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STABILITY PROFILING AND SHELF-LIFE PREDICTION OF SOLID DOSAGE FORMS UNDER ACCELERATED AND REAL-TIME CONDITIONS

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ABSTRACT

Background: Stability profiling is a critical aspect of pharmaceutical development, ensuring that solid dosage forms maintain quality, efficacy, and safety throughout their shelf life. Accelerated and real-time stability studies, combined with kinetic modeling, provide a scientific basis for predicting shelf life and supporting regulatory compliance.

Objective: This study aimed to evaluate the stability of a representative solid dosage form under accelerated (40 °C ± 2 °C/75% RH ± 5%) and real-time (25 °C ± 2 °C/60% RH ± 5%) conditions, assessing physical, chemical, and dissolution parameters, and to predict shelf life using kinetic models.

Methods: Tablets were stored under real-time and accelerated conditions for 12 months and 6 months, respectively. Periodic evaluations included appearance, hardness, friability, disintegration, assay, dissolution, and degradation-product analysis. Degradation kinetics were analyzed using zero-order, first-order, and Arrhenius models to estimate shelf life.

Results: Tablets remained physically and chemically stable under real-time conditions, with assay above 98% and dissolution above 96%. Accelerated conditions caused minor physical changes and reduced assay to 94.5% over six months. Kinetic modeling indicated a predicted shelf life of 24–32 months.

Conclusion: Combining real-time and accelerated stability studies with kinetic modeling provides a reliable framework for predicting the shelf life of solid dosage forms, ensuring product quality and regulatory compliance.

INTRODUCTION

Pharmaceutical stability is one of the key factors that predetermine the safety, effectiveness, and the quality of the pharmaceutical product. Of the dosage formulations that are most likely to be manufactured, solid dosage formulations like tablets and capsules are the most convenient, precise dose administration, and adherence by patients. Nevertheless, solid dosage forms are also prone to physical, chemical, and microbiological degradation in storage, both of which may impair their therapeutic efficacy and safety profile (Shah et al., 2019). The maintenance of stability during the shelf life of a drug product is thus one of the basic conditions of pharmaceutical development and regulatory standards (International Council for Harmonisation [ICH], 2003). The objective of stability testing is to comprehend how an individual drug quality varies with the time under the influence of environmental factors that include temperature, humidity, and light exposure (Singh and Bakshi, 2019). They are crucial tests that give the necessary data on the shelf life, correct storage and packaging of pharmaceutical products. Under the ICH guidelines, stability studies are either of long-term (real-time) or accelerated. Stability studies are in real time, and are undertaken at conditions that are aimed at simulating the actual conditions of storage, usually 25 C + 2 C and 60 percent + 5 percent relative humidity (RH) and are intended to observe how the product behaves in the desired shelf life, typically 36 months (ICH, 2003; U.S. Food and Drug Administration [FDA], 2022). Real-time studies are accurate, but since they are time consuming, they tend to slow the product development cycle.

Instead, accelerated stability tests relate to the storing of the product under high stress conditions, typically 40 0 C 2 C and 75 0 C 5, in order to accelerate the degradation (Shah et al., 2019; Singh and Bakshi, 2019). The same data that is collected in these studies is then used in extrapolation with mathematical models like zero-order, first-order, arrhenius kinetics among others to identify the stability at long term when under normal conditions in storage. This technique provides a quick way of estimating the shelf life that is particularly important at initial stages of drug development and submission (Carstensen and Rhodes, 2000). Accelerated stability studies rely on the premise that the degradation process of a given drug formulation under stress would be identical to the one under the storage conditions, which must be carefully validated on a case-by-case basis (Sivaraman et al., 2020).

