

A REVIEW ON STABILITY STUDIES IN PHARMACEUTICALS: REGULATORY GUIDELINES

Patel Aksha^{1*}, Dr. Nidhi Chauhan², MohammadNaimuddin Chauhan¹, Keshiha Chauhan¹, Sagar Dixit Kumar Kaushikbhai¹

M. Pharma (Quality Assurance), Laxminarayan Dev College of Pharmacy, Bholav, Bharuch – 392015, India.

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*Corresponding Author: Patel Aksha

M. Pharma (Quality Assurance), Laxminarayan Dev College of Pharmacy, Bholav, Bharuch – 392015, India.

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ABSTRACT

Stability studies play a vital role in the pharmaceutical industry by ensuring the safety, quality, purity, and effectiveness of drug products throughout their shelf life. This review highlights the importance of stability testing in determining suitable storage conditions, expiration dates, and product performance under different environmental conditions. Various factors affecting stability, including temperature, humidity, light, oxygen, pH, and excipients, are discussed along with different types of stability such as chemical, physical, microbiological, therapeutic, and photostability. The review also summarizes major regulatory guidelines provided by ICH, WHO, USFDA, and CDSCO for global harmonization of stability studies. Different testing methods, including accelerated, real-time, cyclic stress, and retained sample testing, are explained. Additionally, the role of packaging systems and smart technologies in maintaining pharmaceutical stability and ensuring patient safety is emphasized.

KEYWORDS: Stability Studies, Drug Stability, Climatic Zones, Shelf Life, Stability Testing Methods.

INTRODUCTION^[1,2]

The ability of a drug substance or drug product to stay within set standards that guarantee its identity, strength, quality, and purity during the time period from when it is tested until its expiration date is called stability in pharmaceutical products. Issues with the product can occur if the drug becomes unstable, leading to unexpected changes in how it works. The expiration date is a key aspect of quality for all types of drug dosage forms. It is best to include clear instructions on how the product should be stored along with the expiration date.

Because stability studies guarantee the identity, potency, and purity of ingredients and formed products, they are among the most important steps in the drug development process. Environmental elements like ambient temperature, humidity, and light, as well as product-related elements like the chemical and physical

characteristics of active ingredients and pharmaceutical excipients, the dosage form and its composition, the manufacturing process, the type of container closure system, and packing material properties, all affect how stable a final pharmaceutical product is.

The primary goal of stability studies is to determine the drug product's shelf life. Stability is the amount of time that can be spent in storage before any degradation product in the dosage form reaches a point where it poses a concern to the patient. The product's shelf life or expiration date is established based on this time.

IMPORTANCE OF STABILITY STUDIES^[3,4]

Under-medication may result from the active drug's product instability, which lowers the drug's dosage form.

Toxic products may result from the drug or product's breakdown.

The medicine has the ability to alter its physical characteristics while being marketed and transported from one location to another.

The concepts of kinetics are used to predict the stability of drugs; nevertheless, there are differences between kinetics and stability studies. Instability may be caused by changes in physical appearance.

TYPE OF STABILITY OF DRUG SUBSTANCE^{5,6}

Chemical stability

guarantees the potency and chemical integrity of the active pharmaceutical ingredient (API). stops deterioration brought on by oxidation, photolysis, hydrolysis, or other chemical processes.

Physical stability

guarantees that the drug product's original physical characteristics, including appearance, texture, solubility, and suspend ability, are maintained. Colour changes, precipitation in solutions, phase separation in emulsions, and variations in tablet hardness are a few instances of instability.

Microbiological stability

guarantees that the medication is free of microbiological contamination for the duration of its shelf life. crucial for both non-sterile (like oral suspensions and creams) and sterile (like injectables and ocular drops) formulations. requires the application of preservatives to stop the growth of microorganisms.

Therapeutic stability

guarantees that the medication will continue to have the desired therapeutic impact throughout time. Drug

efficacy can be affected by degradation products or formulation modifications even if the drug is chemically intact.

Toxicological stability

guarantees the formation of no harmful degradation products throughout time. Stability testing is crucial because certain degradation products may have negative impacts.

Photostability

makes sure that exposure to light, particularly UV, doesn't lead to deterioration. Certain medications, like vitamins and antibiotics, need to be packaged to shield them from light.

Mechanical stability

pertinent to solid dose forms such as powders, pills, and capsules. prevents fracture, caking, or powdering due to physical stress during handling, storage, and transportation.

GUIDELINES FOR STABILITY TESTING^[7]

Because ICH did not adequately address harsh climatic circumstances or previously approved medicinal items, WHO and ASEAN updated ICH recommendations in 2004 and published stability study guidelines for global environments. The US FDA had already released recommendations for stability testing in June 1997. Drug regulation in India is handled by the CDSCO in New Delhi. There was a need for harmonized regulations because different countries had different regulatory standards, making it challenging to organize and review applications. The ICH Steering Committee was established to address this, and it convenes at least twice a year. Furthermore, rules supporting the marketing authorization of pharmaceutical products in Europe were released by the CPMP under the EMEA.

