

A Review: Accelerated Stability Testing and Shelf-Life Prediction of Pharmaceutical Products Using The Arrhenius Equation

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Keywords :	Abstract
Arrhenius Equation; Drug Stability; Shelf Life	Drug stability is an important parameter in ensuring the quality, safety, and effectiveness of pharmaceutical preparations during storage. Conventional stability testing requires a long period of time; therefore, accelerated stability testing methods based on the Arrhenius equation have been developed to accelerate the prediction of drug shelf life. This review article aims to examine the application of Accelerated Stability Testing (AST), Accelerated Shelf Life Testing (ASLT), Accelerated Predictive Stability (APS), and the Accelerated Stability Assessment Program (ASAP) in predicting the stability of various pharmaceutical dosage forms. The research method used was a narrative literature review, analyzing 10 national and international original research articles published between 2016 and 2026, obtained from Google Scholar, ScienceDirect, PubMed, and MDPI databases. The results of the review showed that the Arrhenius approach was able to provide accurate shelf-life predictions for liquid, semisolid, solid, biological, and herbal dosage forms. Temperature, humidity, oxygen exposure, and packaging type were identified as factors affecting the degradation rate of pharmaceutical products during storage. In addition, Arrhenius-based predictive stability models were considered effective in accelerating product development and supporting pharmaceutical registration processes. In conclusion, the Arrhenius kinetic approach is an efficient and valid method for stability evaluation and shelf-life prediction of modern pharmaceutical products.

INTRODUCTION

Drug stability is one of the important parameters in ensuring the quality, safety, and effectiveness of pharmaceutical preparations during the storage process until used by patients (Ghimire et al., 2020; Narayan & Choudhary, 2017; Organization, 2024; Rignall, 2017; Zothanpuui et al., 2020). Drug instability can cause degradation of active substances that have an impact on decreasing therapeutic potential, changes in physical and chemical characteristics, and the formation of potentially toxic degradation products. Therefore, stability evaluation is an essential part of the development, production, and distribution of pharmaceutical products (Akbarian & Chen, 2022; González-González et al., 2022; Halwani, 2022; Musakhanian et al., 2022). The determination of the shelf life of the drug is carried out to ensure that the preparation continues to meet the quality specifications for a certain period of storage according to the recommended conditions (González-González et al., 2023).

Conventional stability tests are generally performed under long-term storage conditions (real-time stability testing), but this method takes a relatively long time and costs a lot of money. This condition is a challenge, especially in the development of new pharmaceutical products that require a faster shelf-life determination. To overcome this, accelerated stability test methods—namely Accelerated Stability Testing (AST) and Accelerated Shelf Life Testing (ASLT)—were developed; these are test methods involving storage at higher temperatures and humidity than normal conditions to accelerate the occurrence of degradation reactions. This approach allows shelf-life predictions to be made in a shorter time without compromising the scientific validity of stability testing (Andrie et al., 2022).

Shelf-life predictions in accelerated stability methods are generally based on a chemical kinetic approach using the Arrhenius equation, which describes the relationship between temperature and drug degradation reaction rate. The Arrhenius equation states that an increase in temperature will increase the reaction rate constant so that degradation takes place faster (Damo et al., 2023; Kucinskis et al., 2022; Yue et al., 2026). This approach is widely used in the pharmaceutical industry to estimate the stability of products under normal storage conditions based on data from storage results at high temperatures. Through this model, the constant rate of degradation and activation energy can be calculated so that shelf-life prediction can be carried out more scientifically and efficiently: $k = Ae^{(-E_a/RT)}$ (González-González et al., 2023).

