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# Evaluation of Brands of Ascorbic Acid Tablets on the Market After Exposure to Sunlight and Temperature in Sierra Leone

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**Abstract:** This study evaluated the quality, stability, and regulatory status of selected vitamin C tablet brands marketed in Freetown under different storage conditions. An experimental study design was employed involving ten (10) brands of vitamin C tablets purchased from registered pharmacies in the Western Area Urban between October and November 2021. Baseline physicochemical analyses were conducted, after which samples were exposed to sunlight and elevated temperature (40 ± 1 °C) for six months, alongside a control stored under recommended conditions. Quality assessment was carried out in accordance with British Pharmacopoeia (BP) 2022 and USP <905> standards, including identification by Thin Layer Chromatography, assay of ascorbic acid content, uniformity of dosage units, friability, and disintegration testing. Results showed that friability values for all samples remained within acceptable limits (⩽1%), indicating adequate mechanical strength. Significant degradation of ascorbic acid content was observed following exposure to sunlight and elevated temperature. At baseline, 7 out of 10 samples (70%) complied with BP assay specifications, while after six months of exposure, only 3 samples (30%)—C2, C5, and C7—remained within specification under both stress conditions. One sample (C9) consistently demonstrated extreme assay failure (⩽58% of label claim) and failed the uniformity of dosage units' test, with acceptance values ranging from 41.87 to 56.5. Additionally, 5 out of 10 products (50%) were unregistered, highlighting gaps in regulatory compliance within the pharmaceutical supply chain. Prolonged exposure to sunlight and high temperature reduces the chemical stability and dosage uniformity of vitamin C tablets, even when physical strength remains acceptable. The findings highlight the need for stronger regulatory oversight, enforcement of product registration, improved storage practices and increased public awareness to ensure the quality and safety of pharmaceutical products.

**Keywords:** Vitamin C Tablets, dosage uniformity, assay compliance, friability, physicochemical quality.

## INTRODUCTION

Ascorbic acid, commonly known as vitamin C, is a six-carbon lactone, essential for humans and other primates, that acts as a vital electron donor and enzyme cofactor in various metabolic processes, such as collagen synthesis. It is an essential water-soluble nutrient and a powerful antioxidant that plays a crucial role in maintaining overall health. Compared to liquid and semi-solid forms, oral dose forms are more stable, easier to administer, and easier

to transport. Tablets are more popular among oral solids because of their low cost, high production, and relatively straightforward manufacturing method (Ghourichay et al., 2021; Herbig et al., 2023). Counterfeit and poor quality medications have been a persistent issue in health system since the early 20th century, with an indisputable impact on the health of the vulnerable population (Enright, 2021; Couffinhal & Socha-Dietrich, 2017).

Stability of a drug product is the period that elapses from the time the formulation is manufactured and packaged until its chemical or biological activity no longer falls below a predetermined level of potency and its physical properties have not changed appreciably or adversely (Chauhan et al 2021; Maheshwari et al., 2018). The disintegration test/dissolution and the pH of the solution obtained after the disintegration stand out among the tests for identification, purity, drug content, and those inherent to the pharmaceutical form, such as hardness, friability, average weight, and uniformity of unit doses (Khan & Iqbal, 2017; Ashokbhai et al., 2024). It is anticipated that the projected trust will exist regardless of the brand or supply firm because vitamin C is a highly advertised product that is not just recommended by doctors. Because the active ingredient can change during storage due to the effects of light, moisture, and heat, loss of quality impedes the effectiveness of the treatment and/or exposes consumers to the escalation of unfavourable or undesirable occurrences (Mieszczakowska-Frąc et al., 2021; Giannakourou & Taoukis, 2021).

The manufacturing and distribution of high-quality pharmaceuticals is crucial since it ensures the medication's effectiveness and safety (Wang et al., 2023; Ahmed, 2024). Ascorbic acid is essential for improving the immune system's performance, including the phagocytic capacities of neutrophils and macrophages, a lack of which might increase a person's vulnerability to several infections. Additionally, by increasing the synthesis of antibodies, promoting antimicrobial responses, and stimulating lymphocytes, ascorbic acid improves immunological function (Khadim & Al-Fartusie, 2021; Mousavi et al., 2019; Aslam et al., 2017). It is an organic acid that is susceptible to instability in the presence of heavy metals, light, oxygen, high temperatures, and humidity (Vega et al., 2022). Ascorbic acid can be administered orally, parentally, or even topically; the right amount depends on a number of variables, including the patient's age, weight, and medical condition (Berretta et al., 2020).