Table 1: Codes and Titles used in ICH Guidelines.

ICH Codes	Guideline titles
Q1A	Stability testing of new drug substances and products (second revision)
Q1B	Photo stability testing of new drug substances and products
Q1C	Stability testing of new dosage form
Q1D	Bracketing and matrixing designs for the stability testing of drug substances and products
Q1E	Evaluation of stability data
Q1F	Stability data package for registration applications in climatic zones 3 and 4
Q5C	Stability testing for biotechnological/biological products
Q6A	Specification: test procedure and acceptance criteria for new drug substances and new drug products: chemical substances
Q6B	Specification: test procedures and acceptance criteria for new drug substances and new drug products: biotechnological/biological products

Table 2: CPMP Guidelines for stability studies.

CPMP Codes	Guidelines Titles
CPMP/QWP/576/96 Rev.1	Guideline on stability testing for application for variations to a marketing authorization
CPMP/QWP/6142/03	guideline on stability testing for active substances and medicinal products manufactured in climatic zones 3 and 4 to be marketed in

	the EU
CPMP/QWP/609/96 Rev.1	Note for guidance on declaration of storage condition for medicinal products particulars and active substances
CPMP/QWP/122/02 Rev.1	Note for guidance on stability testing of existing active substances and related finished products
CPMP/QWP/072/96	Note for guidance on start shelf life of the finished dosage form
CPMP/QWP/2934/99	Note for the guidance for in-use stability testing of human medicinal products
CPMP/QWP/576/96	Note for guidance on stability testing for a type 2 variation to a marketing authorization

CLIMATIC ZONES AND STORAGE CONDITIONS⁷

Pharmaceutical stability is significantly impacted by climate variability, which results in the creation of region-specific stability testing conditions. Based on average temperature and relative humidity, the WHO and ICH have divided the world into four main climatic zones:

In order to ensure that testing replicates the real environmental pressures encountered throughout manufacturing, transportation, and market distribution, these zones specify the storage conditions for stability studies. For example, India is in Zone IVb, where high humidity and temperatures require stringent testing to guarantee stability in tropical conditions.

Additionally, the implementation of Global Stability Testing Conditions—25°C/60% RH for long-term testing and 40°C/75% RH for accelerated testing—has enhanced regulatory region harmonization and promoted uniform product performance globally.

- **Zone I:** Temperate (21°C/45% RH)
- **Zone II:** Subtropical with possible Mediterranean influence (25°C/60% RH)
- **Zone III:** Hot and dry (30°C/35% RH)
- **Zone IVa and IVb:** Hot and humid (30°C/65% RH and 30°C/75% RH, respectively)

Climatic Zone	Representative regions	Long- term storage conditions	Accelerated conditions	Intermediate conditions	Testing frequency
Zone I - Temperate	USA, Northern Europe	25°C ± 2°C / 60% RH ± 5% RH	40°C ± 2°C / 75% RH ± 5% RH	30°C ± 2°C / 65% RH ± 5% RH	0, 3, 9, 12, 18, 24 months
Zone II - Subtropical	Japan, Southern Europe	25°C ± 2°C / 60% RH ± 5% RH	40°C ± 2°C / 75% RH ± 5% RH	30°C ± 2°C / 65% RH ± 5% RH	0, 3, 6, 9, 12, 18, 24 months
Zone III – Hot and Dry	Middle East, Australia	30°C ± 2°C / 35% RH ± 5% RH	40°C ± 2°C / 75% RH ± 5% RH	30°C ± 2°C / 65% RH ± 5% RH	0, 3, 6, 9, 12 months
Zone Iva – Hot and Humid	India, Southeast Asia	30°C ± 2°C / 65% RH ± 5% RH	40°C ± 2°C / 75% RH ± 5% RH		0, 3, 6, 9, 12 months
Zone IVb – Very Hot and Humid	Philippines, Indonesia, Brazil	30°C ± 2°C / 75% RH ± 5% RH	40°C ± 2°C / 75% RH ± 5% RH		0, 3, 6, 9, 12 months

Factor Affecting Stability of Drug^[8,9]

Temperature

A pharmaceutical substance's stability is affected by temperature changes; warmer temperatures accelerate the hydrolysis of medications.

Moisture

A number of physical and chemical dose changes occur when the water-soluble material gets absorbed into any moisture surface and loses its properties.

pH

pH has an impact on the rate of drug deterioration in hydrolyzed solutions, which reduces the potency of

drugs made with buffers at the pH where stability is highest.

Excipient

Starch and povidone affect stability since they contain more water than other excipients. Instability is also lessened by the excipient and medication's chemical interactions.

Oxygen

The presence of oxygen facilitates the oxidation of certain compounds. Products that break down more quickly when exposed to oxygen are stabilized by substituting carbon dioxide and nitrogen for oxygen in the storage container.

Light

In materials exposed to light, the pace of breakdown quickens.

