Infarma CIÊNCIAS FARMACÊUTICAS
e-ISSN: 2318-9312
Vol.: 38, ano 2026
e202605
Original

Effects of domestic storage conditions on the physical integrity and assay of ibuprofen tablets

Efeitos das condições de armazenamento doméstico na integridade física e no teor dos comprimidos de ibuprofeno

doi: 10.14450/infarma.e202605
Recebido em: 13/3/2026
Aceito em: 18/6/2026

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ABSTRACT

Improper domestic storage of medicines may compromise product quality and patient safety, particularly for over-the-counter drugs. This study evaluated the effects of different household storage conditions on the physical integrity and assay of ibuprofen tablets over six months. Tablets were stored in four environments—bedroom, bathroom, kitchen, and car—across five households and analyzed at three time points. Visual inspection and titrimetric assay were performed according to the Brazilian Pharmacopoeia. Physical alterations, including cracking, capping, brittleness, and powder detachment, were mainly observed in tablets kept inside vehicles, suggesting increased physical instability under vehicle storage conditions. The initial assay showed ibuprofen content above the pharmacopeial upper limit, suggesting baseline non-compliance before domestic exposure. During the study, no progressive reduction in active pharmaceutical ingredient content was detected under any condition. Although statistically significant variations over time were found (two-way ANOVA, $p < 0.05$), no consistent decreasing trend indicative of chemical degradation was identified. These findings indicate that domestic storage may impair the physical stability of ibuprofen tablets without measurable loss of assay content by a pharmacopeial titrimetric method, underscoring the need for quality monitoring and public education on proper storage practices.

Keywords: ibuprofen; drug stability; pharmaceutical quality; storage conditions; over-the-counter drugs

RESUMO

Armazenamento doméstico inadequado de medicamentos pode comprometer a qualidade do produto e a segurança do paciente, especialmente no caso de medicamentos isentos de prescrição. Este estudo avaliou os efeitos de diferentes condições de armazenamento doméstico sobre a integridade física e o doseamento de comprimidos de ibuprofeno ao longo de seis meses. Os comprimidos foram armazenados em quatro ambientes — quarto, banheiro, cozinha e interior de veículos — em cinco residências, sendo analisados em três tempos experimentais. A inspeção visual e o ensaio titulométrico foram realizados de acordo com os métodos descritos na Farmacopeia Brasileira. Alterações físicas, incluindo fissuras, *capping*, friabilidade acentuada e desprendimento de pó, foram observadas predominantemente nos comprimidos mantidos no interior de veículos, indicando maior suscetibilidade a estresses mecânicos e térmicos. O doseamento

inicial revelou teor de ibuprofeno acima do limite superior estabelecido pela farmacopeia, sugerindo não conformidade do produto antes da exposição às condições domésticas de armazenamento.
Ao longo do período de estudo, não foi observada redução progressiva no teor do ingrediente farmacêutico ativo em nenhuma das condições avaliadas. Embora tenham sido detectadas variações estatisticamente significativas ao longo do tempo (ANOVA two-way, $p < 0,05$), não foi identificada tendência consistente de diminuição que indicasse degradação química do fármaco. Esses resultados indicam que as condições de armazenamento doméstico podem comprometer a estabilidade física de comprimidos de ibuprofeno, sem, entretanto, provocar perda mensurável no doseamento quando avaliado por método titulométrico farmacopeico. Os achados reforçam a importância do monitoramento da qualidade de medicamentos e da educação da população quanto às práticas adequadas de armazenamento no ambiente doméstico.

Palavras-chave: ibuprofeno; estabilidade de fármacos; qualidade farmacêutica; condições de armazenamento; medicamentos isentos de prescrição

INTRODUCTION

Medicines are pharmaceutical products developed for the diagnosis, prevention, and treatment of diseases, as well as for the alleviation of symptoms, playing a fundamental role in improving quality of life. Their manufacture is conducted under strict technical and regulatory control, in accordance with the requirements established by the Brazilian Health Regulatory Agency (ANVISA), to ensure safety, efficacy, and quality throughout the product lifecycle[1].

