

Stability issues and quality risks of L-Ascorbic acid tablets in tropical climates: A mixed-methods study of the Nigerian pharmaceutical supply chain

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ABSTRACT

Background: L-Ascorbic acid (Vitamin C) is a widely used antioxidant with recognized instability challenges, particularly under tropical conditions. Its degradation compromises therapeutic efficacy, especially in regions with inadequate storage and distribution infrastructure, like Nigeria.

Objectives: To confirm reported trends in the stability and quality of L-ascorbic acid tablets in the Nigerian pharmaceutical supply chain through stakeholder engagement and laboratory evaluation.

Methods: A mixed-methods study was conducted involving 214 pharmaceutical stakeholders. Concurrently, nine NAFDAC-registered brands of L-ascorbic acid tablets were subjected to physicochemical and microbial testing. The USP method was used for the assay. Stability testing was conducted over 30 days under accelerated conditions (40 ± 2 °C, (75 ± 5) % RH).

Results: Over 90 % of stakeholders reported observing colour changes and degradation in 100 mg L-ascorbic acid tablets. Laboratory tests revealed that 44.4% of brands showed initial colour non-conformance, and one brand (11.11%) failed. Observed quality issues may be linked to inadequate packaging and poor storage conditions.

Conclusion: Significant stability issues persist with L-ascorbic acid tablets in Nigeria. Regulatory enforcement, reformulation, climate-adapted packaging, and robust supply chain controls are essential to enhance product integrity and safeguard public health.

Keywords: L-ascorbic acid, stability, pharmaceutical quality, degradation

**Problèmes de stabilité et risques liés à la qualité des comprimés d'acide L-ascorbique dans les climats tropicaux:
une étude à méthodes mixtes sur la chaîne d'approvisionnement pharmaceutique nigériane**

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RÉSUMÉ

Contexte: L'acide L-ascorbique (vitamine C) est un antioxydant largement utilisé qui présente des problèmes d'instabilité reconnus, notamment en climat tropical. Sa dégradation compromet son efficacité thérapeutique, notamment dans les régions où les infrastructures de stockage et de distribution sont inadéquates, comme au Nigéria.

Objectifs: Confirmer les tendances observées en matière de stabilité et de qualité des comprimés d'acide L-ascorbique dans la chaîne d'approvisionnement pharmaceutique nigériane, par le biais de la participation des parties prenantes et d'une évaluation en laboratoire.

Méthodes: Une étude utilisant des méthodes mixtes a été menée auprès de 214 acteurs du secteur pharmaceutique. Parallèlement, neuf marques de comprimés d'acide L-ascorbique enregistrées auprès de la NAFDAC ont été soumises à des analyses physicochimiques et microbiologiques. La méthode USP a été utilisée pour l'essai. Les tests de stabilité ont été réalisés sur 30 jours dans des conditions accélérées (40 ± 2 °C, (75 ± 5) % HR).

Résultats: Plus de 90 % des parties prenantes ont signalé des changements de couleur et une dégradation des comprimés d'acide L-ascorbique de 100 mg. Les tests en laboratoire ont révélé que 44,4 % des marques présentaient une non-conformité initiale de couleur, et qu'une marque (11,11 %) était non conforme. Les problèmes de qualité observés pourraient être liés à un emballage inadéquat et à de mauvaises conditions de stockage.

Conclusion: D'importants problèmes de stabilité persistent avec les comprimés d'acide L-ascorbique au Nigéria. L'application de la réglementation, la reformulation, un emballage adapté au climat et des contrôles rigoureux de la chaîne d'approvisionnement sont essentiels pour améliorer l'intégrité des produits et protéger la santé publique.
Mots-clés : acide L-ascorbique, stabilité, qualité pharmaceutique, dégradation

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INTRODUCTION

L-Ascorbic acid, commonly known as Vitamin C, is an essential nutrient vital for human health due to its powerful antioxidant properties and involvement in numerous physiological functions, including collagen synthesis, immune system support, and iron absorption. Since the human body cannot naturally synthesize this vitamin, adequate dietary intake is necessary to prevent deficiencies, such as scurvy, a condition associated with severe health complications.¹ As a result, L-Ascorbic acid is extensively formulated into pharmaceutical tablets, available as over-the-counter supplements and prescription medications, serving therapeutic purposes such as enhancing immunity and addressing vitamin deficiencies. Given its widespread use and critical role in maintaining health, ensuring the quality and stability of L-Ascorbic acid tablets is of utmost importance, particularly in regions with limited dietary diversity and poor storage conditions. The high demand for Vitamin C supplements and their inherent instability pose a potential risk to the pharmaceutical supply chain, especially in environments with challenging conditions and chaotic drug distribution systems.²

