

Analysis of plant samples marketed in pharmacies of natural products in the extreme South of Bahia

Análise de amostras de plantas comercializadas em farmácias de produtos naturais do extremo Sul da Bahia

DOI:10.34117/bjdv7n2-495

Recebimento dos originais: 10/01/2021

Aceitação para publicação: 10/02/2021

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ABSTRACT

The work with medicinal plants is above all a way of seeking natural and economic alternatives that can benefit the population as a whole. This work aimed to know teas and medicinal leaves sold in pharmacies in Porto Seguro. For this purpose, the quality of the samples was evaluated by analyzing the flavor, aroma, appearance and labels of the teas and leaves, checking the presence or absence of any quality control of these products. The pharmacognostic analyzes of the samples allowed to verify that of the 25 samples evaluated, 12% of them had labels. Only 12% contained information on the labels such as expiration date and no information on proper conservation, forms of use, recommendations, or both. Only 8% of herbal medicines had a scientific name, weight specification and company logo with CNPJ data, state registration. Information on SAC number, acronym and number at the Ministry of Health, package insert and technical responsible were not included in the product packaging. It was found that 100% of the surveyed products are not registered with the Ministry of Health and are therefore considered illegal before ANVISA. All samples observed were adequate for the color that characterizes the species. As for turbidity, most samples (81%) did not show any indication of this parameter. As for the conservation aspect, natural products were within the standards. As for the flavor of herbal medicines, all samples evaluated presented the characteristic taste of the species. Regarding the sweetness parameter, most of the species evaluated (77%) presented a weak sweet taste and 23% strongly sweet. 80.77% of the samples analyzed showed no acidity. Of the 25 samples analyzed, 69% of these had a pleasant, strong aromatic odor, 15% did not have a strong aromatic odor and 16% odorless. When preparing teas, it was observed that 23.1% of the samples had a sweet aroma, 50% did not exhibit this type of odor and 5% exhibited an artificial plant odor. It is concluded that after carrying out the analysis of taste, aroma, appearance and labels of the samples, in comparison to the pharmacopoeic parameters, it was found that the species already registered had corresponding characteristics and are in accordance with the results of the Quantitative Descriptive Analysis, in relation to the parameters considered in the research.

Keywords: medicinal plants, herbal medicines, teas, pharmacognosy.

RESUMO

O trabalho com plantas medicinais é acima de tudo, uma forma de buscar alternativas naturais e econômicas que possam beneficiar a população como um todo. Este trabalho objetivou conhecer chás e folhas medicinais comercializados em farmácias de Porto Seguro. Para isso foi realizada a avaliação da qualidade das amostras, por meio da análise do sabor, aroma, aparência e dos rótulos dos chás e folhas, verificando a presença ou ausência de algum controle de qualidade destes produtos. As análises farmacognósticas das amostras permitiram verificar que das 25 amostras avaliadas, 12% delas apresentavam rótulos. Apenas 12% continham nos rótulos informações como data de validade e nenhuma informação sobre conservação adequada, formas de uso, recomendações ou ambos. Somente 8% dos fitoterápicos apresentavam nome científico, especificação do peso e logomarca da empresa com dados de CNPJ, inscrição estadual.

Informações sobre número de SAC, sigla e número no Ministério da Saúde, bula e responsável técnico não constavam nas embalagens dos produtos. Constatou-se que 100% dos produtos pesquisados não estão registrados junto ao Ministério da Saúde, sendo, portanto considerados ilegais perante a ANVISA. Todas as amostras observadas se apresentaram adequadas quanto à cor que caracterizam a espécie. Quanto à turbidez a maioria das amostras (81%) não apresentou nenhum indício deste parâmetro. Quanto ao aspecto de conservação os produtos naturais estavam dentro dos padrões. Quanto ao sabor dos fitoterápicos todas as amostras avaliadas apresentaram o gosto característico da espécie. Em relação ao parâmetro de doçura a maioria das espécies avaliadas (77%) apresentaram um sabor adocicado fraco e 23% fortemente adocicado. 80,77% das amostras analisadas não apresentaram acidez alguma. Das 25 amostras analisadas 69% destas apresentavam odor aromático, agradável e forte, 15% não tinham um odor aromático forte e 16% inodoras. Ao preparar os chás observou-se que 23,1% das amostras apresentavam um aroma adocicado, 50% não exibiram este tipo de odor e 5% exibiram um odor artificial da planta. Conclui-se que após realização das análises de sabor, aroma, aparência e rótulos das amostras, em comparação aos parâmetros farmacopéicos, verificou-se que, as espécies já registradas apresentaram características correspondentes e que estão de acordo com os resultados da Análise Descritiva Quantitativa, em relação aos parâmetros considerados na pesquisa.

Palavras-chave: plantas medicinais, fitoterápicos, chás, farmacognosia.