Because some drugs are photosensitive, it is possible to assess how well they withstand exposure to light vs storage in the dark.

STABILITY TESTING METHODS^[10,11]

At different phases of the product development process, stability testing is a standard practice carried out on pharmacological ingredients and products. Pharmaceutical stability testing's main goal is to give patients a reasonable level of assurance that the products will continue to be of acceptable quality and fitness for the duration that they are on the market, available for patient supply, and fit for consumption until the patient uses the last unit of the product. Four types of stability testing methodologies have been identified:

Accelerated stability testing

In rapid stability testing, samples are stressed, cooled, and then concurrently tested. Compared to real-time stability testing, the analysis's brief duration lowers the possibility of measurement system instability. Additionally, in accelerated stability testing, the recovery of the stressed sample is stated as a percentage of the recovery of the unstressed sample, and the unstressed product and stressed material are compared within the

same assay. It is advised to do the therapy in expedited stability predictions at four distinct stress temperatures for statistical reasons. However, when denaturing stress temperatures are avoided, relatively accurate stability estimates are achieved for thermolabile and proteinaceous components.

The accelerated stability testing concept is based on Arrhenius equation:

$$\ln K = \ln A + \frac{\Delta E}{RT}$$

where K = degradation rate/s, A = frequency factor/s, ΔE = activation energy (kJ/mol), R = universal gas constant (0.00831 kJ/mol), T = absolute temperature (K)

The modified Arrhenius equation:

$$\log(k_2/k_1) = -E_a/2.303R(1/T_2 - 1/T_1)$$

where k_1 and k_2 are rate constants at temperatures T_1 and T_2 expressed in degree kelvins; E_a is the activation energy; R is the gas constant.

These formulas explain the connection between degradation rate and storage temperatures. For some degradation processes, the Arrhenius equation can be used to estimate stability from the degradation rates seen at high temperatures.

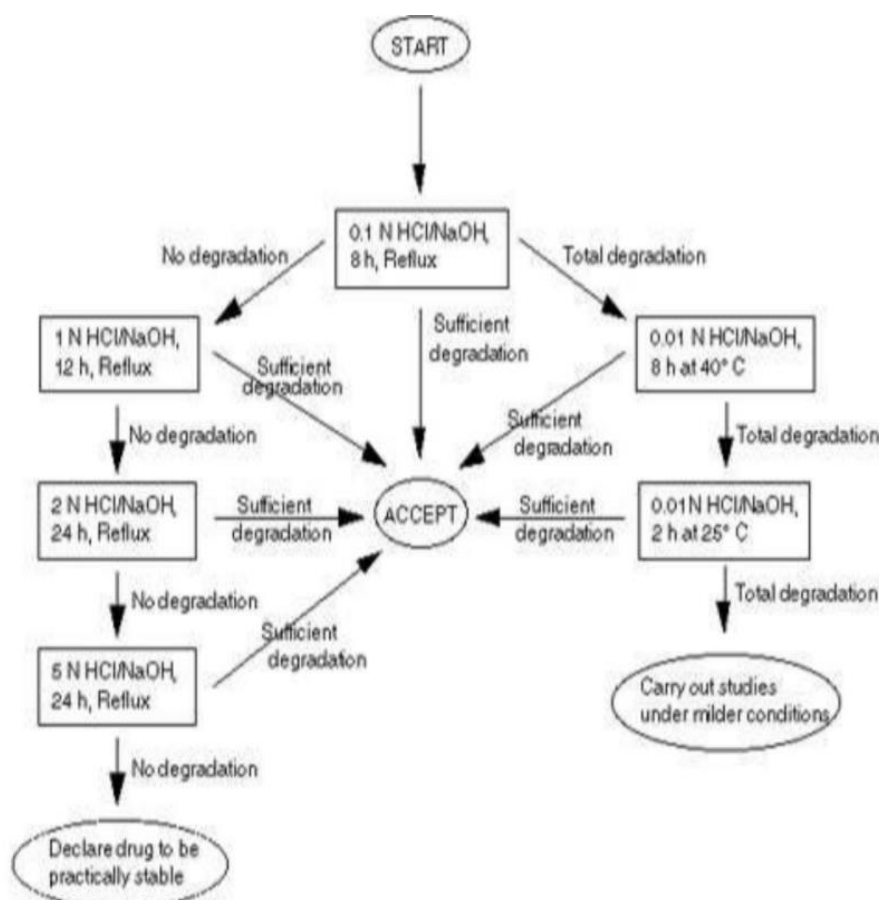


Fig. 1: Hydrolytic Degradation under Acid and Alkali Conditions.^[22]

➤ Real-time stability testing

In order to allow for significant product degradation under suggested storage settings, real-time stability testing is typically conducted over a longer test period. The test's duration is determined by the product's stability, which must be lengthy enough to show

unequivocally that no discernible deterioration takes place and to allow for the separation of degradation from inter-assay variance. Data is gathered at a suitable frequency during the testing so that a trend analysis can differentiate between daily ambiguity and instability.

