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RESEARCH ARTICLE

EFFECT OF STORAGE CONDITIONS ON VITAMIN C DOSAGE FORMS IN ADEN, YEMEN

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Abstract

Vitamin C is an essential antioxidant used in pharmaceutical formulations. However, its stability is affected by environmental factors like temperature, humidity, and light exposure. In Aden, Yemen, frequent power outages and high temperatures exacerbate these stability concerns, making proper storage difficult. This study investigates the impact of different storage conditions on the stability of vitamin C dosage forms, including tablets, sachets, injections, and capsules available in Aden. A comparative experimental study was conducted to evaluate the stability of these dosage forms under continuous air-conditioned storage (20-25°C) and non-continuous air-conditioned (35-40°C). The analysis was performed using redox titration with potassium iodate in the presence of potassium iodide and UV-visible spectrophotometry with potassium permanganate. Redox titration results showed that vitamin C content in all dosage forms ranged from (91.23±2.3 - 102.38± 1.09 %) under continuous air-conditioned storage (20-25 ºC). On the other hand, the samples of studied vitamin C forms stored under non-continuous air-conditioned (about 35-40 ºC) with long periods of power outage during summer ranged (89.76±0 - 98.59±0.72 %). There was significant degradation of vitamin C content under elevated temperatures, with percentage loss ranging from (0.32% to 4.4%). In addition, the content of vitamin C in the selected forms was analyzed by the Spectrophotometric method, and the vitamin C content was determined from the regression equation of the calibration curve (y=0.0229x−0.0453, R2 = 0.9996) and expressed in content percentages, the loss percentages ranged from (0.48 to 6.6%). Furthermore, the incubation of vitamin C at different temperatures (40, 50, 60 ºC) for one week caused decreasing in its content, where the vitamin content lost about (18.64 - 42.71%). These findings emphasize the importance of appropriate storage conditions to maintain the stability and efficacy of vitamin C pharmaceutical products and heat-sensitive medication, especially in regions affected by climate change and frequent power outages. This study recommends further studies exploring the impact of climate change, humidity and packaging materials on heat- sensitive medication.

Keywords: Air-conditioned, Pharmaceutical Dosage Forms, Power Outage, Stability, Storage Conditions, Temperature, Vitamin C.

1. Introduction

Vitamin C (ascorbic acid) is a crucial water-soluble vitamin known for its antioxidant properties and role in immune function, collagen synthesis [1], and iron absorption. It is found in citrus and other fruits and vegetables. Humans lack the enzyme *L-gulonolactone oxidase*, which is essential for synthesizing vitamin C. Hence, vitamin C can't be produced or stored by humans and must be taken daily through supplements or food [2].

Vitamin C's biological roles are based on its ability to provide reducing equivalents for a variety of reactions [3]. Its powerful reducing action t can reduce most physiologically relevant reactive oxygen species. It acts as a cofactor for reactions requiring a reduced iron or copper metalloenzyme and as a protective antioxidant that operates in the aqueous phase both intra- and extracellularly [4]. Vitamin C also plays a vital role in the formation of several hormones and chemical messengers [4].

Adult vitamin C requirements are based on body tissue levels, which help protect against harmful free radicals. Adult's daily requirement of vitamin C from 19 years old and older is 90 mg for men and 75 mg for women [5]. For pregnant and lactated women, the amount increases to 85 mg, and 120 mg daily, respectively [5]. Smoking depletes vitamin C levels in the body, so an additional 35 mg beyond the recommended dietary allowance is suggested for smokers [5].

The upper intake level of vitamin C is 2000 mg daily which is the maximum daily intake unlikely to harm the body [5], levels beyond this may cause gastrointestinal distress and diarrhea, formation of kidney stones, increased uric acid levels (a risk factor for gout), and increased iron absorption, particularly in individuals with hemochromatosis- a condition characterized by high iron levels in blood [6]. However, high doses can be administered in specific cases under medical supervision or in controlled clinical trials [5].

