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STABILITY STUDIES OF TABLET DOSAGE FORMS AND THEIR INFLUENCE ON PHYSICOCHEMICAL CHARACTERISTICS: A REVIEW

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ABSTRACT

Tablet dosage forms generally exhibit better stability compared to liquid formulations; however, stability testing remains essential to evaluate both physical and chemical parameters. This study aimed to compare the stability of tablet formulations under various testing conditions in terms of their physicochemical properties. This study aimed to compare the stability of tablet formulations under various testing conditions in terms of their physical and chemical properties. This study employed a literature review approach. Scientific articles were retrieved from Scopus, ScienceDirect, PubMed, MDPI, Web of Science, and Google Scholar, as well as national databases such as GARUDA and SINTA-indexed journals database using the used keywords such as "tablet," "formulation," "optimization," "stability evaluation," and "stability studies." The search covered publications from 2016 to 2026. A total of 2,201 articles were initially identified and then screened based on their relevance to the research topic. The main inclusion criterion was studies focusing on the stability of tablet dosage forms, particularly those evaluating both physical stability (such as hardness, friability, and disintegration time) and chemical stability (including active ingredient content and degradation). Based on these criteria, 8 relevant articles were selected and further analyzed to evaluate the physicochemical stability of tablet formulations. The findings indicate that several tablet formulations experienced deterioration in physical and chemical parameters, including changes in hardness, disintegration time, and decreased active ingredient content. These alterations were primarily associated with changes in excipient properties and interactions with environmental factors such as light exposure and moisture. Furthermore, inappropriate storage conditions contributed to the instability of the formulations. The stability of tablet dosage forms is therefore influenced by both formulation factors and storage conditions. The application of drug–excipient compatibility studies (DECS) and crystallo-co-agglomeration techniques during the formulation stage, along with proper control of temperature and humidity and the use of suitable packaging such as aluminium blisters and silica gel are crucial to maintaining tablet stability during storage.

Keywords: excipient compatibility; physicochemical stability; stability studies; tablet stability

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INTRODUCTION

Tablets are solid dosage forms containing one or more active pharmaceutical ingredients along with excipients. Compared to liquid forms such as syrups, solid dosage forms generally exhibit superior stability. However, the stability of tablet formulations can be influenced by both formulation factors and storage conditions. Excipients, which are often present in higher concentrations than active ingredients, may potentially interfere with the physical stability of tablets. In addition, excessive temperature and humidity during storage can significantly reduce tablet stability (Maclean et al., 2021).

Drug stability refers to the ability of a pharmaceutical product to maintain its quality, safety, and efficacy throughout its shelf life, making it a fundamental aspect of quality assurance (Mamgain & Gahtori, 2022). A decrease in tablet stability may lead to reduced bioavailability, diminished therapeutic efficacy, and compromised drug safety. Indicators of instability in tablet dosage forms

include changes in color, taste, and odor, as well as polymorphic and crystallization. Therefore, stability testing is essential to ensure both the physical and chemical integrity of pharmaceutical products.

Stability studies are conducted to evaluate the quality of drug products over a specific period under various storage conditions, including differences in temperature, humidity, and light exposure. These evaluations are crucial for determining appropriate shelf life and optimal storage conditions for maintaining the quality of tablet formulations (Othman et al., 2025). Therefore, this study aims to analyze and compare the stability of tablet formulations under various testing conditions, focusing on their physical and chemical characteristics based on evidence from previous studies.

METHOD

This study employed a literature review approach without experimental laboratory work. Articles included were national and international publications published between 2016 and 2026. Literature searching was conducted through international databases, including Scopus, ScienceDirect, PubMed, MDPI, Web of Science, and Google Scholar, as well as national databases such as GARUDA and SINTA-indexed journals. The search strategy used keywords such as "tablet," "formulation," "optimization," "stability evaluation," and "stability studies." Relevant articles were selected based on their focus on tablet stability, particularly physicochemical properties, excipient interactions, and storage conditions. A total of 2.201 articles were identified and 8 relevant articles were analyzed descriptively to compare findings and draw conclusion.

RESULT

This study synthesized findings from eight previous studies on the physical and chemical stability of tablet dosage forms, focusing on physical parameters such as organoleptic properties, pH, weight uniformity, hardness, friability, thickness, disintegration time, and dissolution, as well as chemical parameters including the active pharmaceutical ingredient (API) content after the testing period.