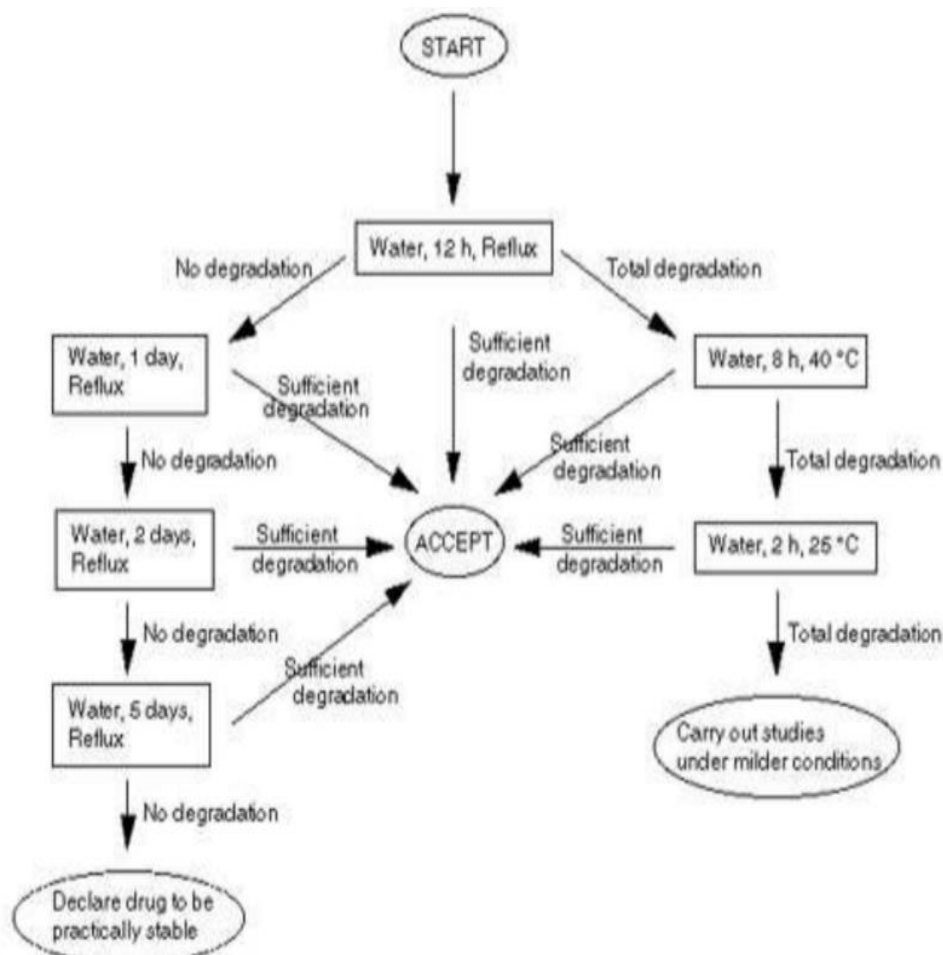


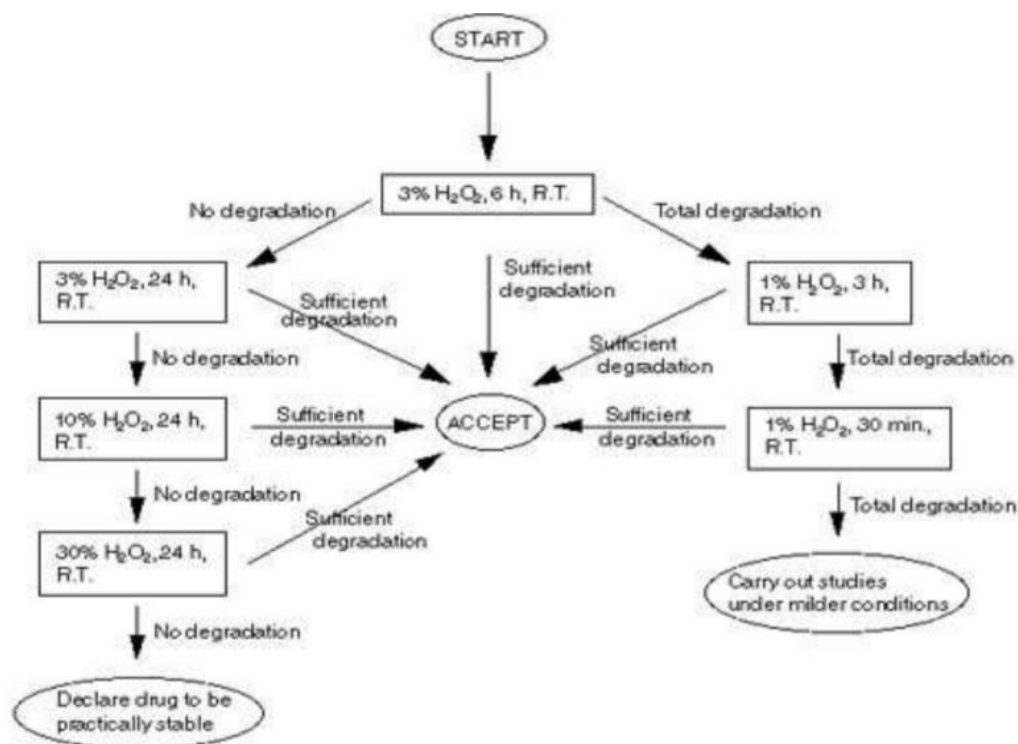
Fig. 2: Hydrolytic Degradation under Neutral Conditions.^[22]