However, the widespread availability of over-the-counter (OTC) medicines, combined with consumption incentives, has contributed to irrational use and improper storage in households. In domestic environments, medicines are frequently stored under conditions that differ from those established during product development and regulatory approval. Such inadequate storage may compromise therapeutic efficacy, promote misuse and intoxication, and represent a significant public health concern[2]. Exposure to unsuitable environmental conditions can accelerate chemical degradation of the active pharmaceutical ingredient (API), potentially leading to the formation of toxic degradation products[3].

To ensure medicine quality during storage, ANVISA defines Good Storage Practices (GSP) as a set of measures aimed at maintaining product integrity throughout the storage process[4]. Shelf life and recommended storage conditions are established based on stability studies designed to guarantee the safety, efficacy, and quality of medicines over their intended period of use, including the identification of degradation pathways and the establishment of acceptable impurity limits[3].

Despite appropriate storage conditions being maintained throughout manufacturing and distribution, medicines are often stored under inadequate conditions in households. Exposure to heat, light, and moisture may compromise drug stability, reduce therapeutic efficacy, and increase the risk of adverse effects and intoxication[5,6]. OTC medicines, particularly analgesics and anti-inflammatory drugs such as ibuprofen, are among the most frequently stored in domestic environments, making them especially susceptible to these risks.

Ibuprofen is one of the most dispensed and consumed nonsteroidal anti-inflammatory drugs (NSAIDs) in Brazil[7]. It is a widely used, low-cost, non-prescription drug belonging to the class of propionic acid derivatives, with anti-inflammatory, analgesic, and antipyretic properties. Clinically, ibuprofen is indicated for the treatment of mild to moderate pain, fever, dysmenorrhea, gout, joint pain, and muscle pain.

The stability of ibuprofen is strongly influenced by storage conditions and the composition of the pharmaceutical dosage form. Accelerated degradation studies conducted on commercial tablets have demonstrated that the presence of certain excipients, such as polyethylene glycol (PEG) and polysorbate 80, may accelerate degradation of the API, leading to the formation of impurities such as 4-isobutylacetophenone, a compound recognized for its toxicity[8].

Other studies have identified several ibuprofen degradation products under oxidative, thermal, and photolytic stress conditions, including novel acids, alcohols, and phenolic compounds derived from the original molecular structure. These

findings indicate that ibuprofen may undergo multiple degradation pathways depending on the type of stress applied[9].

In forced degradation studies conducted in accordance with the guidelines of the International Council for Harmonisation (ICH), losses of the active pharmaceutical ingredient ranging from 5% to 20% have been reported, highlighting the need for rigorous control of storage conditions and formulation quality[10].

Conversely, a study evaluating sustained-release formulations (polymer-coated tablets) subjected to accelerated stability testing at different temperatures (25, 37, and 45 °C for six months) reported no significant changes in the crystalline structure of ibuprofen or evidence of degradation, based on differential scanning calorimetry (DSC) and infrared spectroscopy analyses[11].

Ibuprofen was selected for this study because it is a widely marketed OTC medicine and is commonly stored in household environments. Given the frequent inadequacy of domestic storage conditions, this study aimed to evaluate the impact of storage in different household environments on tablet quality and the safety of their use. Specifically, the objectives were to: (i) assess the visual characteristics of tablets stored in different household environments; (ii) perform the initial assay of the tablets; (iii) conduct periodic assays over time using analytical methods described in the Brazilian Pharmacopoeia, 6th Edition[12]; and (iv) compare the monthly assay results with the initial sample used as a control.

MATERIALS AND METHODS

SAMPLES AND DOMESTIC STORAGE CONDITIONS

The ibuprofen tablets evaluated in this study were generic medicines manufactured by Prati-Donaduzzi® (batch 23C563; expiration date: February 2025). The blisters were separated, labeled, and distributed to five different households in October 2023.

Each residence received blisters of ibuprofen tablets, which were stored under the following domestic conditions:

- Bedroom, preferably inside a cabinet and protected from light;
- Bathroom, inside a cabinet;
- Kitchen, on the refrigerator door;
- Car, inside the glove compartment.

These locations were selected because they are commonly used for medicine storage in domestic environments.

