6. In-usestability testing

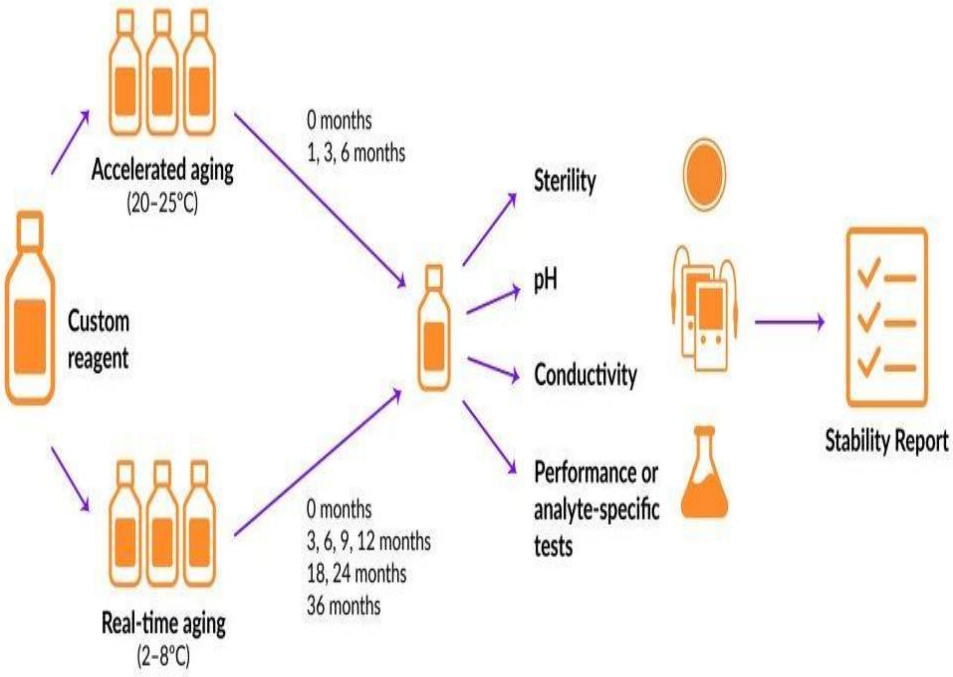


Figure 3: Stability Study Method

1. Stabilitytestinginrealtime:

Typically, real-time stability testing is undertaken over extendedduration of time to enable substantial deterioration of the product when stored as advised. The time frame of time for the product's test depends onits stability, which makes it evident that inter-assay variation prevents the product from deteriorating or breaking down for a prolonged time. During testing, samples are gathered atregular intervals, hence information is gathered at the right frequency the analyst can identify the daily degradation. By addingthe one lot of standard material forwhich thecharacteristicsofstability havebeendetermined. To ensure reliable results, the same instruments and reagents should be used throughout the stability assessment. The management of drift and instruments and reagents should be kept an eye on when discontinuity occurs. In this testing therapeutic formulation is maintained under designed preservation requirement for prolonged duration to evaluate its long-term stability, maintain quality, and establish its shelf life.

2. Acceleratedstabilitytesting:

Elevated temperature conditions are applied during stability testing, that breakdown compound decided. Evidence utilized to forecast retention period to contrast comparativeperformance of different formulations. Rapid stability investigation is simple to predict shelf life, which shortens the time needed to determine the substance's stability within stress factors like moisture, light, pH, gravity employed in addition to temperature. Time is also shortened compared to real-time for measurement of instability. Testing. The stability projections for the accelerated stability studies are completed at four distinct Temperatures under stress. On theother hand, denaturing stress temperatures yield projections. TheArrhenius method makes it simple to predict the accelerated stability studies. Formula

$$K=Ae^{-Ea/RT}$$

Where,

Kisthespecificrateconstant.
A is the Arrhenius factor or frequency factor.
Ea is the activation energy.
Tistheabsolutetemperature

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

Inthismethod,pharmaceuticalproductsareexposedtodifferenttemperatureconditions,suchas