In addition to having a major impact on the country's economy, low-quality pharmaceuticals can cause therapeutic failure, drug resistance, poor consumer health, and even death (Ekeigwe, 2019; Chabalenge et al., 2025). Pharmaceutical product to be approved for marketing, it must maintain stability for comparatively long storage periods at room temperature or at the actual temperature at which it is shipped and stored until its intended use. Therefore, this study evaluates the brands of ascorbic acid tablets on the market after exposure to sunlight and temperature.

## RESEARCH METHODOLOGY

### Study Design

This study adopted an experimental design to evaluate the quality and stability of vitamin C tablets under different environmental conditions. Ten (10) different brands of vitamin C tablets were purchased between October and November 2021 from registered pharmacies

in Freetown. Baseline analyses were conducted immediately after purchase, after which the samples were stored for a period of six months for stability assessment.

### Study Area

The study was conducted in the Western Area Urban of Sierra Leone, where the majority of pharmaceutical outlets are located. All samples were obtained from registered pharmacies within the study area and transported under controlled conditions to prevent unintended exposure prior to laboratory analysis.

### Sampling Technique and Sample Size

A convenience sampling method was employed. Pharmacies were visited to confirm the availability of vitamin C tablets that met the study requirements, including batch uniformity, expiration date, and minimum quantity. A minimum of 500 tablets per brand was collected to ensure adequate samples for identification, uniformity of dosage units, assay, friability, and disintegration tests.

### Selection Criteria

Inclusion criteria comprised finished pharmaceutical products labeled as vitamin C or ascorbic acid tablets with at least ten months of remaining shelf life. Exclusion criteria included non-tablet dosage forms, combination vitamin products, and tablets with less than six months of shelf life remaining.

### Sample Preparation and Storage Conditions

Samples were coded C1 to C10 for identification. All tablets were removed from their original containers and placed in transparent zip-lock bags to allow maximum exposure to test conditions. The samples were divided into two groups: Sunlight exposure (“outside”), and Temperature exposure in an oven at 40 ± 1 °C. A control group was stored under recommended storage conditions. Analyses were conducted at baseline, after three months, and at the end of six months.

### Laboratory Analysis

Physicochemical analyses were performed at the National Pharmaceutical Quality Control Laboratory of the Pharmacy Board of Sierra Leone, while friability testing was conducted at the College of Medicine and Allied Health Sciences (COMAHS), University of Sierra Leone. The tests conducted in accordance with British Pharmacopoeia (BP) 2022 included: Identification of active pharmaceutical ingredient, Uniformity of dosage units, Assay for ascorbic acid content, Friability testing, Disintegration testing (only one non-chewable sample, C7, qualified), Identification Test. Identification of ascorbic acid was performed using Thin Layer Chromatography (TLC) with a reference standard, as specified in BP 2022. Analyses were carried out at baseline and after storage using ethanol–water (6:1) as the mobile phase.

**Uniformity of Dosage Units**

Ten tablets from each brand were individually weighed to determine average tablet weight. Content uniformity was assessed using the weight variation method, and acceptance values were calculated according to BP 2022 and USP <905> guidelines. Samples meeting an acceptance value (AV) of not more than 15.0 were considered compliant.

**Assay of Active Ingredient**

Ascorbic acid content was determined using a titrimetric method, selected for its simplicity, cost-effectiveness, and reliability, as supported by previous studies. Results were compared against BP 2022 specifications.

**Materials and Reagents**

Materials included vitamin C tablets, silica gel TLC plates, UV detector (254 nm), ethanol, distilled water, 1M sulphuric acid, 0.1M ammonium cerium (IV) sulphate, analytical balance, disintegration tester, friabilator, burettes, pipettes, volumetric glassware, and other standard laboratory equipment.

**Tests for the Presence and Quality of Active Pharmaceutical Ingredients**

***Identification***

Ascorbic acid in the tablet formulations was identified using Thin Layer Chromatography (TLC) in accordance with the British Pharmacopoeia (BP) 2022. A reference standard solution (0.5% w/v) and tablet sample solutions were analysed at baseline and after storage, using an ethanol–water (6:1) mobile phase.