Various studies show that the Arrhenius approach can be used to predict the stability of various forms of pharmaceutical preparations, including liquid, semisolid, solid, and biological products. Research by González-González et al. (2023) shows that the Accelerated Predictive Stability (APS) approach based on the Arrhenius equation can be used to accurately estimate the shelf life of chlorhexidine formulations under various storage conditions. The results of the study showed that increasing storage temperature accelerated the degradation of active substances and affected the shelf-life value of the preparation. In addition, other studies also reported that the factors of temperature, humidity, light, oxygen, and packaging type had a significant influence on the stability of pharmaceutical products during storage.

In addition to being applied to synthetic pharmaceutical preparations, the Arrhenius-based ASLT method is also widely used in herbal products and preparations based on natural ingredients, which tend to have lower stability due to the content of complex and environmentally sensitive active compounds. Research by Nurhikmah et al. (2025) reported the use of the Arrhenius method in determining the shelf life of instant granules made from a combination of broccoli and gotu kola extract, stored at various accelerated temperatures. The study showed that an increase in storage temperature causes changes in the physical and chemical parameters of the preparation, allowing the shelf life of the product to be estimated at normal temperatures. Other research by Andrie et al. (2022) also showed that accelerated stability testing was effectively used to evaluate the stability of a combination ointment of snakehead fish extract and kelulut honey through the observation of physical quality changes during accelerated storage.

The development of current stability modeling technology further supports the use of kinetics-based predictive approaches to accelerate the development of pharmaceutical products. Methods such as the Accelerated Stability Assessment Program (ASAP), advanced kinetic modeling, and artificial intelligence-based approaches have begun to be developed to

improve the accuracy of drug shelf-life predictions. This approach is considered capable of helping the pharmaceutical industry accelerate product development without neglecting the aspects of quality, safety, and effectiveness of drugs (Lennard et al., 2024). Therefore, this review article aims to comprehensively review the concept of accelerated stability assays and drug shelf-life prediction based on the Arrhenius equation, including the principles of degradation kinetics, factors affecting stability, and the application of the method to various pharmaceutical preparations. The benefits of this review are twofold: theoretically, it provides a comprehensive synthesis of the Arrhenius-based stability testing approach, serving as a scientific reference for researchers and academics in the field of pharmaceutical stability; practically, the findings can guide the pharmaceutical industry in selecting appropriate accelerated testing strategies, reducing development time and costs, and supporting regulatory submissions for drug registration.

METHOD

This research uses a literature review method with a narrative approach to various research results related to accelerated stability tests and drug shelf-life prediction based on the Arrhenius equation. Literature sources were obtained through searching reputable national and international scientific databases, such as Google Scholar, ScienceDirect, PubMed, and MDPI, using the keywords "accelerated stability testing," "accelerated shelf life testing," "Arrhenius equation," "drug stability," "shelf life prediction," and "pharmaceutical stability." The literature used consists of original research articles published between 2016 and 2026 related to the application of the Arrhenius method in evaluating the stability and determining the shelf life of pharmaceutical preparations. The journal selection process was carried out based on the suitability of the topic, completeness of the research data, validity of the method, and the reputation of the journal used.

A total of 10 research journals were selected and analyzed systematically based on research objectives, stability testing methods, accelerated storage conditions, evaluation parameters, degradation kinetics models, and drug shelf-life predictions. The data obtained were then compared and synthesized to evaluate the application of the Arrhenius equation in estimating the stability of various pharmaceutical preparations, including solid, liquid, semisolid, and herbal products. The analysis was carried out descriptively to identify the relationship between the increase in storage temperature and the rate of drug degradation, as well as the effectiveness of the accelerated stability testing method in determining the shelf life of pharmaceutical products. This approach is expected to provide a scientific overview of the development of Arrhenius kinetics-based drug stability prediction methods in the field of pharmaceuticals.

RESULTS AND DISCUSSION

The results of the literature review in this review article are compiled based on an analysis of 10 national and international research journals that discuss accelerated stability tests and predictions of drug shelf life using the Arrhenius equation approach. The discussion focused on the basic principles of drug stability, factors that affect the degradation of pharmaceutical preparations, accelerated stability testing (AST) and accelerated shelf life testing (ASLT) methods, and the application of the Arrhenius kinetics model in estimating the shelf life of

pharmaceutical products. In addition, the study also covers the different types of pharmaceutical preparations tested, stability evaluation parameters, and the development of modern predictive methods in the field of drug stability.