DRUG SAMPLING AND LABORATORY HANDLING

Three post-storage sampling collections were performed in December 2023, February 2024, and April 2024. At each sampling time, one blister was collected from each storage location in each residence, resulting in a total of 20 blisters per collection.

After collection from the households, the samples were transported to the research laboratory at the University Center of Lavras, where visual evaluation and assay determinations were performed. During laboratory storage, the samples were maintained in a cabinet at room temperature and protected from light.

VISUAL EVALUATION

Visual inspection was initially performed on the tablets in October 2023, prior to storage, and subsequently at each sampling time. The tablets were visually examined both inside the blister packs and after removal from the primary packaging. The evaluation focused on changes in color and physical integrity.

ASSAY OF IBUPROFEN TABLETS

An initial assay of the ibuprofen tablets was performed, and the obtained values were considered the reference (baseline) sample for comparison with subsequent analyses.

The assay procedure was conducted according to the methodology described in the Brazilian Pharmacopoeia. Ten tablets were accurately weighed and pulverized. An amount of 0.250 ± 0.001 g of the powdered sample was weighed, followed by the addition of 50 mL of ethanol and phenolphthalein solution as an indicator. The solution was titrated with 0.1 M sodium hydroxide until the appearance of a persistent pink endpoint.

Each milliliter of 0.1 M sodium hydroxide corresponds to 20.629 mg of ibuprofen. The experiments were conducted in triplicate, considering sub-samples obtained from the same blister pack.

The absence of continuous environmental monitoring of temperature, relative humidity, and light

exposure represents an important limitation of this study, since it prevents direct correlation between specific environmental parameters and the observed physical alterations in the tablets. The lack of chromatographic analyses for impurity profiling also represents a limitation of this study. The method quantifies total acidic content and may not discriminate degradation products with similar titration behavior. However, the use of a titrimetric assay was justified because it is an official analytical method described in the Brazilian Pharmacopoeia and widely accepted for routine quality control of ibuprofen tablets. Additionally, titrimetric analysis is suitable as an initial screening tool for stability assessment, allowing the detection of significant variations in active pharmaceutical ingredient content over time. This approach enables a preliminary evaluation of the impact of domestic storage conditions on tablet quality, supporting future investigations using more selective and sensitive chromatographic methods.

STATISTICAL ANALYSIS

Statistical analysis was performed using repeated-measures analysis of variance (repeated-measures ANOVA), considering storage condition (car, bathroom, kitchen, and bedroom) and time (December 2023, February 2024, and April 2024) as within-subject factors, with each household treated as the repeated experimental unit. Prior to analysis, data normality was assessed using the Shapiro–Wilk test and homogeneity of variances was evaluated using Levene's test. A significance level of $p < 0.05$ was adopted. Although minor deviations from normality and homogeneity assumptions were observed, repeated-measures ANOVA was maintained due to its robustness in balanced experimental designs with repeated observations.

This study was designed as an exploratory evaluation of domestic storage conditions using a single commercial batch from one manufacturer, distributed across five households and evaluated at three sampling time points. Therefore, the findings should be interpreted considering the limited representativeness of the sampling design.

RESULTS AND DISCUSSION

VISUAL EVALUATION

The tablets from the initial sample were intact and presented with a uniform white color. In subsequent collections, no changes in color were observed; however, several integrity issues became evident. Powder adhering to the blister pack was frequently observed and detached during handling after removal from the primary packaging. In addition, cracked, capped, and broken tablets were identified. Figure 1 illustrates the main physical defects observed during the study.

Figure 1 – Problems observed in the tablets. A: Broken pills inside the blister. B: Capped pills. C: Cracked pills. D: Tablet powder adhered to the blister. E: Tablet powder upon handling outside the blister.

Source: Author, 2024

Most of these defects were observed in tablets stored inside vehicles. These findings suggest increased tablet friability under such storage conditions. Friability reflects a tablet's susceptibility to erosion during handling and transport; excessive friability can lead to mass loss, compromising dose uniformity and therapeutic efficacy[13]. Friability is therefore directly associated with the physical stability of solid dosage forms.

