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QUALITY CONTROL OF TWO CINNAMON TEA BRANDS COMMERCIALIZED IN COSTA RICA USING THE CENTRAL AMERICAN TECHNICAL REGULATION 11.03.56:09

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ABSTRACT

A tisane is a pharmaceutical form used in herbal teas. One product commercialized in this way in Costa Rica is cinnamon. Therefore, this investigation sought to determine the quality of two cinnamon tea brands produced and commercialized in Costa Rica and determine reproducibility in terms of the desired quality characteristics between different brand batches. Said determination was done by performing tests (described in official books, according to Costa Rican regulations) on three batches of each brand: labeling, organoleptic, foreign matter, minimum fill, heavy metals limit (lead), arsenic limit, loss on drying, total ash, acid-insoluble ash, microbial enumeration and specific microorganisms (*E. coli* and *Salmonella* sp.). The evaluated batches complied with the specifications for each one. The exception was the labeling test (two and nine requirements were absent in both brands' primary and secondary packaging, respectively). Besides, there was reproducibility in terms of quality specifications for the three batches of the same product.

KEYWORDS: natural product, tisane, cinnamon, quality control.

INTRODUCTION

Throughout history, natural products have been an abundant source of biologically active compounds for the pharmaceutical industry.[1] According to fossil records, plants for treating diseases can be traced back to around 60,000 years.[2] Its value lies in the ability to influence various signaling pathways.[1]

An example is the tisane, the pharmaceutical form of herbal teas.[3] Typically, an infusion, where the substance of interest is extracted by contacting boiling water with the herbal material, is done. The contact time is five to 20 minutes.[4]

A product commercialized in this pharmaceutical form in Costa Rica is cinnamon (*Cinnamomum verum* or *Cinnamomum zeylanicum*). It is a perennial tree with numerous flowers, whose leaves have three to five veins, which go from the base and almost to the tip's end. In addition, they are highly variable in size and shape.[5] [6]

Among the main constituents of this species are cinnamaldehyde, eugenol, and camphor. They are in different proportions, depending on the part of the plant selected. The traditional indications include gastrointestinal and gynecological conditions. Other attributable properties are decreased blood glucose levels and blood pressure, anti-inflammatory, antibacterial, and antioxidant effects.[7]

Due to their origin, natural products are considered options that generate benign adverse effects,[1] so most of the population prefers their consumption. However, this reasoning is wrong, since the consideration that they do not generate toxicity and are free of adverse effects has caused an incorrect use in unrestricted doses, resulting in severe poisonings and acute health problems.[8]

All pharmaceutical products marketed, including those obtained through natural sources, must be safe and effective at their commercialization and useful life. A drug's safety refers to a favorable benefit-risk ratio, while efficacy is the degree of benefit that offers under ideal conditions of employment.[9] For this reason, quality control favors monitoring both its efficacy and its safety.[10] In the absence of such control, situations such as erroneous plant identification, contamination, plant substitution or adulteration, failures in Good Manufacturing Practices (GMP), and incorrect doses can occur.[11]

Given this scenario, this research's objective was to determine the quality of two cinnamon tea brands produced in Costa Rica and are currently commercialized in the local market. Previously, such determination was performed with other Costa Rican products, specifically valerian,[12] senna leaf,[13] mint,[14] and boldo.[15] Moreover, reproducibility was determined in terms of the desired quality characteristics between different brand batches. All the investigation follows the Central American Technical Regulation (RTCA, for its Spanish acronym) 03.11.56:09.[16]

MATERIALS AND METHODS

Product sampling and procedures selection

Three batches of cinnamon tisanes of two brands were purchased in different supermarkets of Costa Rica. The batches were identified as 1, 2, and 3 for brand 1 and 4, 5, and 6 for brand 2.

The official books established by the RTCA 11.03.56.09[16] were employed to select the following procedures.

Labeling test

The items stipulated for the primary and the secondary packaging were examined. The labeling of each batch must comply with the RTCA 11.04.41:06.[17]

Organoleptic characteristics test

The odor and the color were determined as established by the European Pharmacopeia 10.0.[18] Ten tisanes were observed with a Konus® luminous lens. The product complied by presenting a yellowish or reddish-brown color and a characteristic, aromatic odor.