The analysis was carried out by comparing the study method, accelerated storage conditions, observation parameters, and kinetic approaches used in each study. Through this approach, it is hoped that a comprehensive picture can be obtained of the effectiveness of the use of the Arrhenius equation in predicting the stability and shelf life of pharmaceutical preparations, as well as its relevance in the development of quality, safe, and effective pharmaceutical products.

Table 1. Drug Stability Research Summary

No	Researcher	Preparation	Test Parameters	Research Results
1	(González-González et al., 2023)	Larutan chlorhexidine	Degradation of active substances, activation energy, shelf life	The <i>Accelerated Predictive Stability</i> (APS) approach based on the Arrhenius equation is able to accurately predict the shelf life of chlorhexidine. The predicted shelf life of preparations at 5°C reaches 26.67 months, while at 25°C and 30°C temperatures are 5.75 and 2.24 months, respectively.
2	(Lennard et al., 2024)	Biological and biotechnology products	Physicochemical stability, degradation kinetics, shelf life	Arrhenius-based stability modeling and advanced kinetic modeling (AKM) are considered effective in accelerating the prediction of shelf life of pharmaceutical products without waiting for complete long-term stability data.
3	(Zidar et al., 2025)	Biological and biotherapeutic proteins	Protein aggregation, first-order kinetics, biological stability	The Arrhenius-based first-order kinetics model is able to provide more accurate predictions of long-term biological stability than linear extrapolation methods, especially in protein aggregation assays.
4	(Andrie et al., 2022)	Snakehead fish extract ointment and kelulut honey	Organoleptic, homogeneity, dispersiveness, adhesion, acid number	The addition of 0.1% BHT provides the best stability to the ointment preparation during 28 days accelerated storage at $40 \pm 2^\circ\text{C}/\text{RH } 75 \pm 5\%$, with the lowest increase in acid count.
5	(Syska et al., 2025)	Purslane leaf herbal tea	Moisture content, sorption isotherms, shelf life	The Arrhenius model Accelerated Shelf Life Testing (ASLT) method was successfully used to estimate the shelf life of herbal tea. The aluminum foil packaging provides the best stability protection compared to HDPE and PP during storage.
6	(Luo et al., 2025)	Formulasi antibodi monoklonal anti-SARS-	<i>High molecular weight</i> (HMW), <i>low molecular weight</i> (LMW),	The Arrhenius-based predictive stability approach is able to accurately predict the long-term stability of monoclonal antibodies

		CoV-2 konsentras tinggi	<i>acidic species, shelf life</i>	using 1-month accelerated stability data at a temperature of 25–40°C. The kinetics model successfully predicts stability for up to 36 months at 5°C.
7	(Nurhikmah et al., 2025)	Instant granules combination of broccoli and gotu extract	Organoleptik, loss on drying (LOD), waktu dispersi, pH, kadar flavonoid	The Arrhenius model of <i>Accelerated Shelf Life Testing</i> (ASLT) method was successfully used to determine the shelf life of instant granules. The preparation showed a shelf life of 13.2 weeks or 92 days at room temperature (25°C).
8	(Syska et al., 2023)	Teh pegagan (<i>Centella asiatica</i>)	Moisture content, pH, yield, shelf life	Storage temperature and packaging type affect the stability of the tea baggagan. Aluminum foil and vacuum plastic packaging provide better shelf life prediction than paper sacks based on the Arrhenius model ASLT method.
9	(Modhave et al., 2024)	GLPG4399 capsules	Product degradation, moisture, activation energy, shelf life	The <i>moisture-modified Arrhenius equation-based Accelerated Stability Assessment Program (ASAP) approach</i> was effectively used to predict the shelf life of GLPG4399 capsules. The model shows a good validity value with $R^2 > 0.95$ and $Q^2 > 0.80$.
10	(Pavcnik et al., 2025)	Sediaan parenteral carfilzomib	Total impurities, diol impurity, ethyl ether impurity, stabilitas	The use of <i>Accelerated Predictive Stability Testing</i> (APS) and ASAP models is able to accelerate the evaluation of the stability of parenteral preparations and provide accurate degradation predictions to support the determination of drug shelf life.