40°CR=4.184 j/mol

The real gas constant, 60°C, 70°C, 80°C, and 100°C, depending on the purpose of the study. Samples may also be kept at normal temperature and refrigerated conditions to assess their stability under varying storage conditions. At predetermined intervals, samples are collected and analyzed to assess changesin product quality and stability. The sampling frequency dependson the study protocol andtherateof degradation of the product. Products that degrade rapidly require more frequent sampling. Generally, rise in temperature accelerates the decomposition of pharmaceutical substances.In accordance with ICH and WHO, standard enhanced degradation condition for many pharmaceutical products is 40°C ± 2°C and 75% ± 5% relative humidity (RH). If relevant changes occur under these conditions, intermediate testing may be conducted at 30°C ± 2°C and 65% ± 5% RH, where applicable under the relevant guidelines. Sampling schedules may vary according to the applicable regulatory guideline and study design. Under the ICH Q1A(R2) guideline, during a six-month accelerated study, pharmaceutical samples are commonly examined at the beginning, after three months, upon completion of testing period. More frequent sampling may be necessary for products with a higher risk of degradation. These studies help to analyzing suspected stability concern related to temperature, moisture, and other environmental factors. This testing approach applicable to various types of medicinal preparations including emulsions and suspensions, which may undergo physical changes during storage.

3. Stabilitytestingofretainedsamples

For anymarketedproductthatrequires stability,this is standard procedure.In this kind of onebatch is chosen for a year in order to test for stability. If the quantity of samples surpasses fifty, they are separated into two categories. When the initial introduction of the product to the market, representative samples are obtained from every batch, whichmay drop from 2% to 5% of the batches that were later marketed. The stability studies of the samples aid in thedetermination of shelf life. Thiskind of sampling testing further credible by naturebecauseittestsmaterial in both real marketplace and also during controlled storage of retained samples.

4. Cyclicthermal stressassessment:

The approach is not as frequently used for product sampling. Using this technique, pharmaceutical products under repeated temperature changes are created using product knowledge to simulate likely circumstances in the marketplace storage. The sampling used in this test is follows a 24-hour cycle, which is known as the daily cycle. Inthis testofsamples, theproduct'sminimumand maximum temperatures arerecordedbyproduct based on temperature, storagecircumstances, and physicaland chemicaldeterioration of theitem. Itis advised to use cycles of 20 to predict the shelf life. The pharmaceutical product is subjected to extreme conditions, including elevated temperature, humidity, light exposure, oxidation, and extreme pH, to determine its degradation pathways and evaluate the ability of analytical methods to detect stability-related changes.

5. Photo-stabilitytesting[15]

Photo-stability testing is carried out by exposing pharmaceutical products to controlled light conditions to determine whether light exposure leads to chemical decomposition, physical alterations, or loss of drug potency. This method helps identifyphotosensitivemedicines and establishappropriatepackaging andstorage requirements to preserve their quality and stability. This test is usually performed by following the ICH Q1B guideline.

6. In-usestabilitytesting[16]

In-use stability testing evaluates whether a product remains safe, effective and acceptable quality while it is being used after opening, reconstitution, or dilution. The product is stored under specified conditions and examined at regular intervals to detect changes in drug potency, physical characteristics, and microbiological quality. This evaluation helps establish the permissible period of use after opening and appropriate storage recommendations, especially for multidose formulations, oral suspensions, and reconstituted antibiotic preparations.

Guidanceforstabilitytesting[17]

In 1996, WHO adapted the ICH stability guidelines to address the requirements of countries with different climatic conditions. As the existing ICH guidance did not cover every region climatic challenge, the WHO issued further proposal in 2004

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Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

for analyzing how environmental conditions influence the quality of medicine. These recommendations especially significant to drugpreparations intended for distribution in tropical and other challenging climatic zones.InJune 1997, United StatesFDAoutlinedguidance relatedto pharmaceutical stability requirements. In India, drugs and pharmaceuticals are regulated at national level by theCentral Drugs Standard Control Organization (CDSCO), which isheadquartered in New Delhi. Differences in national regulations can make the preparations and submission of documents for medicine registration become more complex. Consequently, harmonizing regulatory standards across countries is essentialto simplify registration procedures, improve consistencyin stability data requirements, andmaintain product quality, safety, and efficacy. Framework for pharmaceutical stability assessment are reviewed and updated at least twice a year.