Pharmaceutical stability is defined by the World Health Organization as the ability of a pharmaceutical product to maintain its physical, chemical, microbiological, and biopharmaceutical properties within specified limits throughout its shelf life[14]. Loss of stability may result in reduced efficacy or the occurrence of adverse events related to toxicity.

Stability can be affected by extrinsic factors—such as temperature, humidity, and light—and intrinsic factors, including hydrolysis and oxidation. Temperature elevation accelerates chemical degradation reactions, while humidity can promote physical degradation by increasing surface moisture and altering drug reactivity, a condition commonly observed in bathrooms. Light exposure may initiate oxidation or reduction reactions, particularly in environments exposed to direct sunlight. Intrinsic degradation mechanisms are often intensified by these extrinsic conditions[15].

In the present study, tablets stored inside vehicles showed a higher frequency of physical defects. Although temperature fluctuations and mechanical stress are plausible contributing factors, the absence of environmental monitoring prevents direct attribution of the observed alterations to specific environmental conditions.

ASSAY OF IBUPROFEN TABLETS

INITIAL SAMPLE

The mean tablet weight was 0.865 ± 0.005 g, corresponding to an expected ibuprofen content of 600 mg per tablet. Based on the mass of powdered tablets weighed (250 mg), an expected ibuprofen content of 173.4 mg was calculated. The titration volumes obtained were 9.4, 9.5, and 9.5 mL, resulting in a mean value of 9.5 ± 0.1 mL. Considering that each milliliter of 0.1 M sodium hydroxide corresponds to 20.629 mg of ibuprofen, the calculated ibuprofen content was 196.0 mg.

The initial assay performed in October 2023 revealed ibuprofen content exceeding the pharmacopeial upper specification limit (156.1–190.7 mg), corresponding to 90–110% of the declared content according to the Brazilian Pharmacopoeia. This result indicates non-compliance at baseline, prior to exposure to domestic storage conditions.

Several factors may explain this finding. First, variability in active pharmaceutical ingredient (API) content may occur due to manufacturing deviations, including blending uniformity, compression variability, or calibration inaccuracies during production. Although pharmaceutical manufacturing is conducted under Good Manufacturing Practices (GMP), small deviations can result in systematic overfilling to ensure that products do not fall below the minimum specification throughout shelf life. Intentional overages are sometimes applied during formulation to compensate for potential degradation; however, excessive overages may lead to values exceeding pharmacopeial limits if not properly controlled.

Second, analytical considerations must be addressed. The titrimetric method described in the Brazilian Pharmacopoeia quantifies total acidic content through neutralization with sodium hydroxide. While this method is officially recognized and widely used for routine quality control, it does not provide selectivity comparable to chromatographic techniques. Any acidic degradation products or excipient-related interferences capable of reacting with the titrant may contribute to the measured value, potentially leading to slight overestimation of ibuprofen content. Furthermore, titrimetric assays rely on endpoint detection, which introduces a degree of operator-dependent variability, even when performed in triplicate.

Importantly, the consistency of elevated assay values across subsequent sampling times and storage conditions suggests that the deviation observed at baseline was not a consequence of domestic storage but rather reflects the initial content of the evaluated batch. No progressive increase or decrease in assay values was observed over time, reinforcing the interpretation that the baseline excess was inherent to the product rather than storage-induced.

From a regulatory and clinical perspective, ibuprofen is associated with dose-dependent adverse reactions, including gastrointestinal, renal, and car-

diovascular effects[16]. Although the magnitude of excess observed in this study was relatively small, sustained exposure to doses above labeled content may increase the risk of adverse events, particularly in populations using high doses or long-term therapy.

Given these findings, complementary analyses using stability-indicating chromatographic methods, such as HPLC with impurity profiling, would be valuable to confirm the specificity of the assay and to exclude the presence of degradation products contributing to the measured content. Such approaches would provide greater analytical resolution and strengthen the interpretation of baseline non-compliance.

Overall, the elevated ibuprofen content detected at time zero represents a batch-specific characteristic and constitutes an important finding of this study, highlighting the need for continuous quality monitoring of over-the-counter medicines even before domestic storage exposure.

COLLECTED SAMPLES

Assay determinations for the collected samples were performed following the same procedure applied to the initial sample. The results obtained for tablets stored in vehicles, bathrooms, kitchens, and bedrooms are presented in Tables 1–4, respectively.