➤ Cyclic temperature stress testing

Based on product knowledge, cyclic temperature stress tests are created to replicate conditions that are likely to occur in commercial storage. Since the earth's diurnal rhythm is 24 hours, which is what marketed medications are most likely to encounter during storage, 24 hours is the length of cycle that is typically taken into consideration. It is advised that the minimum and

maximum temperatures for the cyclic stress testing be chosen on a product-by-product basis, taking into account elements such as the product's suggested storage temperatures and particular chemical and physical degradation characteristics.

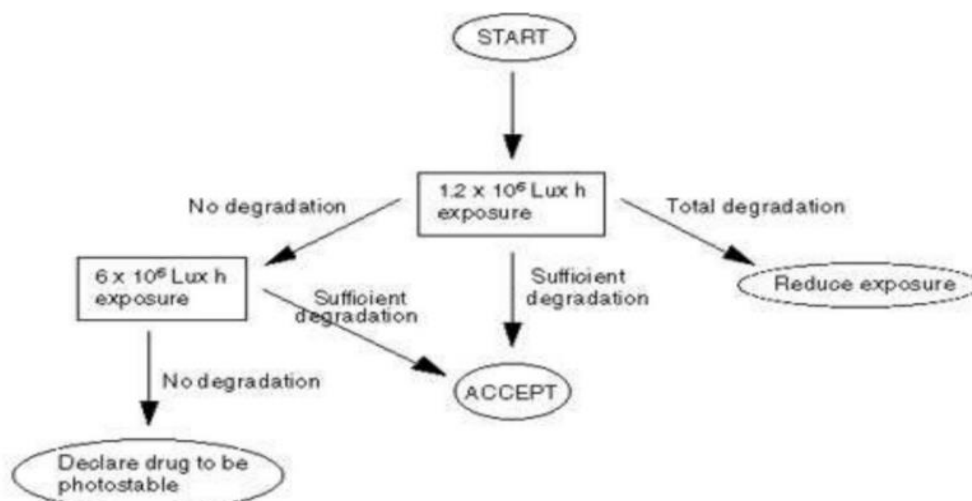
Additionally, it is advised that the test typically consist of 20 cycles.

Fig. 3: Oxidative Degradation Stress Study.^[22]

➤ Retained sample stability testing

This is a standard procedure for all marketed products that need stability data. Stability samples are chosen for this investigation in order to be stored for at least one batch annually. It is advised to collect stability samples from two batches if there are more than fifty batches sold. Stability samples from each batch may be taken

when the product is first introduced to the market; later on, this number may be reduced to just 2% to 5% of marketed batches. The stability samples in this study are evaluated at predefined intervals. For example, if a product has a five-year shelf life, it is customary to test samples at three, six, nine, twelve, eighteen, twenty-four, thirty-six, forty-eight, and sixty months.

Fig.4 Photolytic Degradation Stress Study.^[22]

SHELF LIFE AND EXPIRATION DATE^[11,12,13]

A drug product's shelf life is the amount of time that it will remain fit for use (i.e., preserve at least 90% of the marked potency claim) if stored properly in accordance with the manufacturer's recommendations. Therefore, the date after which a product could no longer be suitable for use is known as the expiration date. The period of time that a batch of a pharmaceutical product is anticipated to

stay within the authorized shelf-life requirements, beyond which it should not be utilized, is another definition of the expiration date.^[11,13]

Estimation of shelf life

The Garret and Carper approach and the Free and Blythe method explain how the principle of chemical kinetics may be used to predict shelf life.

Shelf-life determination based on Arrhenius plot (Garret and Carper method)

The Arrhenius equation, which demonstrates that the relationship between the rate constant, k , of a chemical process and the thermodynamic temperature, $1/T$, is a straight line, serves as the foundation for the mathematical prediction of shelf life. The value of k can be ascertained by calculating the slope of this line through experiments conducted at various temperatures. This k number can then be substituted into the correct order of reaction to determine the quantity of breakdown after a given period of time. However, earlier research is needed to determine the order of the reaction.

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

$$\log K = \log A - E_a/2.303 \cdot RT$$

Where,

K = rate constant

R = gas constant = 1.987 cal/mol

T = absolute temperature

A = frequency factor

E_a = energy of activation

STEPS

1. It entails keeping medication samples at three distinct temperatures: 40°C, 50°C, and 60°C.
2. Determining the order of the breakdown reaction by tracking the drug content over time and charting the results.
3. The drug product's shelf-life is then determined by extrapolating the reaction rate constant at 25°C using an Arrhenius plot.