In Europe, CPMP, which operated within EMEA, has issued a setestablished protocols for stability analysissupport regulatory approval of medicinal products toensure the safety, effectiveness, stability, and quality of medications. The goalof thesestabilityguidelines is tooffer proof of how variouselements(suchaslight,humidity,andtemperature)inadditiontothedeteriorationprocessesthatoccur.

ICH(InternationalCouncilofHarmonisation)Stabilityguidelines:

ICH guidelines from the early 1990s outlined the procedures for updating drug storage result from medications produced in an industrial setting. In 2000s the WHO modified these recommendations in a few ways. Severe weather conditions for some nations were included, and established standards for the global environment were added Details about the stability data, the testing of novel drug ingredients and products, data analysis, impurity analysis, and storage conditions. These guidelines included and clearly defined the climate zone (ICH)Q1A-QF, 2003). The quantity of replicates, the storage conditions, the frequency of testing, and the studies duration should be specified in the dossier to account for usage, shipping, and storage are all covered.

The ICH and WHO have developed guidelines (ICH Q1A-E, Q3A-B, Q5C, and Q6A-B) to standardize the requirements for the EuropeanUnion, Japan, and US to enabletheexchangeof stability measurement sufficient to thesejurisdictions' regulatory bodies to register. In general, ICH stability Research involves testingAPI material under controlled surrounding conditions to determine its thermal stabilityandmoisturesensitivity.Time frame forlong-termtestingmust last for minimum 12monthsat25°C± 2◦C/60 ± 5% RH/65 ± 5% RH. The Middle ground and minimum of six months at 30 °C ± 2 should be covered by accelerated Testing °C/65% RH ± 5% RH and 40 ◦C ± 2◦C/75 RH ± 5% RH, correspondingly.

ICHCODES	TITLESOFGUIDELINES
Q1A	Stabilitytestingofnovelpharmaceuticalingredientsandgoods (Secondrevision)
Q1B	Investigation of light sensitivity in novel drug compounds and products
Q1C	Stability evaluation ofmodified drug formulation
Q1D	Bracketing and Matrixing Approaches for pharmaceutical stability studies
Q1E	Examining stability test results
Q1F	Stability documentation requirements for regulatory submission in Climatic zones III, IV
Q5C	Testingforstabilityinbiotechnologicalandbiologicalproducts
Q6A	Specifications:NewDrugAcceptanceCriteriaandTest methods chemicalsubstancesandnovelpharmaceuticalproducts
Q6B	Specifications:NewDrugAcceptanceCriteriaandTestMethods Biotechnological/Biologicalsubstancesandnovelpharmaceuticalproducts

Table 3: ICH Stability Guidelines

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Climaticzonesin Pharmaceutical stability assessment [18]

Pharmaceutical stability testing is performed under a range of environmental conditions to assess how variations in temperature, humidity and other climate related factors across different geographical regions may alter the quality and stability of medicines. Therefore, the world historically categorized into four major climatic zones based on their environmental conditions. This classification helps evaluate the degradation of pharmaceutical products and predict their stability and shelflife under different storage conditions. Based on these climatic data, real-time and elevated temperature stability studies established to estimate shelf life of pharmaceutical preparations under diverse climatic conditions.

TheWHOclassifies distinct climatic regions applicabletopharmaceuticalstabilityassessment andspecifiedthecorrespondinglong-termstorageconditions,includingtemperatureand relative humidity, as summarized in the table.

ClimaticZones	Description	Temperature	RelativeHumidity (RH)	Representatives geographical regions
Zonel	Temperate climatic conditions	21°C	45%RH	Southern Canada, Europe,andsome parts of Russia
ZoneIl	Mediterraneanor subtropical climatic conditions	25°C	60%RH	Mediterranean regions, parts of Australia, and the southern United States
ZoneIII	WarmandAridclimaticconditions	30°C	35%RH	NorthAfrica, MiddleEast,and arid areas of US
ZoneIV(A)	Hotandhumid tropical conditions	30°C	65%RH	Southeast Asia, CentralAfrica,and certain regions of South America
ZoneIV(B)	Hot climatic conditionswith veryhighhumidity	30°C	75%RH	Equatorialregions and areascharacterized by dense tropical rainforests

Table 4: ClimaticZones with their Representatives GeographicalRegions

Approachestoovercomeeffectofclimaticchangeon drugstability:

Addressingthesestabilitychallengesrequirescomprehensiveimprovementsinpackagingtechnology,storagemethods,andclinicalguidelines.Themajorstrategiesfor managing these issues are discussed in recent biomedical literature.