The World Health Organization (WHO) has established comprehensive guidelines emphasizing good storage and distribution practices to ensure the quality and integrity of medical products [7]. However, ascorbic acid is susceptible to environmental conditions such as temperature, light, and oxygen, which can significantly impact its stability and effectiveness [8]. Additionally, Climate change has contributed to rising global temperatures, which accelerate drug degradation [9], particularly in tropical and subtropical regions such as Aden, Yemen, where high temperatures and power outages are common. A study found that storage temperatures in southern Malawi ranged from 13.8°C to 42°C, with a mean kinetic temperature of 25.3°C, which provides valuable insights into the challenges of maintaining appropriate storage conditions for pharmaceuticals in resource-limited settings [10]. Elevated temperatures can compromise the stability and efficacy of medications, as many drugs require storage within specific temperature ranges to maintain their therapeutic properties [11]. For instance, certain medications can become less effective or even harmful if exposed to temperatures outside their recommended storage conditions [12]. Additionally, frequent power outages in Aden disrupt temperature-controlled storage, accelerating the breakdown of heat-sensitive medications. The instability of the electrical grid in Yemen has led to prolonged periods without power [13], affecting the storage of essential medical supplies. Healthcare facilities often rely on generators, which may not provide consistent power [14], further jeopardizing the integrity of temperature-sensitive drugs

These challenges underscore the critical need for reliable electricity and effective storage solutions to ensure the safety and efficacy of medications in regions vulnerable to climate change and infrastructural instability [15]. The degradation of vitamin C can lead to reduced therapeutic efficacy, making it vital to understand the effect of storage conditions on its stability. This study examines how different storage conditions influence the stability of vitamin C dosage forms available in Aden, Yemen.

2.Methodology

2.1 Study Design and Setting

This experimental study was conducted on various pharmaceutical forms of vitamin C, obtained from several pharmacies in Aden. From June to September 2022, laboratory analysis was performed at the Faculty of Pharmacy, Aden University.

2.2 Inclusion Criteria

The study analyzed products such as *Remo-C*® injection, *C-Retard*® capsules, *Vita Ced*® tablets, and *Vitamin C-Sedico*® sachets, which were obtained from pharmacies in Aden where the storage durations were not specified. Samples were stored in pharmacies under two primary conditions:

Continuous air-conditioned storage (20-25°C): Continuous cooling control to simulate optimal storage conditions.

Non-continuous air-conditioned storage (35-40°C): Exposure to fluctuating high temperatures typical of Aden's climate, exacerbated by frequent electricity shortages.

2.3 Analytical Methods

The study evaluated the impact of storage conditions on different vitamin C dosage forms using two analytical techniques: titration and spectrophotometry. The impact of temperature on these dosage forms was assessed to ensure accurate measurement of vitamin C stability under varying storage conditions.

2.3.1 Redox Titration:

This method determines the vitamin C concentration in a solution by a redox titration with Iodine in the presence of potassium iodide. It is the iodine that oxidizes the ascorbic acid to dehydroascorbic acid as the iodine is reduced to iodide ions [16].

Ascorbic acid + I_2 → 2 I^- + Dehydroascorbic acid **Equation 1**

Due to this reaction, the iodine formed is immediately reduced to iodide as long as there is any ascorbic acid present. Once all the ascorbic acid has been oxidized, the excess iodine is free to react with the starch indicator, forming the blue-black starch-iodine complex, and determining the endpoint of the titration [16].

2.3.2 UV-Visible Spectrophotometry:

The absorbency of the mixture was measured by a UV-visible spectrophotometer at 530 nm using potassium

permanganate to determine vitamin C concentration. For 5 different (25 mL) volumetric flasks 40 µg/ ml (ppm) KMnO4 was added, then 1, 4, 8, 12, and 16 ppm ascorbic acid was added for each respectively [17].