The behavior of solid dosage forms depends on several factors affecting their chemical stability such as the physicochemical characteristics of the active pharmaceutical ingredient (API), the compatibility of excipients, moisture, and packaging materials (Shah et al., 2019). The common degradation mechanisms are as follows: hydrolysis, oxidation, isomerization, photolysis and polymerization, which can destroy the drug activity or produce toxic degradation products (Carstensen & Rhodes, 2000). Additional effects that may undermine the quality and bioavailability of the product are physical changes, e.g., changing the hardness of the tablet, friability, time to disintegrate, dissolution profile, or appearance (Sivaraman et al., 2020). This means that there should be a well-rounded stability program that will consider chemical and physical properties of the product as time goes by. Kinetic modeling is central in the process of interpreting the stability data and predicting the shelf life. Zero-order kinetic is said to occur when the degradation rate does not depend on the drug concentration, while first-order kinetic is said to exist when the rate proportion depends upon the remaining drug content (Singh & Bakshi, 2019). A Arrhenius equation can be used to predict degradation rates under normal storing conditions by using accelerated study

data by taking into account the temperature dependence of the rate-constant. These models have a great potential of decreasing the shelf-life determination time when properly used and have high predictive power (Carstensen and Rhodes, 2000; Sivaraman et al., 2020).

A number of studies have shown that accelerated stability testing together with kinetic modeling is effective in solid dosage forms. As an example, Shah et al. (2019) found that stability data collected at temperatures below 40 0 C/75 percent RH conditions were predictive of the shelf life of different tablet formulations, when degradation mechanisms remained similar across conditions. Equally, Sivaraman et al. (2020) put forward similar views stating that not only physical but also chemical characteristics are important during the study of the stability as sometimes accelerated conditions can hasten physical changes, which are not normally observed during normal storage, hence overestimating the degradation. Such results highlight that it is important to combine real-time and fast tracked studies in order to achieve a solid stability profile.

Stability tests are also required by the regulation environment during drug approval and post-marketing surveillance. According to both ICH and FDA guidelines, stability data will be necessary to justify the proposed shelf life and storage conditions, as well as making sure that the patients are provided with drugs that will not compromise their safety or efficacy over the proposed period of use (ICH, 2003; FDA, 2022). Additionally, stability research enhances the decisions taken about packaging materials and storage conditions, which is part of the general quality control of the pharmaceutical product. Although the significance of stability profiling has been established, there are still issues associated with making predictions about shelf life of new formulation or drugs with complicated degradation profiles. Changes in the API properties, excipient reactions, and environmental factors may make kinetic modeling complicated and require attentive experimental design (Singh and Bakshi, 2019). The sensitivity and accuracy of stability tests have also been enhanced by the development of analytical methods which include high-performance liquid chromatography (HPLC), differential scanning calorimetry (DSC) and dissolution testing that can be used to accurately predict the shelf-life(Carstensen and Rhodes, 2000).

To sum up, stability profiling at both real-time and accelerated method is an essential part of solid dosage forms development and lifecycle management. These data of empirical stability and predictive kinetic models provide pharmaceutical scientists with the opportunity to determine shelf life, compliance with regulations, and quality of drugs during storage. This paper is a geometrical analysis of a representative solid dosage formulation to investigate its stability at both accelerated and real-time profiles in determining the degradation kinetics and use of the same to determine shelf life. The study will combine chemical and physical evaluation with mathematical modeling, and therefore, make a contribution to the best practices in pharmaceutical stability testing.

LITERATURE REVIEW

The dosage forms of solid drug are classified into Stability Principles.

The pharmaceutical industry extensively depends on solid dosage forms as they are convenient, precise in the dosage, and patients follow them. These however, are susceptible to chemical, physical and microbiological degradation during storage (Carstensen & Rhodes, 2000). The most typical means of chemical degradation are hydrolysis, oxidation, isomerization, and photolysis, and usually depend on the availability of moisture or pH, as well as oxygen or light (Shah et al., 2019). Physical instability may be reflected in terms of hardness, friability, disintegration

time, profile, dissolution of a compound, or color, whereas polymorphic transformations can affect drug solubility and bioavailability (Sivaraman et al., 2020). Stability is thus very important in the selection of the right excipients and the package (Singh and Bakshi, 2019). Some of the studies point to the fact that the contact of the active pharmaceutical ingredient (API) with excipients may speed up degradation. As an example, lactose, which is a widely used filler, can undergo Maillard reactions with amine-containing APIs, resulting in a loss of potency and the creation of colored impurities (Rathore et al., 2020). Likewise, APIs that are sensitive to moisture need to be packaged in a protective way to avoid being hydrolytically degraded (Singh et al., 2021). This is so that the knowledge of these mechanisms is key to the design of sound formulations and viable stability procedures.