Table 1.
Summary of Stability Studies of Tablet Dosage Form

No	Article	Stability Studies	Result	References
1	Formulation, Evalution and Stability Studies of Paracetamol IR Tablets	Long-term stability testing was conducted at 25 ± 2°C and 60 ± 5% relative humidity (RH) for at least 12 months, while intermediate stability testing was performed at 30 ± 2°C and 65 ± 5% RH for 6 months. Accelerated stability testing was carried out at 40 ± 2°C and 75 ± 5% RH for 6 months.	The study reported that organoleptic properties, weight uniformity, tablet hardness, and disintegration time remained within the specifications established by ICH throughout the study period. However, dissolution testing showed a slight decrease, from 96.43% to 92.57% after 6 months of storage.	(Natarajan *et al*., 2023).
2	Formulation and Stability Studies Evaluation of the Selected Captopril Mouth Dissolving Tablet MDTs	Accelerated stability testing under conditions of 40°C and 75% relative humidity (RH) for 6 months. Sampling was performed at predetermined intervals, specifically at 0, 1, 2, 3, 4, 5, and 6 months.	The study reported that organoleptic properties, weight uniformity, friability, and hardness met specifications. Faster disintegration was observed in phosphate buffer saline (pH 6.8) with a mean time of 11 seconds and a wetting time of 13 seconds. The active pharmaceutical ingredient (API) content decreased to 90.4% after 6 months but remained within acceptable limits.	(Othman *et al.,* 2025).
3	Formulation and Stability Studies of Fast Disintegrating Tablets of	Real-time stability testing was conducted in a stability chamber at 30 ± 2°C and controlled relative humidity,	The study reported that organoleptic properties, weight uniformity, friability, disintegration time, thickness, and dissolution met	(Ahsan *et al.,* 2019).

No	Article	Stability Studies	Result	References
	Amlodipine Besylate	while accelerated stability testing was performed at 40 ± 2°C and 75 ± 5% relative humidity (RH) for 6 months.	specifications under both conditions. The active pharmaceutical ingredient (API) content slightly decreased to 99.65% under real-time conditions and 95.90% under accelerated conditions, remaining within acceptable limits.	
4.	Accelerated Stability Testing and Evaluation of Telmisartan Brands: A Comparative Study	Accelerated stability test on two different brands of telmisartan tablets under storage conditions of 40 ± 2°C and 75 ± 5% relative humidity (RH) for 6 months.	The study reported that organoleptic properties, tablet hardness, friability, disintegration, and dissolution met the required specifications for both brands throughout the testing period. However, the active pharmaceutical ingredient (API) content decreased after 6 months of storage, from 99.26% to 91.60% for Sartel-20 and from 98.97% to 91.12% for Telsartan TM-20.	(Bankhele *et al.,* 2022).
5.	A Novel Stability Study of Simvastatin Generic Tablet in Public Pharmacy Facilities of Purwakarta, Indonesia	Long-term stability of tablet formulations under various environmental storage conditions over a period of 6 months. Testing was conducted at specific time intervals, namely at 0, 3, and 6 months. In addition, stress testing was performed to assess the stability of the drug under extreme conditions.	Organoleptic properties and disintegration met specifications. Hardness decreased and friability increased (<1%). Dissolution declined, with some samples failing after storage. The active pharmaceutical ingredient (API) content decreased to 90–95% but remained within limits. Tablets were more prone to degradation under accelerated conditions.	(Yulianita *et al.,* 2021).
6.	Development of Stability-Indicating HPLC Methode and Accelerated Stability Studies for Osmotic and Pulsatile Tablet Formulatons of Clopidogrel Bisulfate	Accelerated stability testing of tablet formulations in accordance with ICH Q1A (R2) guidelines at 40 ± 2°C and 75 ± 5% relative humidity (RH) for 6 months, with sampling performed at 0, 1, 3, and 6 months.	All parameters met specifications, including weight uniformity, hardness, and dissolution. The active pharmaceutical ingredient (API) content ranged from 93.56–94.34% (osmotic tablets) and 94.55–98.23% (pulsatile tablets). Floating lag time was 1.20–1.47 minutes and burst lag time ≤ 6 hours. The %RSD values were 1.6145% and 1.9121%.	(Deshmukh *et al.*, 2019).
7.	Formulation and Physical Stability Test of Effervescent Tablets Containing *Lactobacillus bulgaricus* Probiotic Bacteria Using the Wet Method	A seventh study evaluated tablet stability under accelerated high- and low-temperature conditions at 8 ± 2°C and 75 ± 5% relative humidity (RH) for 2 months, as well as real-time conditions for 5 weeks at 30 ± 2°C and 75 ± 5% RH.	All formulations (F1, F2, and F3) met the required specifications for organoleptic properties, weight uniformity, thickness, hardness, friability, dissolution time, and pH. Among them, F1 was identified as the optimal formulation, showing relatively stable results across all parameters, except under accelerated high-temperature conditions where more noticeable changes were observed.	(Tanujaya & Riniwasih, 2019).
8.	Quality Assesment and Stability Studies of Metronidazole Tablets Formulations Obtained via Crystallo Co-Aggromeration Technique	Long-term stability by storing tablet samples in a desiccator containing silica gel at 25 ± 2°C and 60 ± 5% relative humidity (RH) for 12 months, with sampling conducted at 0, 6, and 12 months.	No significant changes were observed in physicochemical parameters, including organoleptic properties, weight and size uniformity, thickness, hardness, friability, content uniformity, in vitro dissolution, tensile strength, and CSFR ratio, across metronidazole CCA formulations (F1–F5) during the 12-month evaluation period.	(Abdullahi *et al.*, 2024).