1. AdvancedPackagingandEngineeringInnovation [19]

Moisture-Barrier Packaging Materials:

Using high-barrier blister packs, such as aluminium–aluminium packaging or high-density polymers, act as a barrier to moisture penetration into the product. This protects moisture-sensitive tablets from chemical degradation due to hydrolysis and premature disintegration underconditions of high relative humidity.

Thermal Protection Technologies:

Incorporating phase-change materials (PCMs) and advanced insulated packaging systems into regional transportation helpscontroltemperaturefluctuationsandreducesuddentemperatureincreaseswhen medicinesaretransportedtoregionswithhigh temperatures.

2. DecentralizedandClimate-ResilientColdChains [20]

Controlled “Storage-in-a-Box” Units:

Installing modular, off-grid, or solar-powered storage units can keep pharmaceutical products with

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Volume 11, Issue 6, Nov.-Dec.2026, pp:99-110 www.ijprajournal.com ISSN:2456-4494

optimal temperature conditions.These systems protect essential medicines, such as antibiotics and insulin, from temperature-related degradation during prolonged power failures andheatwaves, particularly when ambient temperatures exceed 35°C.

Real-Time Temperature Monitoring:

Implementing IoT-based data loggers throughout the pharmaceutical supply chain enables continuous monitoring oftemperaturechanges.Thesesystemshelpidentifyandalertpersonneltomedicinebatchesexposedto excessiveheat, impaired stabilityandquality.

3. FormulationModificationandAPIStabilization [21]

Solid-State Form Modifications:

Modifying the solid-state structure of drugs by selecting more heat-stable crystalline polymorphs or using co-crystals can improvetheir resistance to degradation caused by elevated temperatures and humidity.

Excipient Optimization:

Using specialized moisture-resistant binders and desiccants in pharmaceutical formulations helps preserve the physical structure ofmedicinesand maintain consistent drug bioavailability, even when environmental conditionsfluctuate.

4. Post-DispensingEducationandHeatPrecautions [22]

ClinicalCommunication:

Healthcareprofessionalsshouldtrainpharmacistsandclinicianstoguidepatientsontheproperstorageofmedicinesathome,helpthemidentifysignsofheat-relateddegradation,suchaschangesincolourorconsistency,andadvisethemtoavoidstoring medicinesinhigh-temperatureenvironments,particularly inside vehicles during heatwaves.

Future Perspectives:

In the coming years, influence of climate change on medicine stability is projected significant area of pharmaceutical research. Increasing temperatures,high humidity, extreme climatic events, and interruptions in transportation and storage may compromise the quality, safety, and effectiveness of pharmaceuticalproducts.Future workshould concentrate on the developmentofclimate-resistantdrugformulations,innovativepackagingmaterials,andimprovedstoragetechnologiesto preservemedicine stability under changing environmental conditions. Pharmaceutical companiesshould emphasizethedevelopment of advancedpackaging materials, moisture-protective formulations, and drug delivery systems capable of withstanding elevated temperatures. Stability testing should beconductedunderdiverseenvironmentalconditions toassesshowchangingclimaticfactorsmayinfluence thestability and storage lifeofmedicines.Additionally,improvingcold-chaininfrastructure,optimizingstorageandtransportationpractices,andimplementingcontinuoustemperatureandhumiditymonitoringareessential,especiallyinareas prone to heatwaves and frequent power failures.

II. Conclusion:

Minimizing theoutcomes of climatevariation on medicinestabilityrequiresongoing scientificresearch, technological advancementsin pharmaceuticalmanufacturing,effectiveregulatory guidelines,andproperstorageandhandlingpractices. Increasingawarenessamongpharmacists,healthcare professionals,andpatients about the correct handling andstorage ofmedicines is equally important to prevent theirexposure to unsuitable environmental conditions.Adoptingtheseestrategies, maintainpharmaceuticalquality,protectpatientsafety,preservetherapeuticeffectiveness,andensurethea vailabilityofsafeandreliablemedicines despite changing climatic conditions.

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