Accelerated vs Real Time Stability Testing Methods.

The test of stability is usually divided into real-time (long-term) and accelerated. Real-time techniques mimic normal storage environments (25 o C + 2 o C/ 60 per cent RH + 5 o C) during the target shelf life, typically 24-36 months (ICH, 2003). These researches give the most valid data but are time consuming and might give a delay in launching of the product. Instead, accelerated tests subject goods to more severe temperatures and humidity (40 o C + 2 o C + 50 RH + 5) to accelerate the degradation process and can estimate the shelf life in a shorter time (Singh and Bakshi, 2019; Shah et al., 2019). Both of these forms of stability studies are well-defined by the International Council for Harmonisation (ICH) and WHO. ICH Q1A(R2) indicates storage, sampling and testing approaches to be used in analysis in order to provide conformity and regulatory use (ICH, 2003). It has been demonstrated that rapid conditions can be used to correctly forecast long-term stability in the event that the degradation process remains similar in various conditions (Sivaraman et al., 2020; Rathore et al., 2020). Physical changes, however, can be induced by stress on some formulations when they are not stored normally, like cracking of tablets or dissolution rate changes, resulting in an overestimation of degradation (Singh et al., 2021). Consequently, combination of real time and accelerated studies is advisable in the strong prediction of shelf-life.

Prediction of Shelf-Life on the basis of Kinetic and Mathematical Model.

Shelf life is predicted by means of mathematical modeling of degradation kinetics. Zero-order kinetics holds that the rate of degradation is not dependent on drug concentration, whereas first-order kinetics implies that the rate is dependent on the residual concentration of the API (Carstensen and Rhodes, 2000). Arrhenius equation is more often compared to the dependence of the rate of degradation on the temperature and helps to extrapolate accelerated stability data to the standard storage conditions (Shah et al., 2019). Another simplified method that estimates the shelf life is the Q10 method that involves the dependence of degradation on the temperature. A number of studies have shown that kinetic modeling is effective in the case of solid dosage forms. According to Shah et al. (2019), Arrhenius method was able to forecast the shelf-life of various formulations of tablets under conventional conditions of storage. Likewise, Sivaraman et al. (2020) emphasized that predictive accuracy is greater when the data of chemical and physical stability are combined with kinetic models. Rathore et al. (2020) pointed out that to ensure reliable modeling, the degradation mechanism needs to be understood, since the assumption that it is linear can be inaccurate in case a different mechanism occurs at high temperatures.

Stability testing and kinetic modeling are all integrated to help in regulatory submissions,

package design and quality insurances and help in reducing product development timelines (Singh & Bakshi, 2019; FDA, 2022). Another way of improving the accuracy of shelf-life estimation is the use of modern analytical approaches, including high-performance liquid chromatography (HPLC), differential scanning calorimetry (DSC), and dissolution tests (Carstensen and Rhodes, 2000; Sivaraman et al., 2020).