DISCUSSION

The stability of tablet dosage forms is influenced by multiple factors, primarily formulation composition and storage conditions. The reviewed studies consistently demonstrate that excipient selection and environmental exposure play crucial roles in determining both the physical integrity and chemical stability of pharmaceutical tablets. Formulation design is a critical determinant of tablet stability, as excipients can directly affect mechanical strength, disintegration behavior, and drug release profiles. Drug–excipient compatibility studies (DECS) have been shown to be effective in predicting potential interactions that may compromise product stability. Othman et al. (2025), reported that captopril mouth dissolving tablets (MDTs) developed using DECS met all pharmacopeial specifications throughout stability testing. Although slight increases in wetting and disintegration times were observed after six months of storage, these changes remained within acceptable limits, indicating that the formulation maintained adequate performance over time.

The role of excipient composition in maintaining tablet stability is also demonstrated in several studies included in this review. Natarajan et al. (2023), reported that paracetamol 500 mg tablets formulated with microcrystalline cellulose, sodium starch glycolate, magnesium stearate, and talc experienced a decrease in dissolution from 96.43% to 92.57% after six months of storage. In contrast, Ahsan et al. (2019) showed that amlodipine besylate tablets prepared with an optimized combination of excipients were able to meet all required physical quality parameters, including organoleptic characteristics, weight uniformity, friability, thickness, and disintegration time. Furthermore, the tablets demonstrated faster drug release, with more than 70% of the drug released at the sixth minute, compared with approximately 48% for conventional tablets at the same time point. Changes in mechanical properties during storage were also documented. Bankhele et al. (2022), reported a decrease in hardness and an increase in friability in two brands of telmisartan tablets, Sartel-20 and Telsartan TM-20, indicating reduced interparticle bonding strength over time. These changes were associated with faster tablet disintegration, suggesting that alterations in excipient functionality or moisture uptake may weaken tablet structure during storage. These findings highlight that appropriate formulation strategies can significantly influence both the physical quality and performance of tablet dosage forms.

Variations in formulation composition were also shown to affect tablet performance and stability in probiotic effervescent tablets. Tanujaya & Riniwasih (2019), reported that three different formulations generally met the physical evaluation requirements, including weight uniformity, size, hardness, friability, pH, and other pharmacopeial parameters. However, differences in dissolution time and stability were observed among the formulations. Formula I, that contains lower concentration of citric acid demonstrated the best performance with the fastest dissolution time and the highest stability during storage. In contrast, Formula III showed the longest dissolution time and lower stability, which may be related to the higher concentration of citric acid used in the formulation.