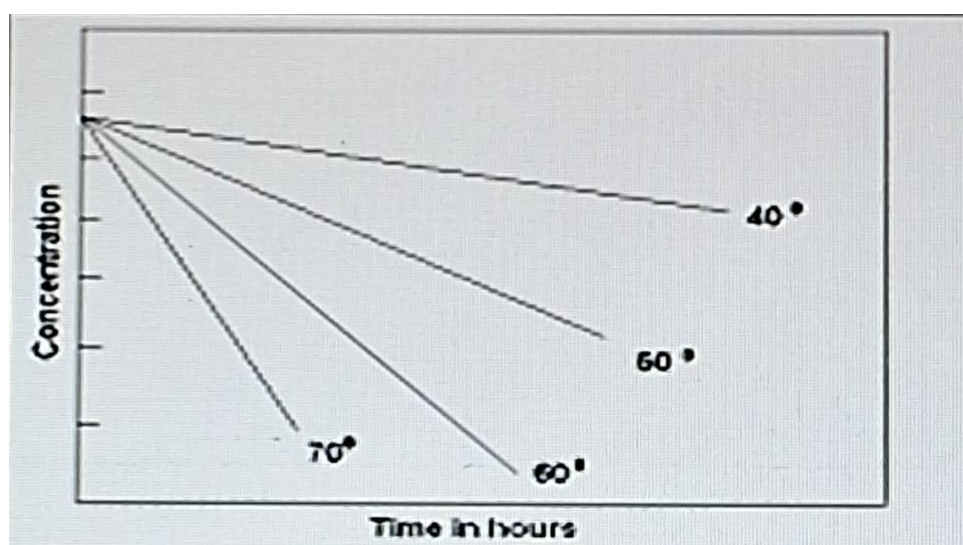


Fig. 5: Arrhenius plot for predicting drug stability at room temperature.

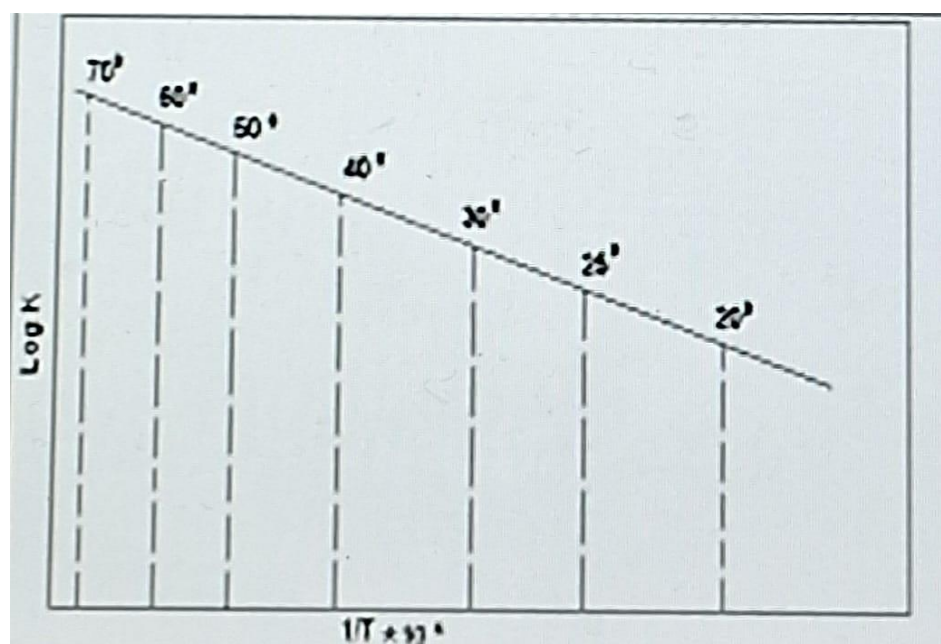


Fig. 6: Arrhenius plot for predicting drug stability at room temperature.

If the reaction is following zero-order.

At 25°C, the expiration date is equal to the initial potency minus the minimum potency or reaction rate.

$$t_x = Y_0 - Y_x / K_0$$

If the first order is being followed by the reaction.

Log initial potency minus log minimum potency/reaction rate at 25°C is the expiration date at 25°C (t_x).

$$t_x = \log Y_0 - \log Y_x / K_1$$

where,

Y_0 = initial potency

Y_x = final potency

K_0 = zero order constant

K_1 = first order constant.^[13]

Shelf – life determination based on t_{90} values (Free and Blythe method)

This method plots the fractional life period against reciprocal temperatures and the number of days needed for the drug to break down to a fraction of its initial potency at room temperature. Plotting the log percent of drug residue against the number of days until the potency drops to 90% of its initial value. Plotting the log time to 90% against $1/T$ yields the shelf life at 25°C.