METHODOLOGY

The research used a systematic method to determine how stability forms of solid dosage forms are maintained in accelerated and real-time conditions in line with the ICH Q1A(R2) guidelines. The representative tablet formulation that contained a model of active pharmaceutical ingredient (API) was chosen to conduct the study. Tablets were produced under the common direct compression methods and were stored in the high density polyethylene (HDPE) containers with desiccants to avoid degradation due to moisture. The tablets were split into two as one used in real-time stability studies, and the other used in accelerated stability studies. To replicate normal storage conditions, real-time samples were kept at 25 degC with 60% relative humidity (RH) with 60 percent +- 2 degrees Celsius, whereas, accelerated samples were kept at 40 degC with 75 percent relative humidity (RH) to cause degradation due to stress in a shorter timeframe (Shah et al., 2019; Sivaraman et al., 2020). Changes in physicochemical and chemical stability parameters were predetermined by the sampling intervals. Samples taken in real-time were measured at 0, 3, 6, 9, and 12 months, whereas the accelerated samples were done at 0, 1, 2, 3 and 6 months. These sampling points were characterized by the full evaluation of the important quality features, such as appearance, hardness, friability, disintegration time, assay, dissolution profile, and identification and quantification of degradation products. Validated methods were used to perform analytical evaluations: tablet hardness and friability were assessed by using a hardness tester and friabilator, disintegration time by using a USP disintegration apparatus, and the content of the drug by using high-performance liquid chromatography (HPLC) with UV detection (Singh and Bakshi, 2019). Dissolution profiles were produced using the USP methods to guarantee homogenous drug release, and any difference between the original profile was reported as a sign of physical or chemical instability.

The rate of degradation was studied by fitting the assay data and degradation-product data to a zero-order and first-order kinetic law and the Arrhenius equation to estimate the rate as a function of temperature. Accelerated studies were extrapolated to obtain the rate constants to predict the stability of the product in real-time conditions and the shelf life could be estimated. The data regarding the stability was then statistically analyzed by the use of regression analysis in order to establish the relationship between the accelerated and real-time degradation rate and determining significant value at $p < 0.05$. Also possible sources of variability, including sampling errors, environmental changes, and the precision of the analytical method were reduced through the use of all tests as triplicates and in controlled laboratory conditions. The process of methodology guaranteed the adherence to the regulatory requirements in addition to delivering adequate data to be used in scientific and practical assessment of shelf-life prediction. The study would offer an extensive insight into the stability behavior of solid dosage forms to various storage conditions by combining empirical stability measurements with kinetic modeling.

Results

Physical Stability Parameters

Table 1. Physical Stability of Tablets under Real-Time and Accelerated Conditions

Parameter	Initial Value	Real-Time 6 Months	Real-Time 12 Months	Accelerated 1 Month	Accelerated 3 Months	Accelerated 6 Months
Appearance	White, smooth	No change	No change	Slight discoloration	Moderate discoloration	Noticeable discoloration
Hardness (kg/cm²)	6.5 ± 0.2	6.4 ± 0.3	6.3 ± 0.2	6.2 ± 0.3	6.0 ± 0.3	5.8 ± 0.4
Friability (%)	0.4 ± 0.02	0.4 ± 0.03	0.5 ± 0.02	0.5 ± 0.02	0.6 ± 0.03	0.7 ± 0.04
Disintegration (min)	5 ± 0.3	5.1 ± 0.2	5.2 ± 0.2	5.3 ± 0.2	5.5 ± 0.3	5.7 ± 0.3

Under real time conditions, the physical parameter of the tablet formulation was not significantly altered over a period of 12 months. There was no significant variation in hardness, friability, and disintegration, which meant that the tablets did not lose their structural integrity and performance. Accelerated conditions caused mild to moderate alterations, and there were friability, slight changes in color and a slight increase in disintegration times. These findings indicate that high temperature and humidity increases the rate of physical degradation without having a serious adverse impact on the quality of the tablets within the 6-month accelerated process. The changes seen are in accordance with the already published literature, with accelerated conditions increasing small-scale physical changes that are insignificant when stored under usual conditions (Shah et al., 2019; Sivaraman et al., 2020). These trends of physical stability are significant in predicting the shelf-life, so that the tablets will be appropriate to be used by patients over the stipulated time of storage.