L-Ascorbic acid is naturally prone to instability, mainly oxidation, due to environmental factors. This instability creates notable difficulties in producing and storing stable tablet formulations. Conditions such as high temperatures, elevated humidity, alkaline pH, exposure to oxygen and light, as well as the presence of catalytic metal ions, expedite its degradation.³ Typically, pure L-ascorbic acid appears as a white to very pale-yellow crystalline powder; however, degradation can result in a yellowish or brown colour due to non-enzymatic browning reactions.⁴ The major degradation pathway consists of oxidation to dehydroascorbic acid (DHA), which retains some vitamin activity but further breaks down into inactive compounds. The complex nature of this instability calls for a comprehensive understanding of how environmental and formulation factors interact to safeguard product quality effectively, as well as the packaging systems.

The significance of pharmaceutical product quality is heightened in developing countries, where healthcare systems can be fragile, access to professionals is limited, and population often incur higher out-of-pocket medical expenses.⁶ In these areas, substandard and falsified medicines may result in treatment failures, drug resistance, adverse reactions, and even death, further putting pressure on healthcare systems. Additionally,

poor-quality pharmaceuticals diminish public trust and create economic challenges.⁷ In Nigeria, ensuring the quality of essential medicines, such as L-Ascorbic acid tablets, is vital for public health, economic stability, and maintaining confidence in the healthcare system.

The pharmaceutical supply chain in Nigeria is intricate, characterized by local production, primarily of generics, and a heavy reliance on imports for finished products and active pharmaceutical ingredients (APIs). This supply chain encounters various challenges, including insufficient storage facilities, transportation issues, counterfeit medications, and complex regulations.⁸ Such challenges can worsen the stability and quality of L-Ascorbic acid tablets, elevating the risks of degradation and inferior products on the Nigerian market. Notable vulnerabilities, like temperature variations during transport and inadequate storage conditions, can significantly affect the stability of temperature-sensitive medications such as L-Ascorbic acid tablets.

Previous studies on L-Ascorbic acid tablet stability largely focus on laboratory conditions and international benchmarks, with limited research specifically addressing Nigeria's unique climate, supply chain, and regulatory context. There is a critical gap in understanding how local storage conditions like high temperatures, humidity, and inconsistent handling impact product integrity across the distribution network. Similarly, empirical data on how indigenous manufacturing, excipient interactions, and packaging affect degradation are scarce.⁹

This study aims to investigate the stability challenges and quality concerns of L-Ascorbic acid tablets within the Nigerian pharmaceutical supply chain. Justified by Vitamin C's public health importance and L-Ascorbic acid's known instability, the research acknowledges the distinct issues in Nigeria's supply chain and the risks of substandard products. Using a mixed-methods approach, the study provided quantitative data on tablet quality and qualitative insights from stakeholders regarding contributing factors. The findings will inform improved formulations, robust packaging, proper storage practices, and policy recommendations to ensure high-quality vitamin C tablets for Nigerians.

MATERIALS AND METHODS

Study Design

This study employed a mixed-methods research design,

integrating both quantitative and qualitative data collection and analysis techniques to provide an understanding of the stability challenges and quality concerns of L-Ascorbic Acid tablets within the Nigerian pharmaceutical supply chain. The questionnaire approach, where stakeholders in the pharmaceutical value chain view on L-ascorbic acid tablets quality, and the actual quantitative analysis and other physicochemical tests of L-ascorbic acid tablets were carried out.

Ethical consideration

Ethical approval for the study was obtained from the Lagos University Teaching Hospital, Health Research Ethics Committee, with assigned number: ADM/DSCST/HREC/APP7115. Informed consent was also obtained from the respondents.

Assessment of stakeholders' views

This study employed a descriptive cross-sectional design to assess the perceptions of stakeholders in the pharmaceutical value chain regarding L-ascorbic acid tablets in Nigeria. The target population included pharmaceutical manufacturers, hospital and community pharmacists, regulatory agencies, academic researchers, distributors, wholesalers, and patients.

The sample size for this study was determined using G*Power statistical software, ensuring appropriate precision and representativeness within the Nigerian pharmaceutical value chain. The calculated minimum required sample size was 196 respondents, ensuring adequate statistical power for meaningful analysis. However, to enhance robustness and account for potential non-responses, 214 stakeholders participated in the study. Those who participated in the study gave their consent, while those who did not respond after three months were excluded.