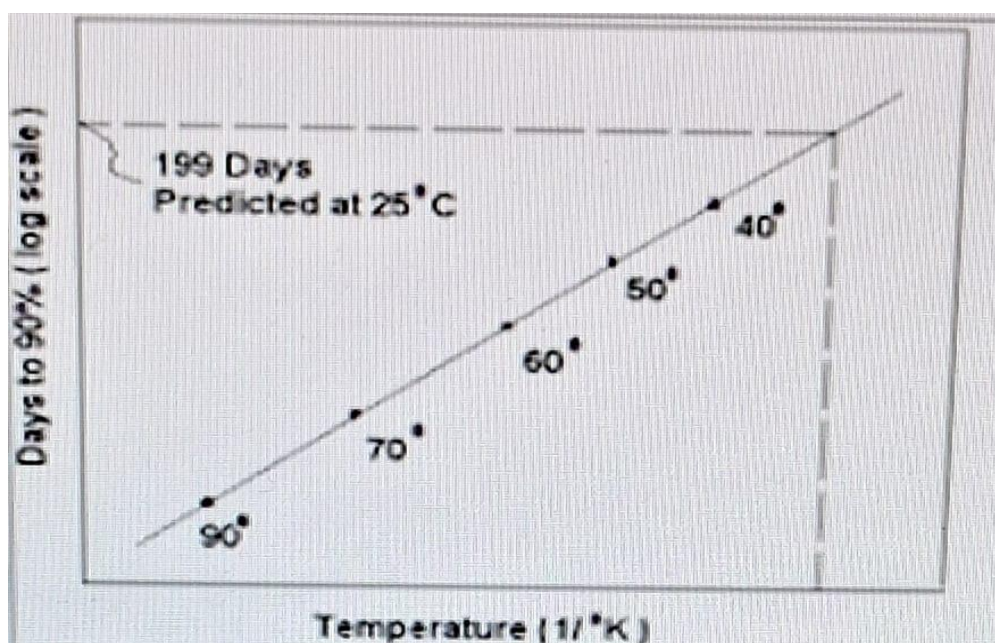


Fig. 7: Time in days required for drug potency to fall to 90% original value.

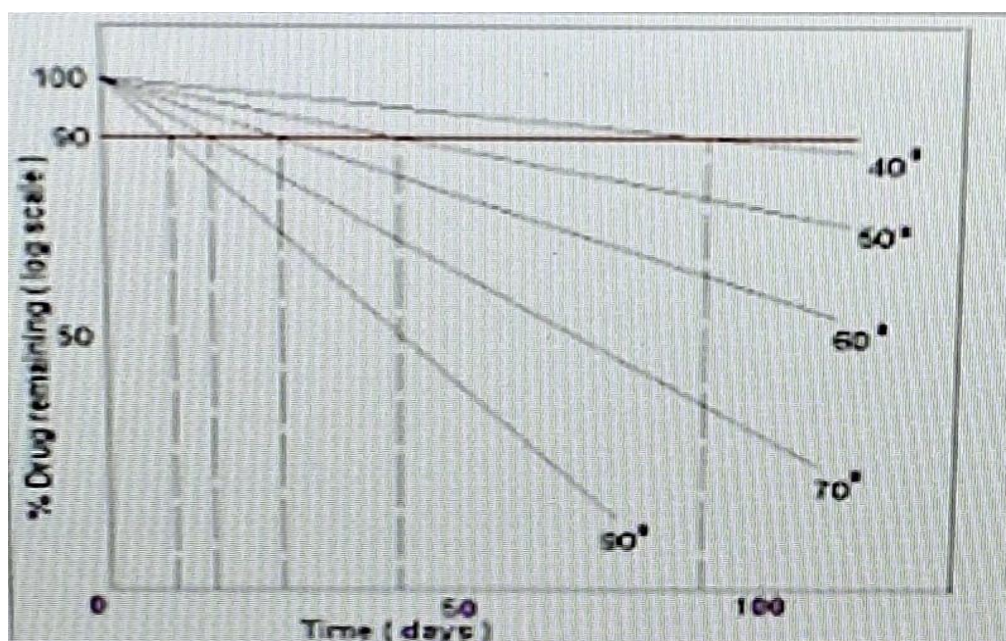


Fig. 8: A log plot of t_{90} on the vertical axis against reciprocal temperature on the horizontal axis.^[14]

ROLE OF PACKAGING AND STORAGE^[15]

As the first line of defence against mechanical, chemical, and environmental challenges that could jeopardize product integrity, packaging is essential to maintaining pharmaceutical stability.^[16] Packaging guarantees compatibility, functioning, and regulatory compliance in addition to containment and protection, which has a direct impact on the product's shelf life and therapeutic dependability. Over the course of the product's lifecycle, an improved container-closure system (CCS) protects the medication against deterioration while preserving microbiological integrity and guaranteeing constant delivery.^[17]

Influence of container-closure system

All packaging elements that come into direct or indirect contact with the drug product—such as bottles, blisters, vials, caps, seals, and liners—are included in the container-closure system.^[16] The dosage form, the physicochemical properties of the active pharmaceutical ingredient (API), and the planned storage conditions all influence the choice of CCS.