***Disintegration Test***

Disintegration testing was conducted in accordance with BP requirements, with chewable vitamin C tablets exempt from this test. Non-chewable tablets were tested using water at 37 °C, and disintegration times were recorded, with acceptable limits ranging from 15 to 30 minutes.

***Assay of Active Ingredient***

The ascorbic acid content was determined using a titrimetric assay method as specified in BP 2022. Twenty tablets were powdered, and a sample equivalent to 0.15 g of ascorbic acid was dissolved in water and 1M sulphuric acid, then titrated with 0.1 M ammonium cerium (IV) sulphate using ferroin as an indicator.

***Friability Test***

Friability was assessed for all ten brands using a friabilator. Twenty tablets were weighed before ($W_1$) and after ($W_2$) tumbling at 25 rpm for four minutes. Percentage weight loss was

calculated, and samples with friability ≤ 1% and no broken tablets were considered compliant. Table 1 shows sample characteristics and storage requirement of the ten brands of Ascorbic acid tablets.

**Table 1: Storage characteristics of various brands of Ascorbic acid tablets.**

| Sample code | Storage condition | Label claim (mg) | MFG Date | EXP Date | Primary package | Secondary package |
|---|---|---|---|---|---|---|
| C 1 | Store at temperature below 30 °C protect from Heat and light | 100 | 03/21 | 03/24 | A transparent plastic with pack | Brown rubber with an Orange cover |
| C 2 | Store in a cool, dry place | 500 | NA | 05/23 | White Polypropylene Plastic container with a white plastic cover | White Plastic wrap |
| C 3 | Store in a cool, dry place below 30 °C | 100 | 04/21 | 04/24 | Thermoformed aluminium blister pack | Transparent plastic plus Orange card box |
| C 4 | Store below 30 °C, protect from light | 100 | 02/21 | 02/24 | Transparent plastic | Grey polypropylene cup with an Orange LDPE cover. |
| C 5 | Store below 30 °C, protect from light | 500 | NA | 09/23 | Transparent plastic | White HDPE Container with a red cover |
| C 6 | Store below 30 °C, protect from light | 500 | 08/20 | 09/22 | Aluminium Blister pack | Orange rectangular folding Card box |
| C 7 | Store in a dry place between 20-25°C | 500 | NA | 07/23 | Brown Polyethylene terephthalate plastic container with a tamper evident seal and Green cover | Brown Polyethylene terephthalate plastic container with Green cover |
| C 8 | Out of the reach of children | 500 | 04/21 | 03/24 | Aluminium Blister pack | Orange rectangular folding card box |
| C 9 | Store in a cool, dry place. | 100 | 02/21 | 01/23 | Transparent plastic | Grey polypropylene cup with an Orange LDPE cover. |
| C 10 | Store at temperature below 30 °C protect from Heat, light and moisture | 500 | 08/20 | 07/23 | Aluminium Blister pack | Orange rectangular folding card box |

**Data Analysis**

Results were analysed using descriptive statistics; including percentages, mean values, and standard deviations. Graphical presentations were generated using Microsoft Excel 2010.

### Ethical Considerations

All findings related to product quality were treated with confidentiality. Any regulatory concerns identified were communicated through appropriate channels of the Pharmacy Board of Sierra Leone for further action.

## RESULTS AND DISCUSSION

### Friability Test for Baseline Samples and After Six (6) Months of Exposure

When tested for brittleness, as shown in Table 6 samples C3, C9, and C4 had significant losses in the initial analysis. This continued for samples stored under sunlight for six months (C1-C4, C6, and C9). For samples stored at 40±1°C, samples C9 and C6 showed a significant loss. However, all of these losses were within one percent (1%) limits specified in the test specification. This implies that friability testing of finished pharmaceutical products reflects the tablet's resistance to wear and abrasion when subjected to mechanical shocks resulting from industrial processes and everyday operations such as manufacturing, packaging, storage, transportation, distribution, and even patient handling (Pardhi et al., 2024; Hofmanová, 2020; Kim et al., 2021). The brittleness of a dosage unit is inversely proportional to its hardness and vice versa. (Sun et al., 2018; Yost et al., 2022). This test makes it essential to choose a suitable packaging material to ensure tablet stability, quality, and shelf life (Oliveira et al. 2020).