A self-administered questionnaire was developed after being validated to collect data from the respondents. The questionnaire comprised over 130 closed-ended questions, though some were similar to suit the area of practice, hence segmented into various categories based on the respondent's role in the pharmaceutical value chain. Each group (e.g., manufacturers, distributors, pharmacists) was asked 33-37 questions tailored to their level of involvement and understanding of L-ascorbic acid tablets.

Data collection and distribution

The questionnaire was distributed via online platforms, including email, social media, and pharmacy association forums (such as the Association of Industrial Pharmacists of Nigeria (NAIP), Association of Community Pharmacists of Nigeria (ACPN), and the Pharmaceutical Society of Nigeria (PSN)). The survey was also disseminated on general platforms like Rx Online Pharmacy groups on Telegram and WhatsApp.

Data analysis

The data generated were analyzed using IBM SPSS Statistics 25. Descriptive statistics summarized categorical variables as percentages and frequencies, while continuous variables were reported as means and standard deviations. ANOVA assessed differences in physicochemical properties across brands, with $p < 0.05$ indicating significance. Pearson's chi-square test and correlation analysis explored associations between stakeholder perceptions and laboratory findings. This integrated approach provides insights into formulation challenges and regulatory needs for improving L-ascorbic acid tablet stability in Nigeria.

Evaluation of L-Ascorbic acid tablets

Nine NAFDAC-registered brands of uncoloured L-ascorbic acid tablets (A-RTO, A-ENL, A-PSA, A-IVT, A-EM, A-SAC, A-PC, A-RCD, and A-OSP), manufactured within six months before the study, were selected for comparative evaluation. The tablets were visually inspected for colour and evaluated for the following properties: hardness, friability, disintegration, weight uniformity, thickness, ascorbic acid content and microbial quality using validated procedures.¹⁰ All parameters were re-evaluated after 30 days of storage in a stability chamber maintained at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ relative humidity.

Tablet hardness

Tablet hardness was determined using a Tablet Hardness Tester (214, Copley Scientific, Nottingham, UK) on 10 tablets randomly selected from each batch. Each tablet was placed individually in the tester, and the force (in Newtons or kgf) required to break the tablet was recorded. The mean and standard deviation were calculated for each batch.

Friability

Friability was assessed using a Copley Friabilator operated at a speed of 25 revolutions per minute for 4 minutes. Ten tablets from each batch, pre-weighed (W_0), were placed in the friabilator and subjected to tumbling. After testing,

tablets were de-dusted and reweighed (W_1).

Friability was calculated as: $\text{Friability (\%)} = ((W_0 - W_1) / W_0) \times 100$. Acceptance criteria of not more than 1% weight loss were applied in accordance with USP 2024 standards.

Disintegration time

Disintegration time was evaluated using a Disintegration Tester (Model: 55004, Copley Scientific, Nottingham, UK) in purified water maintained at $37 \pm 2^\circ\text{C}$. Six tablets from each batch were placed in individual baskets, and the time required for complete disintegration was recorded. Results were expressed as the mean disintegration time (minutes) per batch.

Weight uniformity

Twenty tablets from each batch were individually weighed on a calibrated analytical balance (Model: ME204E Mettler Analytical Weighing Balance), and the mean weight, standard deviation, and percentage deviation were calculated, following specifications outlined in USP 2024.

Tablet thickness

Tablet thickness was measured using a digital vernier caliper (Copley Digital Caliper 500) for ten randomly selected tablets per batch. The mean thickness and standard deviation were reported.

Assay of ascorbic acid content

The ascorbic acid content of tablets was determined using high-performance liquid chromatography (HPLC), as specified in USP 2024,11 Section 11. Briefly, tablet samples were finely powdered; an accurately weighed portion equivalent to one tablet was transferred to a volumetric flask, extracted using 0.1 % phosphoric acid, sonicated for 15 minutes, and filtered ($0.45\ \mu\text{m}$). Standard and sample solutions were prepared similarly. Chromatographic separation was performed under the following conditions: HPLC system (Model, Agilent 1260 series), detection wavelength 245 nm. Quantification was by comparison to the reference standard. Results were expressed as mg of ascorbic acid per tablet.