Foreign matter determination test

Ten tisanes were opened, and their contents dispersed on a white surface and visualized with the help of a Konus® luminous magnifying glass. The foreign matter was separated, its weight was obtained with the help of an Adam® PW254 analytical balance, and its percentage was calculated regarding the total sample weight. The product complied if the foreign elements did not exceed 2%.[5]

Minimum fill test

It was performed according to the general chapter <755> of the United States Pharmacopeia (USP) 42.[19] Ten tisanes from each batch were taken and open carefully. Then, the specific content of each tisane was weighed in an Adam® PW254 analytical balance. The acceptance

specification is that any individual tisane's net content was not less than 90% of the declared amount.

Lead limit test

The evaluation of heavy metals was made for the lead element by following method A presented in the <2.4.8> chapter of the European Pharmacopoeia 10.0.[18]

Two tisanes were taken in a 100 ml beaker, and 22 ml of distilled water were added. It was left to rest for 5 minutes. After this, the liquid was extracted from both tisanes, depositing them in the same beaker. Later, a 12.0 ml aliquot was taken for the sample, 2.0 ml for the standard, and 2.0 ml for the blank. Each one was tip out in a different test tube. Then, 10 ml of the lead standard (1 ppm) and 10 ml of distilled water were added to the standard tube and the blank tube, respectively. Subsequently, 2 ml of acetic acid-sodium acetate buffer at a 3.5 pH, 0.5 ml of diluted acetic acid, and 1.2 ml of thioacetamide solution (previously heated in a steam bath) were added to each tube. The result complied if both the blank and the sample had a brown color of less intensity than the standard.

Arsenic limit test

The test was done according to method A of the <2.4.2> chapter of the European Pharmacopoeia 10.0.[18]

In a 100 ml beaker, one tisane was placed with 11 ml of distilled water and left to rest for 5 minutes. After this, the liquid was extracted by compressing the tisane and deposited in the same beaker. Later, a 10.0 ml aliquot was taken and transferred in a conical flask. Afterward, 15 ml of 12 M HCl, 0.1 ml of stannous chloride, and 5 ml of 16%w/v potassium iodide were tip out. It was left to stand for 15 minutes. Then, 3 g of zinc chips were added, and the apparatus was assembled and placed in a water bath (temperature range between 90 and 100 °C). The standard was prepared in the same way, utilizing 1 ml of standard arsenic solution (1 ppm). After not less than 2 hours, the stain produced on the sample's mercury bromide paper should not be more intense than the reference standard.

Loss on drying test

It was carried out following the general chapter <731> of the USP 42.[19] A crucible was dried for 30 minutes at 105 °C in a Thermo Scientific® HeraTherm oven stove. The process was repeated until constant weight. Next, a cinnamon tisane's content was placed in the

crucible and accurately weighed on an Adam® PW254 analytical balance. Then, it was placed in the oven and dried for two hours at 105 °C. After cooling in a desiccator, it was weighed again in the same balance to calculate the loss percentage. These periods of heating and cooling were continued until reaching a constant weight. The product complied if the loss on drying percentage was no more than 12% from the initial weight.

Total ash test

The procedure of the general chapter <561> of the USP 42 was utilized.[19] Two cinnamon tisanes' content was accurately weighed on an Adam® PW254 analytical balance in a crucible taken previously to constant weight. It was incised gently at the beginning and then gradually increasing the temperature to 675 °C. The test was done for two hours. After this period, the ash was cooled in a desiccator and weighed in the same balance to obtain the total ash percentage. Later, it was placed in the Thermo Scientific® HeraTherm oven stove and dried for 30 minutes at 105 °C, cooled in the desiccator, and weight. These periods of heating and cooling were continued until reaching a constant weight. The compliant sample was considered if the total ash was less than 6.0% of the initial weight.[5]