Chemical Stability and Assay

Table 2. Assay (% of labeled drug content) under Real-Time and Accelerated Conditions

Time Point	Real-Time (%)	Accelerated (%)
0 month	100 ± 1.0	100 ± 1.0
1 month	99.8 ± 0.8	98.5 ± 0.9
3 months	99.6 ± 0.7	96.8 ± 1.0
6 months	99.3 ± 0.8	94.5 ± 1.2
9 months	99.1 ± 0.9	—
12 months	98.9 ± 1.0	—

The results of the assays show that there is insignificant chemical degradation in the real-time storage, and the drug contents are not less than 98 percent after 12 months. The degradation was more evident at an accelerated-storage, and the drug content was

reduced to 94.5% in 6 months. These findings indicate that high temperatures and moisture increase the rate of chemical corrosion of the API according to first-order kinetics in which the corrosion rate is proportional to the drug content remaining (Carstensen and Rhodes, 2000). Both accelerated and real time degradation correlate to be used in Arrhenius modeling to predict shelf-life. The information indicates that the tablets are chemically stable at normal conditions at least 240-30 months depending on the kinetic model. This tendency will be consistent with earlier research that highlights the predictability of accelerated stability testing of solid dosage forms (Shah et al., 2019; Sivaraman et al., 2020).

Dissolution Profile

Table 3. Dissolution (% drug released) under Real-Time and Accelerated Conditions

Time Point	Real-Time (%)	Accelerated (%)
0 month	98 ± 1.2	98 ± 1.2
3 months	97.5 ± 1.1	96.0 ± 1.5
6 months	97 ± 1.2	94.5 ± 1.8
12 months	96.5 ± 1.3	—

DISCUSSION

The current research evaluated stability of a representative solid dosage form at real-time and accelerated conditions, which would give a logical idea of physical, chemical, and dissolution stability over time. The findings indicate that the integrity of the tablet formulation was retained even under real-time storage conditions (25 °C + or -2 o C / 60 percent relative humidity + or -5 percent) with little alterations in hardness, friability, disintegration, assay, and dissolution within 12 months. The results are in line with the previous statements that well-designed solid dosage forms that are stored in the conditions recommended tend to maintain their quality to provide therapeutic efficiency and patient safety (Shah et al., 2019; Sivaraman et al., 2020).

Stability tests (accelerated) (40 o C +2 o C /75 percent RH + 5% RH) resulted in detectable physical appearance, chemical composition and dissolution rate. It is worth mentioning that tablet discoloration, enhanced friability, and minor extension of the disintegration rate were noted, which is indicative of the effect of high temperature and humidity on chemical and physical degradation mechanisms. The results of chemical assays demonstrated that the content of drugs dropped to 94.5% in six months with the use of accelerated conditions, which indicated the capability of accelerated conditions to speed up degradation and be used as a predictive factor of shelf life (Carstensen and Rhodes, 2000; Singh and Bakshi, 2019). Although these changes were observed, the dissolution profiles were not significantly affected and thus, the drug release mechanism was not greatly impaired even in the presence of stress condition. The paper used kinetic modeling as the predictor of shelf life. The chemical degradation pattern was well explained in first-order kinetics, which is in line with the principle that the degradation rate is proportional to the amount of drug remaining (Rathore et al., 2020). Moreover, Arrhenius model was used to make extrapolations of accelerated stability results to the real-time conditions, and an estimated shelf life of 24-32 months was achieved. These forecasts are in line with regulatory anticipations and show that it is possible to predict product longevity through the integration of empirical evidence with

mathematical modeling in order to be accurate (Shah et al., 2019; Sivaraman et al., 2020).
Combining real-time and accelerated stability investigation is of great benefit to the development of pharmaceuticals as well as regulatory compliance. Real-time studies indicate conclusive evidence of product stability at normal conditions, and accelerated studies indicate a quick revelation of possible degradation pathways, aids in early formulation modifications, package choices, and regulatory submission (Singh & Bakshi, 2019; FDA, 2022). This twin strategy not only shortens the development cycles, but also makes sure that the products are of quality during the period they are supposed to be in shelves.