3. Results

The results demonstrated that vitamin C remained relatively stable under continuous air-conditioned storage (20 -25°C). In contrast, under non-continuous air-conditioned storage (35-40°C) according to power outages, vitamin C exhibited significant degradation, with loss percentages ranging from (0.32 - 6.6 %). Further incubation tests revealed that degradation was highly temperature-dependent, with losses of (17.69 - 28.48 %) at 50°C and (23.37 - 42.71%) at 60°C.

The redox method is used to estimate vitamin C concentration during storage under continuous air-conditioning states and discontinuous air-conditioning states, then calculate the percentage of loss of vitamin C concentration in selected dosage forms. The results revealed that all the studied vitamin C dosage forms showed approximate percentages between vit c content (101.2±01, 98.59±0.72, 102.38± 1.09, 91.23±2.3) under continuous air-conditioned about (20-25°C**)** of selected pharmacies. On the other hand, the samples of studied vitamin C dosage forms that were stored in pharmacies under non-continuous air-conditioned, according to the power outages about (35-40 ℃), percentages were (96.8±01, 98.27±0.83, 98.3± 1.1, 89.76±0.1).

Vitamin C degradation rates were 4.4% (tablet), 0.32% (sachet), 4.08% (injection), and 1.47% (capsule) **(Table 2).**

The content of vitamin C in the selected forms was analyzed by the Spectrophotometric method, and the vitamin C content was determined from the regression equation of the calibration curve (y=0.0229x−0.0453, R2 = 0.9996) and expressed in content percentages, the loss percentages were (0.48 - 6.6%).

Table 1: List of results by titration method of vitamin C with iodin

NO	Trade Name	Dosage Form	Concentration percent % of continuous air-condition	Mean± Standard Deviation	Concentration percent % of non-continuous air-condition	Mean± Standard Deviation
1	Vita Ced®	Effervescent Tablet	101.2	101.2 ± 0	96.8	96.8 ± 0
			101.2		96.8	
			101.2		96.8	
2	Vitamin C-Sedico®	Effervescent Sachet	97.68	98.59 ± 0.72	99.44	98.27 ± 0.83
			98.65		97.68	
			99.44		97.68	
3	Remo-C®	Injection	101.2	102.38 ± 1.09	96.8	98.3 ± 1.1
			102.1		98.65	
			103.84		99.44	
4	C-Retard®	Capsule	92.4	91.23 ± 2.3	89.76	89.76 ± 0
			88		89.76	
			93.28		89.76	

Table 2: List of percent % of loss efficacy of vitamin C by titration method.

No	Trade Name	Dosage Form	Concentration percent % of continuous air-conditioned	Concentration percent % Of non-continuous air-conditioned	% loss
1	Vita Ced®	Effervescent Tablet	101.2 ± 01	96.8 ± 01	4.4
2	Vitamin C-Sedico®	Effervescent Sachet	98.59 ± 0.72	98.27 ± 0.83	0.32
3	Remo-C®	Injection	102.38 ± 1.09	98.3 ±1.1	4.08
4	C-Retard®	Capsule	91.23 ± 2.3	89.76 ± 0.1	1.47

Table 3: List of results by UV-Spectroscopic Method of Vitamin C Content.

NO	Trade name	Dosage form	Concentration percent % of continuous air-conditioned	Concentration percent % of non-continuous air-conditioned	% loss
1	Vita Ced®	Effervescent Tablet	99.37 ± 0.2	92.77 ± 0.15	6.6
2	Vitamin C-Sedico®	Effervescent Sachet	123.15 ± 0.3	82.16 ± 0.03	0.48
3	Remo-C®	Injection	95.12± 0.3	90.01± 0.6	5.11
4	C-Retard®	Capsule	93.17±1	90.87±0.006	2.3