Source: Compiled from original research articles published between 2016–2026

The Use of the Arrhenius Equation in Drug Shelf Life Prediction

The Arrhenius equation approach is widely used in accelerated stability tests to predict drug shelf life based on the relationship between temperature and the degradation rate of the active substance. This equation explains that an increase in temperature can increase the constant of the reaction rate so that the degradation process takes place faster. This principle is the basis for the Accelerated Stability Testing (AST) and Accelerated Shelf Life Testing (ASLT) to estimate the stability of the preparation in a shorter time than the test real-time (González-González et al., 2023).

$$k = Ae^{(-E_a/RT)}$$

Research by González-González et al. (2023) shows that the Accelerated Predictive Stability (APS) approach based on the Arrhenius equation is able to accurately predict the shelf life of chlorhexidine solutions at various storage temperatures. The results showed that the shelf life of preparations at 5°C reached 26.67 months, while at 25°C and 30°C it decreased to 5.75

and 2.24 months. The decrease in shelf life indicates that the increase in temperature accelerates the rate of degradation of the active substance, resulting in lower stability of the preparation.

Similar results were also reported by Nurhikmah et al. (2025) on instant granules in combination of broccoli extract and sticker. The Arrhenius model ASLT method was successfully used to determine the shelf life of preparations with a shelf life of 13.2 weeks or 92 days at room temperature (25°C). The study shows that the Arrhenius approach is not only effective in synthetic drugs, but also in herbal preparations that have a higher complexity of active compounds.

Effect of Temperature and Storage Conditions on Inventory Stability

Temperature is one of the main factors that affect the stability of the drug during storage. Rising temperatures can accelerate chemical degradation, oxidation, hydrolysis, and physical changes of preparations. Therefore, accelerated stability testing is performed at high temperatures and humidity to accelerate product quality degradation so that the estimated shelf life can be obtained faster (Luo et al., 2025).

Research by Andrie et al. (2022) on a combination ointment of snakehead fish extract and kelulut honey showed that accelerated storage at $40 \pm 2^\circ\text{C}/\text{RH } 75 \pm 5\%$ for 28 days can affect the physical characteristics of the preparation. The addition of 0.1% BHT provides the best stability with the lowest increase in acid count compared to other formulas. These results show that antioxidants play an important role in inhibiting the oxidation process during accelerated storage so that the quality of the preparation can be better maintained.

In addition, Syska et al.'s (2023) research on gotu gotu tea shows that storage temperature and packaging type affect the shelf life of products. Aluminum foil and vacuum plastic packaging provide better stability than paper sacks because they are able to inhibit the penetration of moisture and oxygen from the environment. These results show that the stability of the product is not only affected by temperature, but also by the packaging system used during storage.

Kinetic Modeling in Biological Product Stability

Biological and biotechnology products have more complex stability challenges than conventional chemical preparations because they are susceptible to protein aggregation, denaturation, and changes in molecular structure. Therefore, the development of accurate kinetic models is indispensable to predict biological stability during storage. Lennard et al. (2024) report that Arrhenius-based stability modeling and advanced kinetic modeling (AKM) are effectively used to accelerate the prediction of the shelf life of biological products without having to wait for complete long-term stability data. The model is considered to be able to provide a more efficient scientific approach in the development of modern pharmaceutical products, especially biological and biotherapeutic.