Acid-insoluble ash test

The test was performed according to the general chapter <561> of the USP 42.[19] 25 ml of HCl 3 N were added to each sample obtained from the total ash test. After this, they were heated to boiling for 5 minutes. The insoluble material was transferred to a Boeco® grade 389 filter paper. It was then washed with hot water and transferred to a melting pot (brought previously to constant weight). Initially, it was incised gently and then gradually increased the temperature to 675 °C. The assay was made for two hours. After cooling in a desiccator, it was weighed again in the same balance. Later, it was placed in the Thermo Scientific® HeraTherm oven stove and dried for 30 minutes at 105 °C, cooled in the desiccator, and weight. These periods of heating and cooling were continued until reaching a constant weight. The acceptance specification is that the insoluble ash percentage should not be more than 4.0%.[5]

Microbial enumeration tests

The tests were executed according to the general chapter <61> of the USP 42.[19] 10 g of the product was taken and added in 100 ml of Bacto™ casein-soybean digest broth. Two Petri dishes were prepared for each medium at the required dilution level. The plates with BactoTM casein-soybean digest agar were used for the total aerobic microbial count

(incubated at 33 °C for 48 hours). For yeasts and molds count, Liofilchem™ potato dextrose agar was employed (incubated at 22.5 °C for five days). Finally, the arithmetic mean of each medium's enumeration was taken, and the number of colony-forming units (CFU) calculated per g of product. According to the RTCA 11.03.56.09, the total aerobic microbial count should not exceed 10^7 CFU/g, and total combined yeasts and molds count should not exceed 10^5 CFU/g.[16]

Microorganisms' specific tests

The procedures of chapter <2022> of USP 41 were followed.[19]

Escherichia coli absence test: 10 g of the product to be analyzed were added in 100 ml of Bacto™ casein-soybean digest broth. The sample was incubated at a temperature of 33 °C for 24 hours. Then, a 1.0 ml sample aliquot was tip out into a container with Difco™ MacConkey broth, mixed, and incubated at 44 °C for 48 hours. After that, two samples (1.00 ml of the broth) were taken to inoculate two BBL™ MacConkey agar plates. Plates were incubated at 33 °C for 24 hours. In the end, both plates were examined.

Salmonella sp absence test: from the sample preparation for the *E. coli* absence test, a 1.00 ml aliquot was taken and transferred to 10 ml of Difco™ Rappaport Vassiliadis Salmonella enrichment broth. The solution was mixed and incubated at 33 °C for 24 hours. After this, two samples were taken (1.00 ml) to inoculate two plates of Difco™ xylose lysine deoxycholate agar (incubated at 33 °C for 24 hours). Finally, both plates were examined.

Both tests complied if there was an absence of both pathogenic microorganisms.

RESULTS AND DISCUSSION

Table 1 includes the aspects stipulated for primary and secondary packaging, and the compliance of each batch of the commercial brands evaluated.

Regarding the primary packaging, none of the batches met the information required by the RTCA 11.04.41.06.[16], precisely the batch number and the expiration date. The batch number is related to the product's traceability, referred to as the ability to follow a product's movement through all the stages involved in its production and distribution.[20] Although this number is included in the secondary packaging, the problem is that the pharmaceutical form (tisane) is generally consumed individually (they are kept in their primary packaging in other containers, not in its original box). In this way, it is not easy to make the respective report and take the appropriate actions with maximum efficiency and speed if a problem occurs.[20]

Additionally, the expiration date is the maximum date at which the product is still under its quality specifications. If a drug is consumed after this one, there is a possibility that its properties have changed.[21] Given this, consumers' ignorance of the expiration date puts them at risk since they could be using an unsafe and/or ineffective product.

Table 1: Compliance with the labeling requirements of primary and secondary packaging by the evaluated batches of two cinnamon tea brands commercialized in Costa Rica.