In addition to conventional tablet formulations, advances in formulation techniques have also contributed to improved tablet stability. Abdullahi et al. (2024), evaluated metronidazole tablets prepared using the crystallo co-agglomeration technique and reported that weight uniformity, diameter, and thickness remained consistent over a 12-month period, meeting pharmacopeial standards. In the friability test, formulations F2, F3, and F4 met the required limit (<1%), whereas F1 and F5 did not fully comply with the standard. Nevertheless, all formulations exhibited high tensile strength and crushing strength within the recommended range, indicating sufficient resistance to mechanical stress. Additionally, the tablets showed rapid disintegration times (<5 minutes), which supported optimal drug release. The CSFR ratio analysis further indicated that formulation F5 had the highest mechanical strength, while the CSFR/Dt ratio across all formulations demonstrated a balanced relationship between tablet strength and disintegration ability that remained stable throughout storage. Additional evidence from Deshmukh et al. (2019), further supports these conclusions, as osmotic and pulsatile tablets demonstrated stable mechanical

properties, consistent drug content, and low variability (%RSD < 2%) throughout stability testing. These results highlight that advanced drug delivery systems can maintain stability when designed with appropriate material selection and structural integrity.

Besides formulation factors, storage conditions represent another critical determinant of tablet stability. Tablets stored under high humidity conditions may absorb moisture, which can accelerate degradation of the API and affect the physical properties of the dosage form. Similarly, elevated temperatures can increase the rate of chemical reactions within the formulation, leading to faster degradation during storage. Natarajan et al. (2023), reported a decrease in paracetamol content during storage under various stability conditions, with greater degradation observed at higher temperature and relative humidity levels. A comparable trend was observed in captopril MDTs, where accelerated stability testing at 40°C and 75% RH resulted in a noticeable decline in drug content over six months. Nevertheless, the remaining drug content still complied with ICH acceptance criteria, indicating that the formulations retained acceptable quality despite measurable degradation.

The protective role of packaging was also highlighted in several studies. Ahsan et al. (2019), demonstrated that aluminium blister packaging effectively minimized changes in physical characteristics and chemical stability during both real-time and accelerated storage. Similarly, Abdullahi et al. (2024), reported that the inclusion of silica gel as a desiccant helped maintain consistent dissolution and content uniformity values in metronidazole tablets over prolonged storage, emphasizing the importance of moisture control in preserving tablet stability.

The reviewed literature consistently showed that accelerated stability testing produces more pronounced changes in tablet properties compared with real-time storage. These findings are supported by Tanujaya & Riniwasih (2019), who stated that low temperatures provide the most optimal conditions and maintain it's stability. Bankhele et al. (2022), observed substantial reductions in telmisartan content under accelerated conditions, supporting the use of high temperature and humidity to simulate long-term degradation within a shorter testing period. Yulianita et al. (2021), also reported reductions in tablet hardness, increased friability, and decreased dissolution performance during storage, particularly under stress conditions. Although the active ingredient content remained within acceptable limits, some samples failed to meet dissolution requirements, indicating that physical deterioration may precede significant chemical degradation. These findings suggest that accelerated testing is a sensitive tool for detecting early stability issues that may not be apparent under real-time conditions.

Collectively, the reviewed studies demonstrate consistent patterns in tablet stability behavior. Most formulations exhibited gradual decreases in hardness and active ingredient content over time, accompanied by increased friability and slight reductions in dissolution performance. However, when properly formulated and packaged, the majority of tablet products remained within pharmacopeial and ICH specifications throughout the stability testing period. The findings also indicate that formulation strategy, particularly excipient compatibility and matrix design, plays a decisive role in determining the extent of degradation during storage. Environmental factors such as temperature and humidity primarily influence the rate of degradation rather than the degradation pathway itself. Therefore, the combination of optimized formulation, appropriate packaging, and controlled storage conditions is essential to ensure long-term tablet stability.

CONCLUSION

Based on the analysis of eight reviewed studies, it can be concluded that the physical and chemical stability of tablet dosage forms is influenced by formulation factors, including interactions and changes in excipient properties with active pharmaceutical ingredients, as well as storage conditions such as temperature and relative humidity. Strategies to minimize formulation-related issues include the application of drug–excipient compatibility studies (DECS) and crystallo co-agglomeration

techniques. In addition, the use of appropriate packaging, such as aluminium blisters and silica gel, along with proper control of temperature and humidity, plays a crucial role in maintaining the quality, stability, and effectiveness of tablets during storage.

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