Table 1 – Car storage results

		House 1	House 2	House 3	House 4	House 5
Dec 2023	Average weight (mg)	864 ± 6	864 ± 5	865 ± 3	861 ± 2	864 ± 3
	Expected mass (mg)	172.9	173.8	174.0	174.0	173.6
	Acceptable range (mg)	155.7 – 190.3	156.4 – 191.1	156.6 – 191.4	156.7 – 191.5	156.3 – 191.0
	Dosage (mg)	188.4	190.5	191.1	193.9	191.2
Feb 2024	Average weight (mg)	867 ± 2	863 ± 5	862 ± 7	862 ± 5	864 ± 6
	Expected mass (mg)	173.0	173.8	174.0	174.0	173.6
	Acceptable range (mg)	155.7 – 190.3	156.4 – 191.2	156.7 – 191.4	156.7 – 191.5	156.3 – 191.0
	Dosage (mg)	190.0	193.3	194.2	196.1	191.6
Apr 2024	Average weight (mg)	863 ± 19	863 ± 5	869 ± 5	866 ± 6	863 ± 4
	Expected mass (mg)	173.9	173.8	172.7	173.2	173.8
	Acceptable range (mg)	156.5 – 191.3	156.4 – 191.2	155.4 – 190.0	155.9 – 190.5	156.5 – 191.2
	Dosage (mg)	197.8	194.4	194.4	194.5	193.9

Table 2 – Bathroom storage results

		House 1	House 2	House 3	House 4	House 5
Dec 2023	Average weight (mg)	868 ± 5	871 ± 4	867 ± 3	867 ± 4	867 ± 3
	Expected mass (mg)	172.8	172.2	173.0	173.0	172.9
	Acceptable range (mg)	155.5 – 190.1	154.9 – 189.4	155.7 – 190.4	155.7 – 190.3	155.6 – 190.2
	Dosage (mg)	187.0	191.8	193.2	160.9	161.6
Feb 2024	Average weight (mg)	871 ± 4	870 ± 5	871 ± 5	870 ± 6	870 ± 4
	Expected mass (mg)	172.2	172.4	172.2	172.4	172.5
	Acceptable range (mg)	155.0 – 189.5	155.1 – 189.6	155.0 – 189.4	155.1 – 189.6	155.2 – 189.7
	Dosage (mg)	192.1	194.9	195.2	194.3	193.8
Apr 2024	Average weight (mg)	873 ± 6	870 ± 4	870 ± 5	871 ± 3	870 ± 3
	Expected mass (mg)	171.9	172.4	172.4	172.1	172.4
	Acceptable range (mg)	154.7 – 189.1	155.2 – 189.7	155.2 – 189.7	154.9 – 189.3	155.2 – 189.7
	Dosage (mg)	192.2	196.2	195.8	195.0	194.3

Table 3 – Kitchen storage results

		House 1	House 2	House 3	House 4	House 5
Dec 2023	Average weight (mg)	869 ± 4	870 ± 5	866 ± 4	867 ± 4	871 ± 3
	Expected mass (mg)	172.5	172.3	173.1	173.0	172.3
	Acceptable range (mg)	155.3 – 189.8	155.1 – 189.6	155.8 – 190.4	155.7 – 190.3	155.1 – 189.5
	Dosage (mg)	174.7	200.1	198.0	194.6	191.2
Feb 2024	Average weight (mg)	865 ± 5	865 ± 5	865 ± 4	864 ± 5	867 ± 3
	Expected mass (mg)	173.4	173.3	173.4	173.7	173.0
	Acceptable range (mg)	156.0 – 190.7	156.0 – 190.7	156.1 – 190.8	156.3 – 191.0	155.7 – 190.3
	Dosage (mg)	196.1	195.4	191.5	190.6	197.6
Apr 2024	Average weight (mg)	867 ± 5	867 ± 5	863 ± 4	867 ± 5	865 ± 4
	Expected mass (mg)	173.1	173.0	173.8	173.1	173.5
	Acceptable range (mg)	155.8 – 190.4	155.8 – 190.4	156.4 – 191.2	155.8 – 190.4	156.1 – 190.8
	Dosage (mg)	194.6	194.4	196.3	198.6	196.1