**Table 2: Friability test for baseline samples after six (6) months of storage.**

| Friability test | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | | Sunlight | | | Temperature (40±1°C) | | |
| Samples | Before(g) | After(g) | % Loss | Before(g) | After(g) | % Loss | Before(g) | After(g) | % Loss |
| C 1 | 6.362 | 6.326 | 0.569 | 6.387 | 6.344 | 0.676 | 6.571 | 6.558 | 0.212 |
| C 2 | 11.903 | 11.893 | 0.087 | 11.902 | 11.842 | 0.505 | 11.485 | 11.421 | 0.556 |
| C 3 | 6.320 | 6.259 | 0.971 | 6.358 | 6.302 | 0.881 | 6.542 | 6.523 | 0.298 |
| C 4 | 6.234 | 6.186 | 0.770 | 6.310 | 6.253 | 0.911 | 6.250 | 6.239 | 0.178 |
| C 5 | 13.108 | 13.084 | 0.179 | 13.158 | 13.154 | 0.029 | 10.341 | 10.278 | 0.603 |
| C 6 | 12.530 | 12.517 | 0.101 | 12.546 | 12.440 | 0.842 | 12.453 | 12.337 | 0.930 |
| C 7 | 6.425 | 6.413 | 0.176 | 6.342 | 6.336 | 0.093 | 6.376 | 6.369 | 0.105 |
| C 8 | 10.111 | 10.100 | 0.111 | 10.174 | 10.160 | 0.129 | 10.086 | 10.065 | 0.211 |
| C 9 | 6.222 | 6.180 | 0.680 | 6.418 | 6.377 | 0.631 | 6.580 | 6.523 | 0.877 |
| C 10 | 11.219 | 11.191 | 0.250 | 11.343 | 11.336 | 0.064 | 11.229 | 11.216 | 0.114 |

### Assay Result of Samples

The baseline analysis of the samples taken showed that seven (7) samples had the ascorbic acid content prescribed in the British Pharmacopoeia 2022 (Table 3). However, samples C3, C8, and C9 had levels below the specification of BP. For the samples exposed to sunlight,

after six (6) months, only samples C2, C5, and C7 were found to have active ingredients within the British Pharmacopoeia specification. In addition, the samples exposed to a temperature of 40±1°C were found to have (C2, C5, and C7) levels within specification. Over the six (6) month exposure of the samples, C1, C4, C6, and C10 were observed to have out-of-specification levels of ascorbic acid, as were C3, 8, and 9. Active ingredient content and average weight are critical components in determining the uniformity of dosage units (Lukášová et al., 2017; Emagn Kasahun et al., 2022). For a drug to produce the desired effect in the body, the quality of both the chemical content and the formulation process is critical (Rawal et al., 2019; Pramod et al., 2016; Stielow et al., 2023; Lee et al., 2022).

**Table 3: Assay result of samples**

| | | AFTER 6 MONTHS Under exposed Conditions | | |
|---|---|---|---|---|
| **SAMPLE** | **BASELINE** | **SUNLIGHT** | **TEMPERATURE (40±1°C)** | **Limit (%) BP 2022** |
| C1 | 96.30 ± 1.66 | 92.19 ± 0.42 | 90.80 ± 2.54 | 95.00-107.50 |
| C2 | 103.86 ± 0.86 | 105.59 ± 5.69 | 102.89 ± 0.61 | 95.00-107.50 |
| C3 | 92.08 ± 2.27 | 90.09 ± 2.45 | 88.96 ± 1.01 | 95.00-107.50 |
| C4 | 95.06 ± 0.84 | 91.57 ± 1.77 | 91.39 ± 2.37 | 95.00-107.50 |
| C5 | 100.94 ± 5.56 | 96.76 ± 5.25 | 100.23 ± 1.75 | 95.00-107.50 |
| C6 | 97.06 ± 2.27 | 93.12 ± 2.37 | 91.84 ± 2.40 | 95.00-107.50 |
| C7 | 95.78 ± 1.27 | 98.15 ± 1.64 | 96.97 ± 1.13 | 95.00-107.50 |
| C8 | 93.76 ± 1.00 | 90.69 ± 2.49 | 92.16 ± 0.92 | 95.00-107.50 |
| C9 | 57.80 ± 0.50 | 52.53 ± 5.07 | 50.45 ± 5.52 | 95.00-107.50 |
| C10 | 95.29 ± 0.95 | 89.66 ± 1.86 | 91.90 ± 1.30 | 95.00-107.50 |