1 INTRODUCTION

Brazil has the highest plant biodiversity on the planet, associated with rich ethnic and cultural diversity, with the highest percentage of medicinal plants found in the Amazon, the Cerrado and the Atlantic Forest, respectively (AZEVEDO, 2002).

Medicinal plants contain bioactive substances, many are poisonous or toxic, and must be used in very small doses to have the desired effect. They can be studied in the form of extracts (aqueous, ethanolic or in other organic solvents) in order to investigate their effect taking into account all their substances present or in order to isolate and identify their active principles. Such components may even become a drug. Most bioactive substances are secondary metabolites that have a biological effect not only in humans, but in other organisms, which, depending on their importance, can be synthesized.

The practice of using medicinal plants is common in all known communities. According to the World Health Organization (WHO), about 70% of the population worldwide uses or has at least used herbal medicines. The medicinal plants of the Atlantic Forest are used in family care mainly by women, or in health care by traditional experts and groups organized in the communities. There is an increase in the consumption of

medicinal plants or herbal medicines in all social classes in Brazil and worldwide (TORRES, 2005).

The therapeutic use of medicinal plants is one of the most characteristic features of the human species. Incentives for the use of medicinal plants are very common, contrasting rare publications that focus on the quality aspect, and in the same way as other medicines, the quality of these products must be analyzed with regard to their chemical and physical characteristics.

Phytotherapy is a form of medicinal therapy that has been growing in recent years (JORGE, 1985). The purpose of stimulating the use of herbal medicines is to prevent, cure or minimize the symptoms of diseases, at a cost that is more accessible to the population and public health services, compared to those obtained by chemical synthesis, which are, in general, more expensive, due to the technological patents involved. These natural products can be as efficient as those produced by chemical synthesis, however the transformation of a plant into a medicine must aim at preserving the chemical and pharmacological integrity of the plant, guaranteeing the constancy of its biological action and its safety of use, in addition to to enhance its therapeutic potential. To achieve these objectives, the production of herbal medicines requires previous studies related to botanical, agronomic, phytochemical, pharmacological, toxicological aspects, of the development of analytical and technological methodologies (MIGUEL and MIGUEL, 1999). A major limiting factor is that most plants in use are not described in official codes (forms and pharmacopoeias), and there are no studies on them (EVANS, 2002).

Herbal medicines, as well as all medicines, must offer quality assurance, have proven therapeutic effects, standardized composition and safety of use for the population, without risks to public health. Quality must be achieved by controlling raw materials, the finished product, packaging materials, pharmaceutical formulation and stability studies (ANVISA, 2020). After the great advance of synthetic products, the search for novelties brought the revaluation of nature and, with it, the search for therapies based on medicinal plants. However, like synthetic medicines, herbal medicines must have a regulatory unit to guarantee the necessary biosafety standards (MOURA et al., 2020).

For the maintenance and strengthening of the regional pharmaceutical industry, it is considered necessary to improve the quality of these products, meeting the growing demands of consumers and supervisory bodies. It is necessary for people working in these areas to be aware that products for therapeutic use must be treated in a different and responsible manner. Putting established safety and efficacy products on the market is an

ethical principle that should guide the production of medicines. The quality of a product is given by a set of factors that include from the raw material, processing control and pharmaceutical form control, to the package insert, packaging and advertising. All of these factors can affect the safety and effectiveness of the product, causing losses to the consumer. Regulatory authorities from different countries in the world, in addition to being proactive, must establish effective measures to protect public health, ensuring that all herbal medicines approved for commercialization are safe and of high quality (MOURA et al., 2020).

Brazil has undergone major changes leading the population to self-medication, through the use of herbal medicines (MIGUEL and MIGUEL, 2004). Realizing advantages in the commercialization of these products, some manufacturers launch irregular products in the market (MIGUEL and MIGUEL, 2004). Such irregularities range from adulteration of the raw material, lack of uniformity in the chemical composition, associations of different plants, without proof of efficacy and safety, even products with problems of inadequate labeling under technological and legal aspects (MIGUEL and MIGUEL, 2004).

The current legislation aims to regulate and officialize the development and use of herbal medicines. Several authors have shown that medicinal plants have undesirable and often toxic effects (BRASIL, 2000) and also consider Anvisa Resolutions, which regulate the collection, pharmacological and toxicological study of drugs, including the Resolution that regulates registration of herbal medicines (BRASIL, 2000).

When marketing leaves of species intended for teas, it is important that the drying, packaging and storage processes maintain the leaf's natural color to the maximum, as consumers perceive color as an indicator of food freshness, usually making their purchasing decisions based on the appearance of the product.

The quality control parameters vary from species to species and can be found in the monographs contained in the pharmacopoeias (FARIAS, 2001). The establishment of sensory quality, both in relation to the definition of attributes and the knowledge of the compounds that account for this quality, may guide the herbal medicine industry to obtain products with greater added value. The quality control of a product involves several steps that go from obtaining the raw material, going through the entire production process, culminating in the analysis of the final product (FARIAS, 2001).