In addition, the research shows that it is essential to observe numerous quality characteristics, such as physical, chemical and dissolution parameters. Although degradation chemical is vital in terms of potency, physical alterations that include hardness, friability and disintegration may influence patient adherence and bioavailability. Small physical changes under accelerated conditions provide the example of how stress-induced changes should be viewed with caution because they do not necessarily represent the actual performance but are necessary in the context of identifying the potential risks in the process of development of the formulation (Shah et al., 2019). Finally, the paper has established that properly designed solid dosage forms have strong stability at recommended storage temperatures and accelerated tests can be used to predict the possibility and ease the determination of shelf-life. The result of empirical experimentation and kinetic modeling is a scientifically valid and regulatory compliant methodology of stability profiling, which guarantees quality, efficacy, and patient safety of products. The evidence is valuable in pharmaceutical development practices and provides a viable guide towards the use of shelf life prediction in solid dosage formulations.

Limitations and Future Directions.

As much as the current research offers a detailed analysis of stability and shelf-life prediction of a representative solid dosage form, there are some limitations that must be noted. To start with, one model formulation was used in the study; hence, the results cannot be directly applied to all solid dosage forms, especially those ones including highly moisture-sensitive or thermo labile APIs. A change in the excipient compatibility, tablet matrix composition or manufacturing method may potentially result in various stability results. Second, accelerated stability was only conducted over six months, which, though adequate in prediction of initial shelf-life, may not reflect all potential long-term degradation mechanisms that might take place during real-time practice. Also the conditions of the environment of the real world storage conditions, including variable temperature and humidity, were not modeled and this can have different effects on stability than the controlled laboratory conditions.

Third, although kinetic modeling through the zero-order, first-order, and Arrhenius approaches are reliable predictions, the models are based on the assumption of similar degradation mechanisms at various conditions. Degradation pathway may alter any change in higher temperatures, resulting in poor forecasting of the shelf-life. In addition, the testing did not include photostability testing or advanced stress testing (i.e. freeze-thaw cycles) as other regulatory guidelines recommend to fully test the product.
The predictive models should be validated through future research to generalize the dependability of the research to the broader range of APIs and formulations, including moisture-sensitive, poorly soluble, and modified-release tablets. Prediction of shelf-life might be further improved by

incorporating real-world storage simulation and other stress conditions, i.e. light exposure, temperature cycling. Additionally, further analytical methods like liquid chromatography-mass spectrometry (LC-MS) as a tool of degradation-products identification may contribute to the knowledge of degradation mechanism and increase the accuracy of predictive models. In silico predictive models developed using machine learning can also offer fast and cheap solutions to shelf-life estimation without the need to rely on long-term real-time studies. With the limitations tackled and the proposed directions followed in future, pharmaceutical researchers and manufacturers could obtain more precise, efficient, and robust stability profiling of solid dosage forms, which will eventually guarantee a stable product quality and patient safety.

CONCLUSION

The experiment established that solid dosage forms have a strong stability in real time storage containers with slight variations of physical, chemical, and dissolution parameters throughout the period of 12 months. The accelerated stability test showed that it degraded more rapidly, mainly in chemical content and minor physical properties, and validates the fact that, high temperature and humidity can be used successfully to project the stability. This combination of the empirical stability data with the kinetic modeling with zero-order, first-order, and Arrhenius equations gave the opportunity to reliably estimate the shelf life, which was observed to be on the basis of 24 to 32 months.

These results demonstrate that real-time and accelerated studies should be combined to achieve a comprehensive profile of stability because this method will allow identifying possible risks in formulation early, make decisions in relation to packaging, and comply with regulatory requirements. By following several quality attributes such as drug assay, physical integrity, and dissolution profile, the assurance that tablets retain their safety, efficacy and bioavailability during the desired shelf life is examined. To sum up, the experiment represents a scientifically valid model of estimating the shelf life of solid dosage forms. It highlights the importance of stability studies and kinetic modeling in drug development and shortening the development cycles but maintaining high quality. Next-generation stress testing and more sophisticated analysis is something that may be implemented in the future to help to refine the shelf-life prediction and ensure the quality assurance of a wide range of pharmaceutical preparations even better.

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