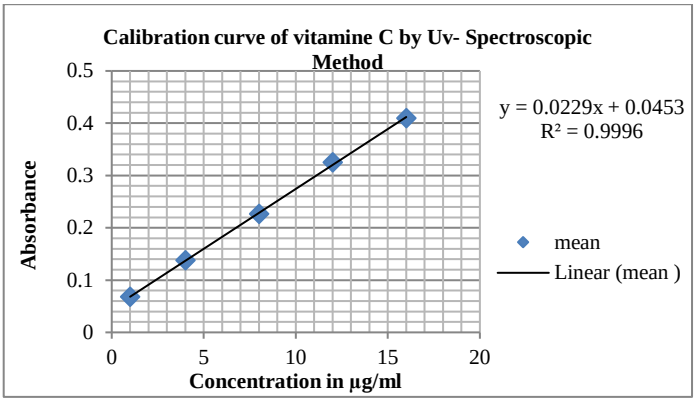

Fig. 1: Calibration Curve of Vit C with KMnO4 by UV-Spectroscopic Method.

The determination of ascorbic acid was based on the redox reaction between ascorbic acid and potassium permanganate. Vitamin C was dissolved in KMNO4 and examined alone to determine the maximum absorbance.

$2KMnO4 + 5C6H8O6 + 3H2SO4 \rightarrow 2MnSO4 + 5C6H6O6 + K2SO4 + 8H2O$ **Equation 2** [18].

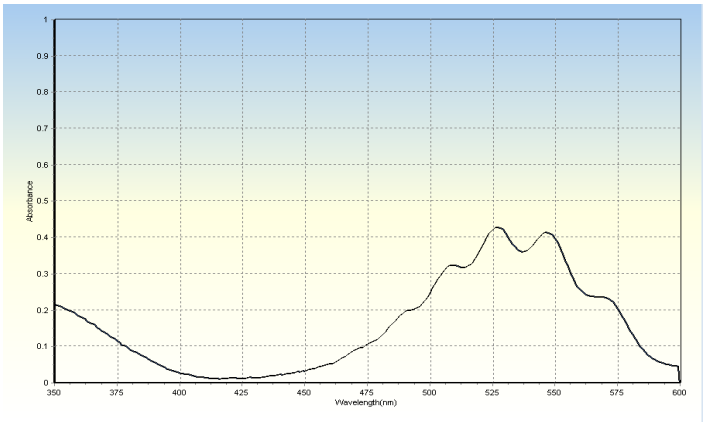

Fig. 2: The UV spectrum of Vitamin C in KMNO4 (ʎmax at 350 nm and 600 nm).

The ʎmax of drugs was found to be 350 nm and 600 nm for Vitamin C as shown in Figure (2). In our Vit C brands, the maximum wavelength that determines the absorbance of ascorbic acid was 526 nm.

The UV spectrophotometric analysis was also used for determining the stability of studied vitamin C forms at different temperature incubation. The stability of vitamin C was found to be decreased significantly with increasing temperature (more than 30), we treated the four vitamin C forms (tablet, sachet, injection and capsule) with different temperature at (40, 50, and 60 °C) for one week incubation time. Among the various dosage forms, capsules exhibited the highest degradation rates where the percent loss was 24.02, 28.48 and 42.71 respectively at different incubations (Table 4).

Table 4: List of The effect of temperature at (40, 50 and 60 °C) by UV-Spectroscopic Method of Vitamin C Content

Vit C form	Tm (ºC)	Concentration (%)	Loss percentage
Tablet	25-30	101.2 ± 01	00
	40	85.58 ± 2.4	15.62
	50	82.56 ± 3.3	18.64
	60	62.97± 0.47	38.23
Sachet	25-30	98.59 ± 0.72	00
	40	91.71± 0.94	6.88
	50	80.90 ± 0.66	17.69
	60	75.22 ± 1.2	23.37
Injection	25-30	102.38 ± 1.09	00
	40	88.05 ± 0.57	14.33
	50	77.79 ± 0.51	24.59
	60	68.80 ± 0.45	33.58
Capsule	25-30	91.23 ± 2.3	00
	40	67.21 ± 0.89	24.02
	50	62.75 ± 0.49	28.48
	60	48.52 ± 0.41	42.71