Microbial quality testing

Microbial analysis included Total Viable Count (TVC), Total Yeast and Mold Count (TYMC), as well as screening for specified pathogens (e.g., *Escherichia coli*, *Salmonella* spp.), in compliance with USP requirements. Samples were tested at baseline and after storage for one month at ambient conditions. TVC and TYMC were performed using pour plate methods on Plate Count Agar and Sabouraud Dextrose Agar, respectively. Pathogen detection was conducted using selective enrichment and differential media, per standard protocols. Results were reported as colony-forming units (cfu) per tablet.

Data were statistically analyzed using ANOVA to compare inter-brand differences, with significance set at $p < 0.05$.

RESULTS

Stakeholder perceptions of L-Ascorbic acid tablets in Nigeria

The survey comprised 214 participants from diverse sectors within the pharmaceutical industry. The majority of respondents (134, 62.6 %) were female, while the predominant age group was 35-44 years (82, 38.3 %). Educational qualifications were predominantly first-degree holders (132, 61.7%). The majority of respondents (178, 83.2 %) were practicing pharmaceutical scientists, with more representation from the community and hospital pharmacist (91, 42.5 %), while others are in the manufacturing, distribution, academia, and regulatory sectors.

Stakeholder awareness and observations on L-Ascorbic acid tablet stability

A significant proportion of respondents 194 (90.7 %) reported having observed a colour change in L-ascorbic acid tablets. The discolouration was predominantly noted in 100 mg strength tablets (92.1 %), with variations including off-white, yellow, or brown hues. Additionally, 78.6 % of respondents indicated that L-ascorbic acid tablets exhibited higher incidences of breakage, with 83.5% of stakeholders reporting excessive powdering and flaking during handling. Patient feedback further reinforced these concerns, as 121 (77.1 %) pharmacists and distributors reported receiving complaints related to tablet degradation. (Fig. 1).