**Uniformity of Dosage Units for Samples Collected**

The figure below shows the uniformity of the dosage units for the collected samples (Figure 1). The analysis of sample C9, both the initial sample and the conditioned samples (exposed to sunlight and temperature), analyzed showed that failed the uniformity of the dosage unit test with an acceptance value of (41.87 - 56.5). This was confirmed by the failure of the same in the assay analysis. Sample C4 also failed the uniformity test for the sample conditioned at a temperature of 40±1°C. The study revealed that exposing the samples to different environmental conditions such as sunlight and a temperature of 40±1°C may cause variations in the uniformity of the dosage units for all tested samples (Ezealisiji et al., 2016; Mehta & Bhayani, 2017; Kashinath et al., 2024). The uniformity of tablets is the guarantee of the amount of active ingredients in each unit, and factors such as homogeneity, weight, and tablet loss/friability affect the efficacy of the drug (Chen et al., 2017; Lukášová et al., 2017; Mazdi et al., 2025; Udem et al., 2024). Drug dosage is critical to administering correct doses to ensure that the amount of declared active ingredient is within the established specifications (Mishra, 2024; Ward et al., 2017).

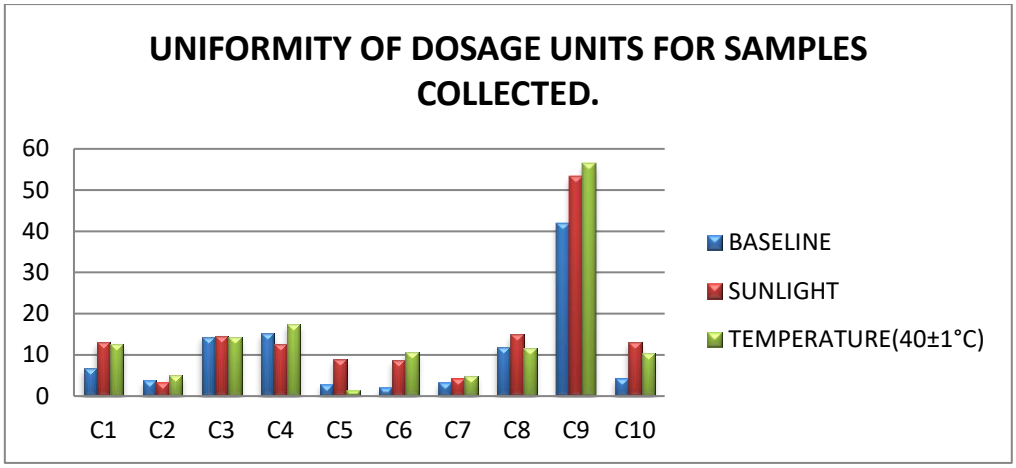


**Figure 1: Uniformity of dosage units for samples collected.**

### Registration Status of the Samples

The samples C1, C2, C5, C7, and C9 were classified as unregistered (Table 4). This demonstrated the need for a comprehensive assessment of the status of drugs or pharmaceutical products within the supply chain through a robust pre-market evaluation and consistent post-market surveillance (Badnjević et al., 2022; Su et al., 2023; Nwokike, 2023). Unregistered does not necessarily mean counterfeit. However, for drug testing, which is routinely conducted by the Medicines Regulatory Body called Pharmaceutical Board Sierra Leone (PBSL), any pharmaceutical product or drug must be registered with the country's recognized institution. This facilitates the withdrawal of medicines, as recently was reported by WHO (WHO Medical Product Alert No. 6/2022) in relation to the contaminated pediatric medicines in the Gambian market. At the time of publication (October 5, 2022), the report stated that drug manufacturers bear the primary responsibility for ensuring the safety, quality, and efficacy of their products. Manufacturers are required to adhere to Good Manufacturing Practices (GMP), a set of international norms that ensure products are consistently produced and controlled to quality standards, aiming to eliminate risks of contamination, poor quality, or mislabelling.