Table 4 – Bedroom storage results

		House 1	House 2	House 3	House 4	House 5
Dec 2023	Average weight (mg)	872 ± 3	869 ± 7	865 ± 4	871 ± 4	867 ± 6
	Expected mass (mg)	172.1	172.5	173.4	172.1	173.0
	Acceptable range (mg)	154.8 – 189.3	155.3 – 189.8	156.0 – 190.7	154.9 – 189.3	155.8 – 190.4
	Dosage (mg)	191.8	193.9	193.9	189.8	193.9
Feb 2024	Average weight (mg)	869 ± 6	868 ± 4	867 ± 6	870 ± 5	871 ± 3
	Expected mass (mg)	172.6	172.9	173.0	172.4	172.3
	Acceptable range (mg)	155.4 – 189.9	155.6 – 190.2	155.8 – 190.4	155.2 – 189.7	155.0 – 189.5
	Dosage (mg)	194.2	195.0	194.6	194.2	194.2
Apr 2024	Average weight (mg)	867 ± 2	865 ± 4	868 ± 6	865 ± 5	866 ± 5
	Expected mass (mg)	173.0	173.5	172.8	173.5	173.3
	Acceptable range (mg)	155.7 – 190.3	156.2 – 190.9	155.5 – 190.1	156.1 – 190.8	155.9 – 190.6
	Dosage (mg)	194.5	190.2	191.4	191.8	194.3

Overall, the assay results demonstrated that most samples exhibited ibuprofen contents above the pharmacopeial limits throughout the storage period. Only a limited number of samples from the December 2023 collection fell within the acceptable range, particularly among tablets stored in vehicles and bathrooms. From February 2024 onward, nearly all samples exceeded the upper specification limit.

Importantly, no progressive reduction in ibuprofen content was observed over time in any storage condition. The assay values obtained in subsequent samplings were comparable to those of the initial sample, indicating that chemical degradation of the active pharmaceutical ingredient did not occur under the evaluated domestic storage conditions. Instead, the consistently elevated assay values suggest issues related to initial drug content or formulation variability rather than storage-induced chemical instability.

These findings reinforce that, although domestic storage conditions—particularly in vehicles—can significantly compromise the physical integrity of tablets, they did not result in measurable loss of ibuprofen content when assessed using a titrimetric screening method. Nevertheless, physical instability may still negatively impact dose uniformity, patient adherence, and overall medication safety.

STATISTICAL ANALYSIS

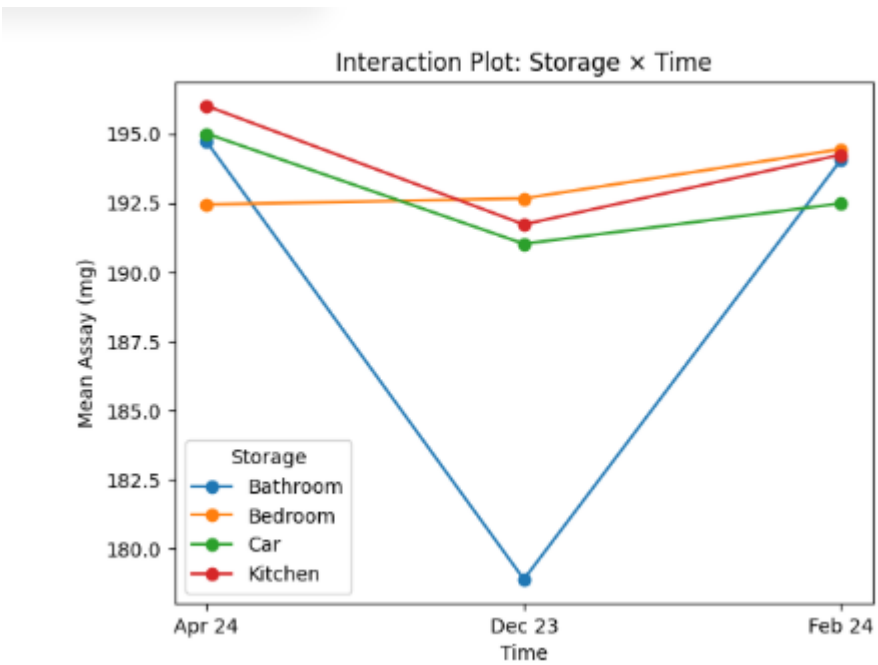
The statistical effects of storage condition and time on ibuprofen assay values were evaluated using repeated-measures ANOVA. A statistically significant effect of time was observed ($F(2,8) = 5.76$, $p = 0.028$), indicating variation in assay values across the sampling periods. In contrast, storage condition did not significantly influence assay results ($F(3,12) = 1.98$, $p = 0.171$).