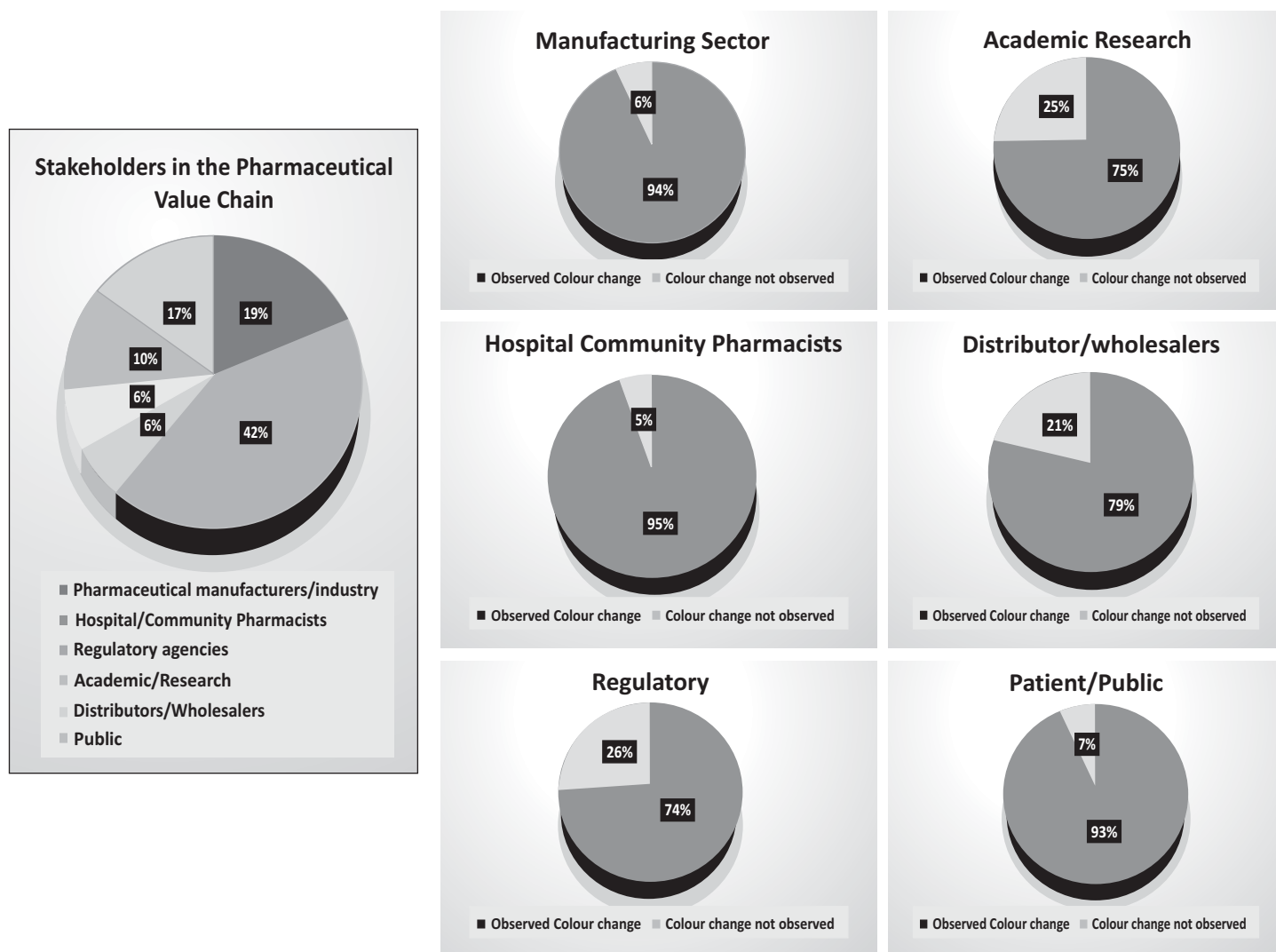


Fig. 1. Stakeholders' Perception of Colour Change in L-ascorbic acid Tablets Formulations

Impact of packaging and storage conditions

Stakeholder perspectives on packaging adequacy revealed that 118 (55.1%) respondents considered the current primary packaging materials inadequate. Preferred packaging alternatives included airtight plastic containers (106, 49.5%), amber bottles 71 (33.2 %), and Aluminium foil blisters 20, (9.3 %). Optimal storage temperature recommendations varied, with 65.4% of respondents advocating storage below 30°C, while 28.0% suggested a range between 15°C and 25°C. The necessity of temperature-controlled transportation was widely acknowledged, with 91.2 % of stakeholders recommending that L-ascorbic acid tablets be transported in vehicles maintaining temperatures below 30°C.

Quality control and stability enhancement strategies

Stakeholders demonstrated strong awareness regarding formulation stability, with 203 (94.9%) asserting that the source of API and excipient selection influences degradation rates. A similarly high percentage 198 (92.5 %) agreed that API-excipient incompatibility contributes to the observed instability of L-ascorbic acid tablets. The suggested interventions for improving tablet stability included: Proper storage conditions 65 (34.4 %), reformulation using enhanced excipients and manufacturing techniques 68 (36.0 %), Improved packaging solutions 51 (27.0 %), Advancements in pharmaceutical technology were widely supported as potential mitigation strategies, with 87 (46.0 %) endorsing a combination of encapsulation, nanotechnology, and tablet coating to enhance tablet stability.

Manufacturing sector insights on stability issues

Within the manufacturing sector, 35 (87.5 %) of respondents confirmed observing progressive friability changes in retention samples stored over time. Similar trends were noted for tablet hardness 36 (90.0%) and disintegration rates 35 (85.0 %). Among industry stakeholders, 35 (87.5 %) reported receiving consumer complaints regarding colour changes and taste alterations in L-ascorbic acid tablets. The necessity of product returns due to quality concerns was noted by 20 (50.0%) of manufacturers. (Fig. 2)