**Table 4: Registration status of the samples**

| Sample code | Product description | Manufacturing country | Registration status |
|---|---|---|---|
| C 1 | Orange circular tablet with the product name inscribed on one of the sides and SAM on the other | Nigeria | Unregistered |
| C 2 | Brown oval tablets | United Kingdom | Unregistered |
| C 3 | Orange circular tablet with the Manufacturer's name inscribed on one of the side. | Nigeria | Registered |
| C 4 | Orange cylindrical tablet with an inscription | Nigeria | Registered |
| C 5 | Brown circular tablet | USA | Unregistered |
| C 6 | Orange Circular tablet scored on one side | India | Registered |
| C 7 | Light Brown circular tablet with a score on one side | USA | Unregistered |

| | | | |
|---|---|---|---|
| C 8 | Yellow Circular tablet with a score and VC 500 inscribed | China | Registered |
| C 9 | Orange Circular tablets with the product name inscribed on both sides of the tablet. | Nigeria | Unregistered |
| C 10 | Orange Circular tablet with a score and VC 500 inscribed | India | Registered |

**Average Weight Deviations of Samples after Exposure to Temperature and Sunlight**

It can be seen that all samples exposed to a higher temperature than required showed a deviation in the average weight of the tablets, with sample C2 showing the highest deviation and C3 the lowest (Figure 2). In the samples exposed to sunlight, high deviations were seen in samples C3 and C9.

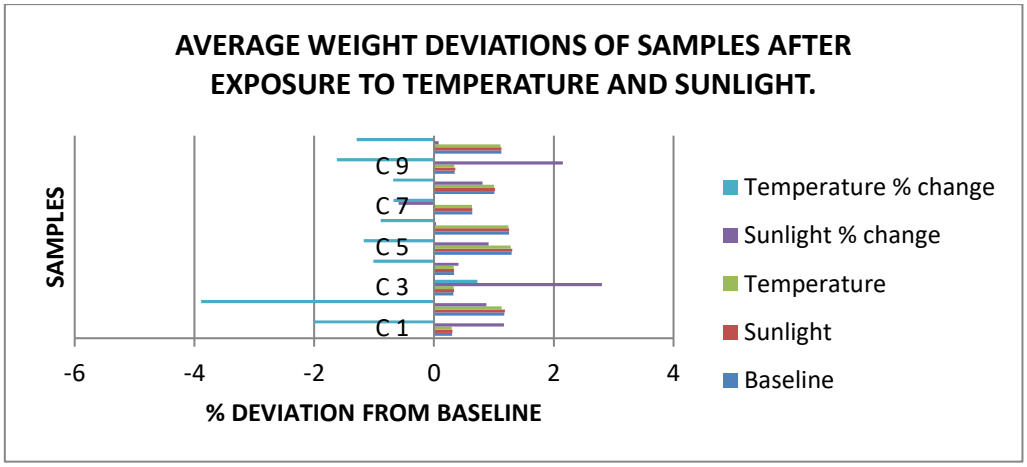


**Figure 2: Average weight deviations of samples after exposure to temperature and sunlight.**

## CONCLUSION

The findings of this study demonstrate that prolonged exposure to sunlight and elevated temperature (40±1°C) significantly reduces the chemical stability and dosage uniformity of vitamin C tablets, even though their physical strength (friability) generally remained within acceptable British Pharmacopoeia (≤1%) limits. While most tablets maintained adequate resistance to mechanical stress, assay results showed that many samples fell below the required active ingredient specification after six months of exposure, indicating degradation of ascorbic acid due to heat and light. Only samples C2, C5, and C7 remained within specification under stressed conditions. Uniformity testing revealed further quality concerns, particularly with sample C9, which consistently failed, and C4 under high temperature, demonstrating that environmental stress can compromise dosage consistency and therapeutic reliability. Additionally, several products were found to be unregistered with the Pharmaceutical Board of Sierra Leone, highlighting regulatory and supply chain weaknesses. The study emphasize that improper storage conditions lead to chemical degradation and dosage variability, underscoring the need for stronger regulatory oversight, improved storage practices, and enhanced quality assurance within the pharmaceutical supply chain.

**Conflict of Interest**: The authors declare no conflict of interest

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