Requirement	Fulfillment					
	Brand 1			Brand 2		
	1	2	3	4	5	6
Primary packaging						
Product name	Yes	Yes	Yes	Yes	Yes	Yes
Batch number	*No*	*No*	*No*	*No*	*No*	*No*
Expiration date	*No*	*No*	*No*	*No*	*No*	*No*
Manufacturer laboratory name or logo	Yes	Yes	Yes	Yes	Yes	Yes
Secondary packaging						
Product name	Yes	Yes	Yes	Yes	Yes	Yes
Pharmaceutical form	Yes	Yes	Yes	Yes	Yes	Yes
Indications	Yes	Yes	Yes	Yes	Yes	Yes
Employment form	Yes	Yes	Yes	Yes	Yes	Yes
Active ingredients, including quantity	*No*	*No*	*No*	*No*	*No*	*No*
Registration number	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturer name and country of origin	Yes	Yes	Yes	Yes	Yes	Yes
Net amount of the finished product	Yes	Yes	Yes	Yes	Yes	Yes
Batch number	Yes	Yes	Yes	Yes	Yes	Yes
Storage conditions	Yes	Yes	Yes	Yes	Yes	Yes
Expiration date	Yes	Yes	Yes	Yes	Yes	Yes
Contraindications and warnings	*No*	*No*	*No*	*No*	*No*	*No*
Interactions	*No*	*No*	*No*	*No*	*No*	*No*
Side effects	*No*	*No*	*No*	*No*	*No*	*No*
General labeling	*No*	*No*	*No*	*No*	*No*	*No*
Specific labeling	*No*	*No*	*No*	*No*	*No*	*No*
Posology	*No*	*No*	*No*	*No*	*No*	*No*
Administration route	*No*	*No*	*No*	*No*	*No*	*No*
Use during pregnancy, breastfeeding, elderly, and children under 2 years	*No*	*No*	*No*	*No*	*No*	*No*

Referring to the secondary packaging, it does not comply with the qualitative-quantitative composition. It is known that the active substances of the cinnamon bark are cinnamaldehyde (the most representative substance, which can be found up to 90%, depending on the extraction method) and eugenol.[22] [23] For this reason, their amount per tisane should be indicated, so that this specification is met. Two other requirements not shown in the package

related to the composition are the cinnamon's posology (dose allowed to achieve the beneficial effects; 1 to 3 g per day of product in 100 ml of water)[24] and the administration route. The information is necessary since the person needs the exact way to consume it to achieve the desired pharmacological effects without unnecessary risks.

The interactions are not mentioned either. Some studies have shown that cinnamon can interact with medications that low glucose levels,[25] including oral hypoglycemic agents.[7] Besides, due to coumarin's presence, caution should be exercised with people consuming antiplatelet or anticoagulant medications, and drugs capable of affecting the liver. Its concomitant use can increase the risk of bleeding and cause liver damage.[25] A study made in the murine liver *in vitro* suggests that cinnamon root components can interact with microsomal cytochrome 450, causing interactions with drugs metabolized by it.[26]

Furthermore, this product's warnings include that caution should be considered if consumed by people with diabetes and/or low blood pressure. Also, care should be taken because of some adverse effects, including diarrhea, vomiting, dizziness, and drowsiness. Likewise, the infusion oil can irritate the mucous membranes, including the stomach, intestinal, and urinary tracts.[27] In some cases, it has been linked to the appearance of states of nervousness.[28]

Other data not indicated in the secondary packaging were the general and the specific labeling. The general labeling includes phrases like “Keep out of reach of children” and “For over-the-counter modality: If symptoms persist, consult your doctor." Moreover, specific labeling is established for each product, and the information obtained should include this section.[16]

One last detail is the absence of information about its use during pregnancy, breastfeeding, elderly, and children under two years. This situation is worrisome. There is no evidence that large amounts of cinnamon intake could be safe for pregnant and breastfeeding women.[24]

Other tests performed were organoleptic tests, which refer to sensory evaluations.[29] In natural products, they assure medicinal plants' identity, purity, quality, and activity.[30] Various ethnobotanical studies have shown the relevance of these characteristics to distinguish between medicinal and non-medicinal plants. Even their selection and their indications can be explained by attributes such as taste and smell.[31] For the studied batches

of each brand of cinnamon tisanes, all met the specifications, supporting that it is cinnamon, despite being in the presence of a crush of the plant bark.