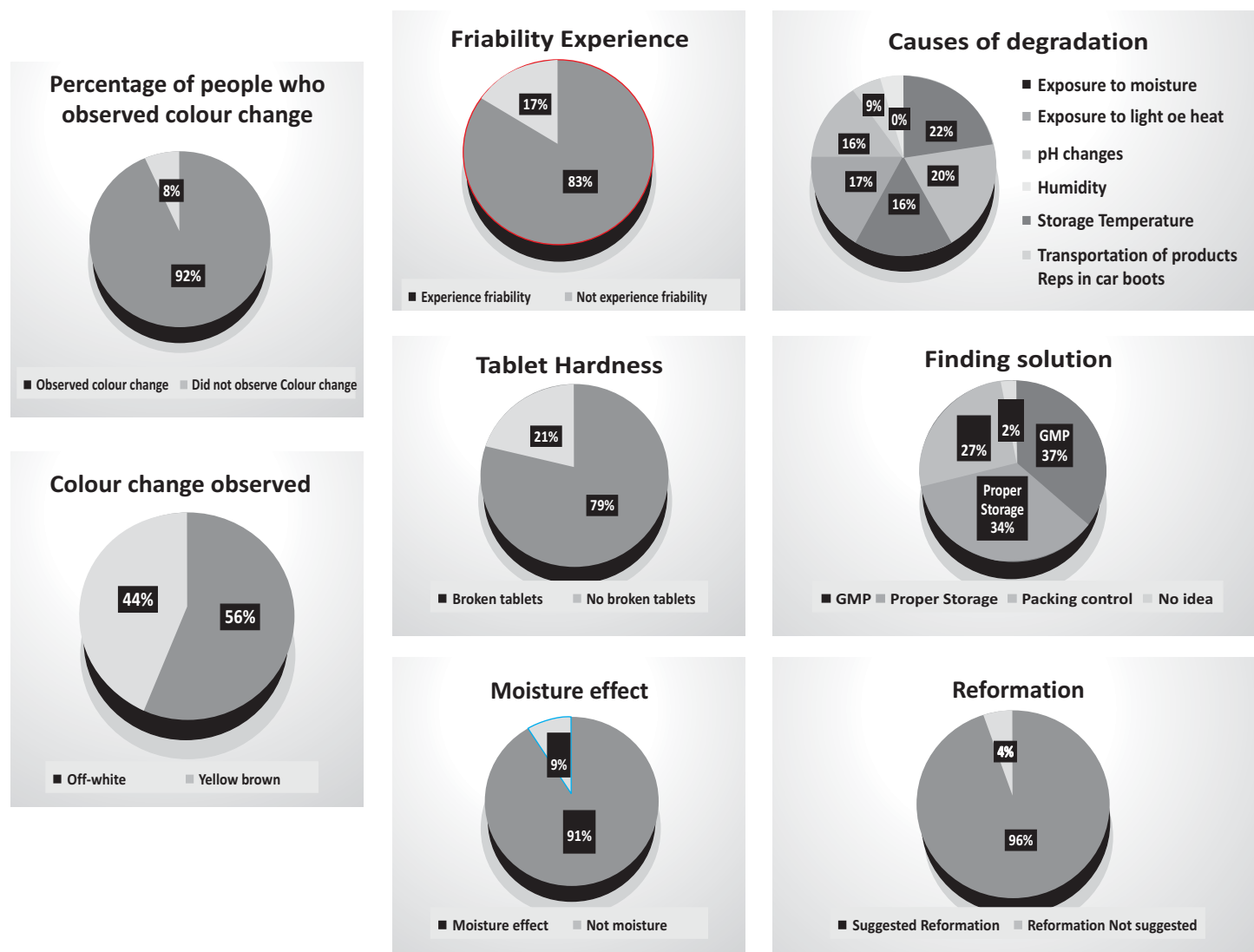


Fig 2. Physicochemical Properties of Stakeholders, highlighting their experience

Physicochemical properties of L-Ascorbic acid tablets

The data for the physicochemical properties after initial testing of various commercialized brands of L-ascorbic acid tablets in Nigeria are shown in Table 1, while the data after 30 days in the stability chamber at $40^{\circ}\text{C} \pm 2$ and relative humidity of $75 \pm 5\%$ are shown in Table 2. The assay data are presented in Fig. 4.

Table 1: Physicochemical Properties of L - Ascorbic acid Tablets

Brands of L-ascorbic Acid Tablets	Average Weight Uniformity (mg)	Initial Thickness (mg)	Initial Average Hardness (kg/cm ²)	Initial Disintegration Time (min)
A-RTO	319.5 ± 9.2	4.3±0.1	2.4±0.1	3.77±4.59
A-ENL	347.0±8.5	4.3±0.2	2.3±0.8	1.96±1.10
A-PSA	339.0±7.1	3.5±0.1	5.8±0.3	4.98±1.03
A-IVT	361.0±12.7	3.8±0.0	2.5±0.5	4.08±2.48
A-EM	302.0±1.4	4.1±0.1	3.2±0.0	2.17±0.24
A-SAC	316.5±12.0	4.2±0.0	3.0±1.4	2.17±0.00
A-PC	306.0±4.2	4.3±0.3	1.9±1.2	9.50±5.66
A-RCD	345.0±14.1	4.6±0.1	2.7±0.2	4.78±1.39
A-OSP	373.5±7.8	4.8±0.0	3.2±0.1	4.50±0.47
P-value	<0.001	<0.001	<0.001	0.132