4. Discussion

The results of this study demonstrate that the stability of vitamin C is significantly influenced by storage conditions, particularly temperature fluctuations caused by power outages. Under continuous air-conditioned storage (20-25°C), vitamin C remained relatively stable across all dosage forms, with minimal degradation. However, in non-continuous air-conditioned storage (35-40°C), there was a notable decrease in vitamin C content, with percentage losses ranging from 0.32% to 6.6% depending on the dosage form. These findings are consistent with previous studies that indicate the extent of ascorbic acid oxidation to dehydroascorbic acid and its hydrolysis to Diketo-L-gulonic acid, depends on concentration, temperature, pH and light [19]. Additionally, the exposure to heat by increasing the temperature for every 10 ℃ accelerates vitamin C degradation, reinforcing the necessity of proper storage conditions [20].

Furthermore, the accelerated stability testing at higher temperatures (40°C, 50°C, and 60°C) revealed a significant degradation trend. At 60°C, vitamin C loss reached up to 42.71% in capsule form, highlighting the vulnerability of heat-sensitive pharmaceuticals in hot climates. This confirms the well-established principle that the rate of vitamin degradation increases exponentially with temperature. As described in previous pharmacokinetic studies, when the heating time increases, the percentage loss of vitamin C increases too [21]. The stability of vitamin C decreased at 40 C° over

1 hour of incubation and a 19.2 % loss of vitamin C was observed [21].

The impact of power outages on pharmaceutical storage in Aden is particularly concerning, as frequent electricity shortages prevent optimal cooling and expose medications to extreme temperatures, exacerbating this issue by limiting refrigeration and air-conditioning access. Consequently, climate change significantly impacts pharmaceutical stability, accelerating drug degradation through increased temperature and humidity [22]. This situation poses a major challenge for drug stability in developing countries with inadequate infrastructure [23], and the worsening impacts of climate change, including extreme heatwaves [24], further complicating pharmaceutical storage, and accelerating degradation rates for heat-sensitive drugs like vitamin C. A study from Malta University emphasizes the necessity of temperature control of pharmaceutical storage, noting that temperature in Malta can reach up to 41.6 C° during summer months, highlighting the challenges to maintaining drug stability [25]. The degradation of vitamin C under these conditions reduces its therapeutic efficacy, potentially compromising health for populations that depend on it for immune support.

5. Limitation

This study has several limitations. Firstly, it was conducted in a single city, Aden, Yemen, limiting the generalizability of the results to other regions with different climatic conditions. Secondly, the study focused on a limited number of dosage forms and did not assess the impact of packaging materials, which could influence drug stability. Thirdly, the research was constrained by available resources and financial difficulties, restricting the scope of the investigating to vitamin C alone, and preventing the analysis of other medications. Finally, only two techniques were employed to analyze the vitamin C concentration. Future studies should aim to include broader geographic areas, more dosage forms, and an in-depth analysis of packaging and humidity effects to provide a more comprehensive understanding of vitamin C stability under various conditions.

6. Conclusion

This study underscores the significant impact of storage conditions on the stability of vitamin C pharmaceutical products. Maintaining air-conditioned storage or refrigeration is essential to minimize degradation, particularly in regions with high temperatures and frequent power outages. The effects of climate change further compound the challenge of maintaining pharmaceutical stability, highlighting the need for improved infrastructure, alternative cooling solutions, and regulatory enforcement of storage guidelines. Additionally, public awareness campaigns are necessary to educate consumers on proper vitamin C storage to prevent degradation due to heat exposure and power outages. Future research should explore the impact of climate change, humidity and packaging materials on vitamin C stability. Finally, policy intervention should promote investment in renewable energy sources and backup power solutions for pharmacies and healthcare facilities to mitigate the impact of prolonged electricity shortages on medication stability.