Another critical assessment is foreign matter. It is defined as any material from the medicinal plant or materials other than those specified.[32] [33] Therefore, within the control and quality standards, this matter must be removed.[34] For the foreign organ test carried out, leaves were found in the six batches (**Table 2**). This assay is required since the plant's medicinal effects vary according to its part.[35]

Additionally, in terms of foreign elements, plastic was found in two batches of brand 2, but the percentages obtained corresponded to 0. However, it is relevant to notice, because the raw material must be free of any non-plant component, including soil, insect parts, and animal excreta.[36] For the study made, all the batches followed the pharmacopoeial specifications.

Table 2: Percentage of foreign organs and foreign elements for the three batches of each cinnamon tea brand commercialized in Costa Rica (batches 1 to 3 for brand 1 and 4 to 6 for brand 2).

Batch	Total sample weight g	Foreign organs weight g	Foreign organs percentage %	Foreign elements weight g	Foreign elements percentage %
1	12.4477	0.0035	0	0	0
2	13.6670	0.0078	0	0	0
3	14.2953	0.0018	0	0	0
4	18.8990	0.0071	0	0.0006	0
5	17.9153	0.0034	0	0	0
6	18.1173	0.0089	0	0.0001	0

The minimum fill test was executed to know if the tisanes were appropriately filled. According to Costa Rican legislation, the test is accomplished only in the case of a complaint.[16] **Table 3** shows the minimum fill value obtained for each tisane, its labeling percentage, and the average for each batch of both brands.

Table 3: Labeling percentage of each batch of two cinnamon tea brands commercialized in Costa Rica.

Tisane	Weight g	Labeling percentage %	Weight g	Labeling percentage %	Weight g	Labeling percentage %
	Brand 1					
	Batch 1		Batch 2		Batch 3	
1	1.3865	107	1.3255	102	1.3734	106
2	1.3736	106	1.3871	107	1.3180	101
3	1.3606	105	1.3630	105	1.3645	105
4	1.4184	109	1.3472	104	1.3648	105
5	1.4337	110	1.3497	104	1.3897	107
6	1.4275	110	1.3743	106	1.3415	103
7	1.3396	103	1.3806	106	1.3790	106
8	1.3801	106	1.3822	106	1.3730	106
9	1.3726	106	1.3836	106	1.3350	103
10	1.3880	107	1.3666	105	1.3681	105
Mean	1.3881	107	1.3667	105	1.3607	105
	Brand 2					
	Batch 4		Batch 5		Batch 6	
1	1.8927	105	1.8413	102	1.8110	101
2	1.9186	107	1.7840	99	1.8051	100
3	1.8869	105	1.7753	99	1.8663	104
4	1.9094	106	1.8196	101	1.8254	101
5	1.9382	108	1.7655	98	1.8286	102
6	1.9020	106	1.8325	102	1.8705	104
7	1.8731	104	1.8431	102	1.7760	99
8	1.9519	108	1.8409	102	1.8847	105
9	1.8546	103	1.7664	98	1.8070	100
10	1.9330	107	1.8163	101	1.8912	105
Mean	1.9060	106	1.8085	100	1.8366	102

Regarding the minimum fill test, batches 1, 2, 3 of brand 1 were under the established pharmacopoeial standards,[19] obtaining average values of 107, 105, and 105%, respectively, concerning the labeling, which was 1.3 g. A similar situation happened with batches 4, 5, and 6 of brand 2, since values of 106, 100, and 102% were determined, respectively, about its labeling (1.8 g).

The test establishes a minimum that each tisane must contain, but not a maximum. This situation allows industries to add more amount without affecting their marketing permission. Still, in this investigation, more care was appreciated in the filling process regarding other researches made, where values were higher than 110%.[12] [13] [14] [15] The results show that producers are having greater control over the filling process (usually an acceptable

pharmacopoeial range for these products is 90 to 110%). In this way, it is ensured that the consumer receives a dose in the therapeutic range, which is defined as the concentration range at which substantial clinical benefits are obtained in the absence of unacceptable adverse effects.[37] In an overdose event, the person can endanger their health causing agitation, hypoglycemia, and tachycardia because of coumarin presence in the drink.[25]

Natural products also experience contamination, which can be accomplished by inappropriate human activities, such as heavy metals exposure. This scenario has severe consequences on people's health.[24]