Table 2: Physicochemical Properties of L-Ascorbic acid Tablets after 30 days

Brands of L-ascorbic Acid Tablets	Average Weight Uniformity (mg)	Thickness (cm)	Average Hardness (kg/cm ²)	Disintegration Time (min)
A-RTO	320.0±0.0	4.4±0.1	2.1±0.3	30.25±42.07
A-ENL	342.5±19.1	4.3±0.5	2.9±0.4	2.59±1.99
A-PSA	341.5±13.4	3.5±0.1	6.2±0.9	4.67±0.24
A-IVT	347.5±3.5	3.7±0.2	2.8±0.0	3.93±0.26
A-EM	298.5±0.7	4.1±0.0	3.1±0.9	1.04±0.06
A-SAC	314.5±10.6	4.3±0.0	3.1±0.3	0.50±0.00
A-PC	303.5±6.4	4.4±0.3	2.0±1.4	51.58±4.43
A-RCD	342.5±12.0	4.6±0.1	3.4±0.1	3.64±1.68
A-OSP	367.0±2.8	4.8±0.0	8.2±8.1	4.13±0.16
P value	0.001	0.002	0.435	0.055

Microbial test

All the brands passed the microbial tests done such as the Total Viable bacterial Count (TVC), the Total Yeast and Mold Count (TYMC), and pathogen test for the initial and testing after one month. No pathogen was detected for all the brands. The TVC and TYMC for all the brands were within the acceptable limit of Not More Than (NMT) 100cfu/g and NMT 20cfu/g respectively.

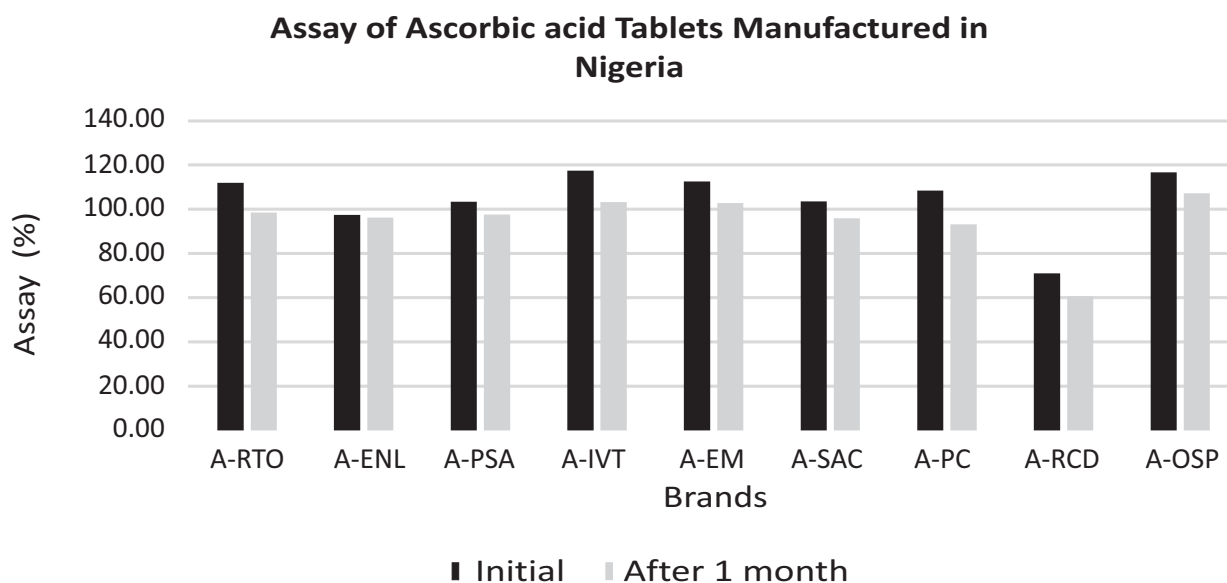


Figure 3: Assay of Ascorbic Acid Tablets Manufactured in Nigeria

DISCUSSION

This mixed-methods study explored the stability and quality of L-ascorbic acid (Vitamin C) tablets within the Nigerian pharmaceutical supply chain, focusing on stakeholder perceptions and laboratory-based physicochemical evaluations. The findings offer a comprehensive understanding of the degradation issues L-ascorbic acid tablets face in a tropical, resource-limited setting.