The interaction between storage condition and time was not statistically significant at the 5% significance level ($F(6,24) = 2.42$, $p = 0.057$), although a trend toward differential temporal behavior among storage environments was observed. Descriptive analysis indicated some variability in assay values over time across storage conditions; however, these differences were not sufficiently consistent to demonstrate a statistically significant interaction.

Overall, the results indicate modest temporal variation in ibuprofen assay values without evidence of a consistent reduction associated with any specific storage condition. All assay values remained within pharmacopeial limits throughout the study period, supporting the interpretation that the evaluated domestic storage conditions did not induce measurable chemical degradation of ibuprofen tablets during the experimental period.

Figure 2 present ibuprofen assay values over time according to storage condition. Error bars represent standard deviation. Although some temporal variability was observed among storage environments, repeated-measures ANOVA did not demonstrate a statistically significant interaction between storage condition and time ($p = 0.057$).

Figure 2 – Temporal variation in ibuprofen assay values according to storage condition during the study period.



The limited sampling design represents an important restriction of the present study. Because only one batch and one manufacturer were evaluated, the results may reflect batch-specific or formulation-specific characteristics. In addition, the relatively small number of households and sampling times limits extrapolation of the findings to broader storage conditions or other commercial products.

CONCLUSIONS

The present study demonstrated that tablets stored under certain domestic conditions, particularly inside vehicles, presented greater physical deterioration, including cracking, capping, brittleness, and powder detachment. These findings indicate that inappropriate household storage may compromise the physical stability of solid dosage forms and potentially affect dose uniformity and patient safety.

However, no progressive reduction in ibuprofen content was observed throughout the six-month storage period under the evaluated conditions. Although statistically significant variations across time were detected, no consistent decreasing trend indicative of chemical degradation was identified using the pharmacopeial titrimetric method.

Importantly, the initial assay revealed ibuprofen content above the pharmacopeial upper specification limit, indicating baseline non-compliance prior to domestic storage exposure. The persistence of elevated assay values across all sampling times and storage environments suggests that this finding was inherent to the evaluated batch rather than induced by household storage conditions.

These results reinforce two critical aspects: (i) domestic storage may compromise the physical quality of tablets even when chemical content remains apparently stable, and (ii) continuous quality monitoring of over-the-counter medicines is essential, including evaluation of potential batch-related variability. Further investigations employing stability-indicating chromatographic methods are recommended to confirm analytical specificity and assess possible impurity formation.

Collectively, the findings highlight the importance of public education regarding appropriate domestic storage practices and support the need for rigorous quality control to ensure the safety and therapeutic reliability of widely used OTC medicines. Because environmental variables were not continuously monitored, the study does not allow direct correlation between specific temperature, humidity, or light exposure conditions and the observed physical alterations.

Although the findings provide relevant preliminary evidence regarding the impact of domestic storage conditions on tablet integrity, the limited sampling design restricts broader generalization. Further studies involving multiple manufacturers, batches, larger sample sizes, and controlled environmental monitoring are necessary to confirm these observations.

FUNDING

The authors acknowledge financial support from the Institutional Scientific Initiation Scholarship Program (PIBIC) of the Centro Universitário de Lavras (UNILAVRAS), Brazil.

CONFLICTS OF INTEREST

The authors declare that they have no financial or commercial relationships that could be construed as a potential conflict of interest. The study was conducted independently, and the manufacturer of the evaluated product had no role in study design, data collection, analysis, interpretation, or manuscript preparation.

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