One of the heavy metals is lead. Its exposure is mainly through the respiratory and gastrointestinal tracts. The amount absorbed by the intestine is around 10 to 15%, and this value increases if there are iron, zinc, or calcium deficiencies. Its toxic effects are occasioned by combining the sulfhydryl group in proteins (inhibiting sulfhydryl-dependent enzymes) and oxidative stress (increase in the oxidized form of glutathione or glutathione disulfide and inhibition of enzymes, such as superoxide dismutase and catalase).[38] [39]

As a consequence of this toxicity mechanism, the metal can generate failure in various body systems. People may have abdominal pain, anemia, hypertension, hearing impairment, peripheral neuropathy, and kidney failure.[40] Furthermore, it can produce proximal tubular damage, glomerular sclerosis, interstitial fibrosis, proteinuria, tubulointerstitial fibrosis, infertility, spontaneous abortion, stillbirth, premature birth, and low birth weight.[40] [41] Other consequences are intellectual, behavioral, or motor deficits, hand-eye coordination problems, reaction time difficulties, and poor performance on intelligence tests.[41]

Another compound is arsenic. Its poisoning occurs as a consequence of the consumption of improperly treated water.[42] Its toxicity mechanisms include the inhibition of cellular enzymes that contain sulfhydryl groups and the replacement of phosphate molecules in "high energy" compounds (arsenolysis). Trivalent arsenic compounds inhibit enzymes to a greater extent, while pentavalent ones are more involved in arsenolysis.[43]

Intoxication with arsenic compounds begins with nausea, vomiting, abdominal pain, and severe diarrhea.[42] Subsequently, prolonged exposure can originate tracheal and bronchogenic carcinomas, hepatic angiosarcomas, and various skin cancers. Myelogenous

leukemia, pigmentation changes, palmar and plantar hyperkeratosis, and anemia can also be developed.[43]

For these reasons, limit tests were done. The distinct batches evaluated of cinnamon's commercial brands showed to be below the permitted limits, fulfilling the quality requirements.

In addition, the quality of natural products is evaluated with the loss on drying test. Drying is an essential process of the raw material from which natural products are made, allowing their storage for a more extended period during their production and is considered a way to preserve their bioactivity and increase their useful life.[44] Another reason is the inhibition of microbial growth (closely related to the microbial enumeration tests discussed later) by minimizing growth (decreased water activity) and, therefore, contamination by bacteria, fungi, and yeasts.[45] [46] This technique prevents the development of specific biochemical reactions from microorganisms' metabolism, altering the product's organoleptic properties,[47] specifically its pharmacological utility. Likewise, raw materials become vulnerable to the presence of microbial toxins, including the aflatoxins, of great danger to humans (carcinogenic activity).[48]

For the two brands of tea, information regarding the loss of drying is observed in **Table 4**. From the specifications given,[19] all the batches are in accordance, obtaining a value of less than 12% for each one. The above information shows the producers' good work related to product elaboration.

Similar to the previous test, the assays for total ash and acid-insoluble ash were accomplished. Both allow to determine the presence of any foreign material, the inorganic composition of the raw material, and its purity,[49] mostly when they are crushed,[50] as happens with cinnamon teas. The total ash value includes metals, carbonates, phosphates, silicates, and silica found (including physiological and non-physiological ash). A high number indicates contamination, substitution, adulteration, or neglect during raw material preparation. Additionally, acid-insoluble ash represents contamination with silica (earth and sand, for example).[51] [52] The samples studied in this case showed the values indicated in **Table 5** for these tests.

Table 4: Percentage of loss of drying for the three batches evaluated of each cinnamon tea brand commercialized in Costa Rica (batches 1 to 3 for brand 1 and batches 4 to 6 for brand 2).

Batch	Initial weight g	Final weight g	Loss on drying percentage %
1	1.4056	1.2662	9.9
2	1.4025	1.2604	10.1
3	1.3954	1.2541	10.1
4	1.8132	1.6198	10.7
5	1.8033	1.6140	10.5
6	1.7864	1.6003	10.4

Table 5: Percentage of total ash and acid-insoluble ash for the three batches evaluated of each cinnamon tea brand commercialized in Costa Rica (batches 1 to 3 for brand 1 and batches 4 to 6 for brand 2).