A large proportion of pharmaceutical stakeholders (90.7%) reported observing colour changes in L-ascorbic acid tablets, particularly the 100 mg strength, with discolouration to brown or yellow, which is indicative of degradation. These observations are consistent with the known instability of ascorbic acid, which readily oxidizes to dehydroascorbic acid and further to inactive products under heat, light, oxygen, and moisture exposure. Moreover, 78.6 % and 83.5 % of respondents noted increased incidence of broken tablets and friability, respectively, aligning with physical degradation that often accompanies chemical instability. These effects compromise dose uniformity, palatability, and patient adherence, a concern especially relevant in Nigeria where drug quality is already under scrutiny due to substandard and falsified medicines.^{12,13}

From the manufacturing perspective, 87.5 % of respondents confirmed friability changes in retained samples, and 90 % reported declining tablet hardness over time. This highlights formulation or manufacturing limitations, such as inadequate compression force or

unsuitable excipient selection. These factors are shown to significantly influence tablet robustness. Interestingly, 77.5 % of manufacturers acknowledged assay values outside acceptable USP limits (90-110 %) in stored reference samples, reinforcing chemical instability. Complaints from patients concerning colour changes and bad taste (72.3 %) further suggest ongoing degradation post-distribution.

Stakeholder feedback revealed concerns regarding packaging adequacy, with 55.1 % considering current materials unsuitable. Many advocated for airtight containers (49.5 %) or amber bottles (33.2 %) to minimize light and moisture ingress, both of which accelerate ascorbic acid degradation⁵. Similarly, 91.2 % of respondents supported the need for temperature-controlled transportation below 30°C. This consensus aligns with global best practices for the handling of thermolabile pharmaceuticals. Inadequate storage and transit conditions in Nigeria, often without temperature control, exacerbate the degradation of sensitive products like Vitamin C tablets.^{14,15}

Excipient selection emerged as a critical issue. Stakeholders (92.5 %) linked API-excipient incompatibility to product instability. This is scientifically valid, as excipients like lactose and magnesium stearate are known to catalyze degradation in acidic APIs.³ Reformulation using inert or stabilizing excipients or employing advanced drug delivery technologies such as microencapsulation or coating was strongly recommended by 95.8 % of respondents.

The study identified three main intervention pathways: proper storage (34.4 %), reformulation with better excipients (36.0 %), and improved packaging (27.0 %). Technologies such as nanotechnology, encapsulation, and tablet coating were endorsed by 46 % of stakeholders as promising solutions. These approaches have been shown to significantly improve the stability of labile compounds like Vitamin C by minimizing environmental exposure.¹ In addition, manufacturers demonstrated some adherence to quality assurance practices, such as the use of data loggers (97.5 %) and temperature records (95.0 %), although such practices may not be universally implemented across all sectors in Nigeria.

Quantitative evaluation of nine L-ascorbic acid tablet brands revealed that after 30 days of storage at accelerated conditions (40°C ± 2, 75 % ± 5 RH), brands such as A-PC and A-RCD displayed marked degradation in appearance and assay content, confirming instability. Assay values dropped significantly over 30 days, with one brand (A-RCD) falling below 70 %, far below pharmacopeial specifications. Disintegration times also varied widely post-storage, with A-PC exhibiting an excessively prolonged disintegration time of 51.58 minutes, suggesting formulation failure. These findings reinforce that some locally manufactured or distributed products, as highlighted in NAFDAC Greenbook may not withstand tropical environmental conditions.¹⁶

Manufacturers confirmed assay failures in stored retention samples (77.5%), aligning with observed assay reductions post 30-day accelerated storage. Previous studies have attributed similar losses to API-excipient incompatibility, which 92.5 % of stakeholders in this study also identified as a major factor. Preferences for airtight packaging and temperature-controlled distribution further reflected awareness of ascorbic acid's environmental sensitivity. This integrated evidence underscores the urgent need for improved formulation practices, storage protocols, and regulatory oversight to maintain tablet stability in Nigeria's tropical climate and complex supply chain.

CONCLUSION

The study reveals widespread instability of L-ascorbic acid tablets in the Nigerian pharmaceutical market, driven by poor excipient compatibility, inadequate packaging, and unsuitable storage conditions. The study established that a significant proportion of commercially available tablets exhibited physicochemical instability,

manifested by discolouration, high friability, assay degradation, and inconsistent disintegration profiles. Stakeholder insights further validated these findings, identifying inadequate packaging and poor storage practices as primary contributors. The study contributes meaningfully to the field by integrating stakeholder perspectives with empirical laboratory data to provide a contextualized understanding of product quality issues in tropical, resource-limited settings. The study offers valuable baseline evidence for urgent measures, including reformulation, robust packaging, controlled distribution logistics, and strengthened regulatory oversight, as essential to improve product quality and protect public health in Nigeria's complex pharmaceutical environment.

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Data availability: Data will be made available on request.

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