Research by Zidar et al. (2025) also shows that the Arrhenius-based first-order kinetics model is able to provide more accurate predictions of long-term biological stability than linear extrapolation methods, especially in protein aggregation assays. This kinetic approach helps to estimate changes in biological quality during storage so that it can be used to support the determination of the shelf life of biotherapeutic products.

Predictive Stability and ASAP Approach in the Pharmaceutical Industry

The current development of stability modelling technology encourages the use of predictive stability approaches to accelerate the development of pharmaceutical products. One of the widely used methods is the Accelerated Stability Assessment Program (ASAP), which is a moisture-modified Arrhenius equation-based approach that utilizes high temperature and humidity conditions to accelerate product degradation. Modhave et al. (2024) report that the ASAP approach is effectively used to predict the shelf life of GLPG4399 capsules with excellent model validity, indicated by R^2 values >0.95 and $Q^2 >0.80$. The model is able to accurately estimate product degradation so that it can be used as an alternative to conventional stability testing that takes longer.

In addition, Pavcnik et al. (2025) showed that the use of Accelerated Predictive Stability Testing (APS) and ASAP models on carfilzomib parenteral preparations was able to accelerate the stability evaluation and prediction of product degradation. This method is considered to be able to support the drug registration process and the determination of shelf life more efficiently without reducing the scientific validity of the stability data.

Application of the Arrhenius Model in Herbal Products and Functional Foods

The Arrhenius-based ASLT method is not only applied to synthetic pharmaceutical products, but also to herbal products and functional foods that have a high sensitivity to temperature and humidity. Herbal products generally contain bioactive compounds that are easily degraded so they require proper stability evaluation to ensure product quality during storage. Research by Syska et al. (2025) on purslane leaf herbal tea shows that the Arrhenius model ASLT method was successfully used to estimate the shelf life of the product based on changes in moisture content and isothermal absorption during storage. The results show that aluminum foil packaging provides the best stability protection compared to HDPE and PP because it has better barrier ability against environmental moisture.

The results of the study are supported by research by Nurhikmah et al. (2025) which shows that instant granules of a combination of broccoli and gotu gotu extract still meet physical and chemical quality parameters during accelerated storage. The use of the Arrhenius model is considered effective in helping to estimate the shelf life of herbal products faster and more efficiently than conventional storage methods.

CONCLUSION

Based on the results of a literature review, the accelerated stability test method based on the Arrhenius equation has proven effective in predicting the shelf life of various pharmaceutical preparations, including synthetic, biological, and herbal preparations. This approach is able to accelerate stability evaluation through increased storage temperature and humidity, so that the rate of drug degradation can be observed in a shorter time. Various studies show that the Arrhenius model, Accelerated Shelf Life Testing (ASLT), Accelerated Predictive Stability (APS), and the Accelerated Stability Assessment Program (ASAP) are able to provide accurate and valid shelf-life predictions to support pharmaceutical product development, packaging selection, and drug registration processes. In addition, the factors of temperature, humidity, packaging type, and active ingredient characteristics are known to have an important influence on the stability of the product during storage. Thus, the use of the Arrhenius-based

kinetics approach has become an efficient, scientific, and relevant method for evaluating the stability and determining the shelf life of modern pharmaceutical products.

Based on these findings, several suggestions are proposed. Future research should expand the application of the Arrhenius model to more complex biological products, including gene therapies and cell-based therapies, where degradation mechanisms are not yet fully understood. Pharmaceutical industries are encouraged to adopt advanced kinetic modeling and the ASAP approach to reduce development time while maintaining scientific rigor in stability studies. Regulatory agencies may consider providing clearer guidelines on the validation and acceptance criteria for Arrhenius-based predictive stability data to support faster drug registration. Additionally, further studies should explore the integration of artificial intelligence and machine learning with Arrhenius kinetics to improve the accuracy of shelf-life predictions under varying storage conditions.

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