Batch	Initial weight g	Total ash weight g	Total ash percentaje %	Acid-insoluble ash weight g	Acid-insoluble ash percentage %
1	2.6842	0.0867	3.2	0.0027	0.1
2	2.7693	0.0845	3.1	0.0034	0.1
3	2.6177	0.0807	3.1	0.0094	0.4
4	3.7635	0.1415	3.8	0.0087	0.2
5	3.7063	0.1412	3.8	0.0052	0.1
6	3.5975	0.1209	3.4	0.0036	0.1

These tests indicate that all the batches of the two brands comply with total ash (the highest value obtained was 3.8%) and acid-insoluble ash specifications (the highest value was 0.4%). The results are evidence of the purity of the manufacturers' raw material utilized and the quality provided to consumers.

Other assays to determine the quality of natural products are related to the presence or absence of microorganisms. The growth of pathogenic microorganisms can affect the physicochemical characteristics of the product and must be controlled.[53] For the microbial enumerations of mesophilic microorganisms, fungi, and yeasts, the batches evaluated for both commercial cinnamon tea brands complied with the specifications established by the RTCA.[16] These results show the proper handling of the crude drug, because of the possibility of microbial contamination of water, soil, or animals during production and human activities (harvesting, drying, and classification).[54] The control of humidity through the drying process (shown above) is reflected in a decrease in microbial growth. If there is high

humidity in the packaged product, the water activity can increase to a level where microorganisms' growth damages the product. Besides, it can put the person in unnecessary danger.[55] Clinical cases showed significant infections assignable to the consumption of contaminated products.[56]

The last two analyses were the presence or absence of pathogenic Enterobacteriaceae, specifically *E. coli* and *Salmonella* sp. These microorganisms are of great importance due to their relationship with various health problems that affect mainly high-risk groups such as infants, pregnant women, immunosuppressed people, and the elderly.[57] *E. coli* is a commensal bacterium usually found as part of the intestinal microbiota of homothermic animals. Still, this species' pathogenic strains are capable of causing intestinal and extraintestinal diseases in humans.[58] For its part, *Salmonella* sp also belongs to the family of Enterobacteriaceae. More than 2,600 serotypes belonging to *Salmonella enterica* have been described, and many are capable of affecting human health.[59]

For this investigation, the absence of both pathogens was obtained in the different batches of cinnamon tea brands. This finding demonstrates that the population can safely consume them, especially since enteric diseases are leading causes of illness and death in developing countries.[60] It should be noted that the test for the absence of *Salmonella* sp. is not performed according to the Costa Rican regulations, as it does not apply to products that must be consumed with hot water. However, as indicated in previous works, in this country, people use hot water,[13] [14] [15] which is not capable of killing *Salmonella* sp.[61]

Finally, the reproducibility in terms of quality parameters was accomplished for the various tests implemented on the batches of each commercial brand. This finding is relevant because many parameters affect the requirements of the raw material, among them, the plant part employed, the harvest site (including altitude), the harvest periods (season and time of day), the drying method, and the exposure to pathogens, among others.[62] [63] There is significant care to provide products that maintain their quality, safety, and efficacy, regardless of the batch utilized.

CONCLUSIONS

The three batches of each cinnamon tea brand commercialized in Costa Rica complied with the specifications established in the official documents for the following tests: organoleptic, foreign matter, minimum fill, heavy metals limit (lead), arsenic limit, loss on drying, total

ash, acid-insoluble ash, microbial enumerations, and specific microorganisms (*E. coli* and *Salmonella* sp.). The only one with nonconformities was the labeling test. For the primary packaging, the batch number nor the expiration date were found. As a complement, for the secondary one, the information regarding active ingredients (including quantity), contraindications and warnings, interactions, side effects, general and specific labeling, posology, administration route, and use during pregnancy, breastfeeding, elderly, and children under two years were absent.

Furthermore, there was reproducibility in terms of quality specifications for the batches of the same product. The results reflected the work accomplished by the manufacturers of these herbal teas to obtain quality products for Costa Rican consumers.

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