High-density polyethylene (HDPE) bottles and blister packs are frequently used for solid oral dosage forms in order to prevent moisture and oxygen intrusion. For items that are sensitive to light, amber glass containers are recommended since they provide excellent UV protection.^[18] Type I borosilicate glass vials continue to be the industry standard for parenteral preparations because of its impermeability, chemical stability, and inertness. Nonetheless, the growing use of cyclic olefin polymers (COPs) provides reduced extractable content and enhanced break resistance.^[18]

Closures and seals are also very important. To avoid microbiological contamination and solvent loss, aluminum crimps and elastomeric stoppers need to keep a hermetic seal. Comprehensive CCS studies, including integrity testing, permeation tests, and transport and storage environment simulation, are mandated by regulatory bodies including the USFDA and EMA.^[19] Therefore, a well-designed container-closure system guarantees that the stability and safety of pharmaceutical products are not jeopardized by external stress factors.

Compatibility and leachable

The compatibility of the formulation and packaging materials is a frequently disregarded part of stability assurance. Adsorption, absorption, or leaching resulting from incompatible interactions can cause contamination or potency loss.^[20] In protein-based or peptide compositions kept in glass or plastic containers, adsorption happens when the active ingredient attaches itself to the container wall. In contrast, absorption entails the movement of drug molecules into the packing matrix, which may change the polymer structure and formulation concentration.

Extractables and leachables are a major issue, especially in plastic and elastomeric packaging systems. Leachables are substances that move into the product under typical use settings, whereas extractables are chemical entities that can be extracted from the packaging under harsh circumstances.^[20] These include monomers, plasticizers, stabilizers, and leftover solvents, some of which may be hazardous or reactive, jeopardizing patient safety and stability.

Compatibility studies serve as a crucial link between formulation science and regulatory compliance, guaranteeing product integrity throughout its storage period. Regulatory bodies like USP <1663> and <1664> require rigorous extractables and leachables studies as part of the stability evaluation process. Analytical techniques like GC-MS, LC-MS, and ICP-MS are used to identify and quantify these contaminants. The data generated guides material selection and supports risk assessment in compliance with ICH Q3C (Impurities: Residual Solvents) and Q3D (Elemental Impurities). These pollutants are identified and quantified using analytical methods such as GC-MS, LC-MS, and ICP-MS. According to ICH Q3C (Impurities: Residual Solvents) and Q3D (Elemental Impurities) recommendations, the data produced supports risk assessment and directs material selection.^[21] Compatibility studies therefore serve as a crucial link between formulation science and regulatory compliance, guaranteeing product integrity during storage.

Smart Packaging Technologies and Real-Time Stability Monitoring

A paradigm shift in stability assurance has been brought about by the development of smart and intelligent packaging technologies, which allow for predictive quality control and real-time environmental monitoring. Throughout the supply chain, smart packaging provides actionable data by integrating sensors, indicators, and digital tags that track temperature, humidity, light exposure, and even oxygen concentration.^[19]

Humidity-sensitive labels aid in tracking moisture intrusion in solid dosage forms, whereas time-temperature indicators (TTIs) are frequently employed in biologics and vaccines to measure cumulative heat exposure. End-to-end traceability is further made possible by Near Field Communication (NFC) and Radio-Frequency Identification (RFID) technologies, which connect packaging data to centralized databases for proactive quality assessment.^[20]

Recent developments include wireless biosensors and embedded microsensors that can send manufacturers or regulatory agencies real-time stability data. By offering continuous quality assurance instead of static testing, these technologies are in line with the concepts of Quality by Design (QbD) and the Pharmaceutical Quality System (ICH Q10).^[21] Additionally, these devices' predictive algorithms may foresee degradation events

before they happen, reducing product recalls and guaranteeing patient safety.

In conclusion, packaging's function has changed from passive confinement to dynamic stability control, combining data analytics, material science, and regulatory compliance. Intelligent packaging and real-time stability monitoring will transform how stability is maintained and validated throughout the global pharmaceutical supply chain as the pharmaceutical industry moves toward digitalized and sustainable manufacturing.

CONCLUSION

Stability studies are an essential part of pharmaceutical product development because they ensure the identity, strength, quality, purity, and safety of drug products throughout their shelf life. The review shows that environmental factors such as temperature, humidity, light, oxygen, and packaging materials greatly influence drug stability. Different types of stability including chemical, physical, microbiological, therapeutic, and photostability help in maintaining product effectiveness and patient safety. Regulatory guidelines by organizations such as ICH, WHO, USFDA, and CDSCO provide standardized methods for stability testing under various climatic conditions. Accelerated, real-time, and retained sample testing are important techniques for predicting shelf life and expiration date. The review also highlights the growing importance of advanced packaging systems and smart monitoring technologies in improving pharmaceutical stability and ensuring global quality compliance.

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