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مقالة بحثية

تأثير ظروف التخزين على الأشكال الصيدلانية لفيتامين C في عدن، اليمن

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المُلخّص

يُعد فيتامين C من مضادات الأكسدة الأساسية والعوامل المساعدة التي تُستخدم على نطاق واسع في التركيبات الصيدلانية. ومع ذلك، يتأثر ثباته بشكل كبير بالعوامل البيئية مثل درجة الحرارة والرطوبة والتعرض للضوء. وتؤدي التغيرات المناخية وانقطاعات الكهرباء المتكررة إلى تفاقم هذه المشكلات، لا سيما في المناطق مثل عدن، اليمن، حيث تعيق درجات الحرارة المرتفعة وانقطاع الكهرباء المستمر عملية التخزين السليم للأدوية. تهدف هذه الدراسة إلى التحقيق في تأثير ظروف التخزين المختلفة على استقرار أشكال فيتامين C الصيدلانية، بما في ذلك الأقراص، الأكياس، الحقن، والكبسولات المتوفرة في عدن. تم إجراء دراسة تجريبية مقارنة لتقييم استقرار هذه الأشكال تحت التخزين في بيئة مكيفة باستمرار (20-25 درجة مئوية) والتخزين في بيئة متقطعة التكييف مع درجات حرارة مرتفعة (35-40 درجة مئوية). تم تحليل العينات باستخدام طريقة المعايرة بالأكسدة والاختزال باستخدام يودات البوتاسيوم في وجود يوديد البوتاسيوم، بالإضافة إلى التحليل الطيفي بالأشعة فوق البنفسجية باستخدام برمنغنات البوتاسيوم. أظهرت نتائج المعايرة بالأكسدة والاختزال أن محتوى فيتامين C في جميع الأشكال التي تمت دراستها تراوح بين (91.23±2.3 - 102.38± 1.09 %) أثناء التخزين في درجات حرارة منخفضة تحت التكييف المستمر (20-25 درجة مئوية). من ناحية أخرى، أظهرت العينات المخزنة تحت التكييف غير المستمر (حوالي 35-40 درجة مئوية) مع فترات طويلة من انقطاع التيار الكهربائي خلال فصل الصيف، أن محتواها تراوح بين (89.76±0 - 98.59±0.72%). تم تسجيل تدهور كبير في محتوى فيتامين C عند التعرض لدرجات حرارة مرتفعة، حيث تراوحت نسبة الفقد بين (0.32% إلى 4.4%). بالإضافة إلى ذلك، تم تحليل محتوى فيتامين C باستخدام طريقة التحليل الطيفي، وتم تحديد محتوى الفيتامين من خلال معادلة الانحدار لمنحنى المعايرة (y=0.0229x−0.0453, R2 = 0.9996)حيث تراوحت نسب الفقد بين (0.48% إلى 6.6%). علاوة على ذلك، أدى حضانة فيتامين C عند درجات حرارة مختلفة (40، 50، و60 درجة مئوية) لمدة أسبوع إلى انخفاض في محتواه بنسبة تتراوح بين (18.64% - 42.71%). تؤكد هذه النتائج أهمية توفير ظروف تخزين مناسبة للحفاظ على استقرار وفعالية المستحضرات الصيدلانية المحتوية على فيتامين C والأدوية الحساسة للحرارة، لا سيما في المناطق المتأثرة بالتغيرات المناخية وانقطاعات الكهرباء المتكررة. توصي هذه الدراسة بإجراء المزيد من الأبحاث لدراسة تأثير التغير المناخي والرطوبة ومواد التعبئة والتغليف على الأدوية الحساسة للحرارة.

الكلمات المفتاحية: التكييف، الأشكال الصيدلانية، انقطاع التيار الكهربائي، الثبات، ظروف التخزين، درجة الحرارة، فيتامين C.

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