The organoleptic characteristics are those determined by the sense organs, without the need for the use of optical instruments. In the case of teas, the flavor determines the

quality of the product and its market price. The color of vegetables is due to four main groups of natural pigments: chlorophylls, carotenoids, flavonoids and betalains. Through the analysis of the organoleptic characters of plant and herbal drugs, which, although natural, medicinal plants, if not processed with quality, can be harmful.

The present work had as objective to know and to evaluate the information contained in the labels of herbal medicines, the effect of storage on the coloring of dry leaves and, or bark of medicinal plants, the quality of natural products sold in the city of Porto Seguro - BA using techniques of quantitative descriptive sensory analysis of the aroma and flavor of the samples.

2 MATERIALS AND METHODS

Twenty-five herbal products sold in natural product pharmacies in Porto Seguro, Bahia, which are of the following species of medicinal plants, were defined as objects of evaluation: blackberry (*Morus alba* L.), mastic (*Schinus molle* L.), bilberry (*Peumus boldus*), chamomile (*Chamomilla recutita* L.), gorse (*Baccharis trimera*), green tea (*Camellia sinensis*), cloves (*Dianthus caryophyllus*), lemon grass (*Lippia alba*), fennel (*Pimpinella anisum* L.), holy thorn (*Maytenus ilicifolia*), eucalyptus (*Eucalyptus* sp), guaco (*Mikania* sp.), sunflower (*Helianthus annuus*), hibiscus (*Hibiscus* sp.), mint (*Mentha* sp.), mastruz (*Chenopodium ambrosioides* L.), roasted mate (*Ilex paraguariensis*), melissa (*Melissa officinalis* L.), nutmeg (*Myristica* sp.), oregano (*Origanum vulgare*), picón (*Bidens pilosa* L.), senna (*Cassia angustifolia*), bark (*Plantago* sp.) and commercial products (barks and powdered cinnamon).

ANALYSIS OF THE LABELS

The 25 herbal products defined as objects to be used in the analyzes were evaluated, according to the adequacy of their labeling, according to the general data contained in Resolution RDC No. 333, of November 19, 2003 (ANVISA, 2003). The following analyzed data were included: trade name, botanical nomenclature, content, company logo, manufacturer's name and address, CNPJ, acronym and registration number with the Ministry of Health, SAC, Technical Responsible and CRF number, number of batch, date of manufacture, expiration date, qualitative and quantitative composition, seal, barcode and the expressions "PHYTOTHERAPIC MEDICATION", "ADULT AND / OR PEDIATRIC USE", "BRAZILIAN INDUSTRY", "Technical information to the patient: See package insert", "Keep the product at room temperature

and protected from light and moisture”, “All medications must be kept out of the reach of children”, “Follow the instructions correctly. If symptoms persist, seek medical attention”. The data were collected and later statistically evaluated in a computer program.

FLAVOR EVALUATION

The botanical control of the 25 selected samples was carried out to carry out the analysis of the flavor of the teas prepared with them. The teas were made with 2.5 g of sample and 50 mL of water. The flavor quantification was performed on teas prepared with the 25 medicinal plants selected for the study.

The results attributed to the products were converted into percentage values. The sensory profile of the samples was determined by Quantitative Descriptive Analysis (STONE and SIDEL, 1993). In the present study, the evaluation of the flavor of the teas was made based on six parameters: sweetness, acidity, bitterness, characteristic flavor of the species, astringency (oral sensation resulting from the action of phenolic compounds that cause “tying”) and freshness (sensation of freshness). For the classification of the terms astringency and refreshment as flavor properties, ABNT's (1993) definition of “flavor” was taken into account. This is a simple and quick way to check some quality parameters (FARIAS, 2001). The data were collected and later statistically evaluated in a computer program. Seven tasters participated in the survey sessions of the descriptive terms, being defined, by consensus of the team.

AROMA ANALYSIS

Dry leaves and / or peels from the 25 samples selected for the study were used. The aroma quantification was performed by sensory analysis of the samples and teas prepared with them. The results attributed to the products were converted into percentage values. The sensory profile of the samples was determined by Quantitative Descriptive Analysis (STONE and SIDEL, 1993). In the present study the evaluation of the aroma of teas was made not only from the dry sample but also from the tea prepared with it, based on five parameters: banana odor, yerba mate odor, sweet odor, artificial odor of the evaluated plant and natural odor this. This is a simple and quick way to check some quality parameters, mainly identity and purity (FARIAS, 2001). The data were collected and later statistically evaluated in a computer program.

APPEARANCE ASSESSMENT

Dry leaves and / or peels from the 25 samples acquired were used for the research. The color quantification was performed by visual analysis of the samples and the teas prepared with them.

The results attributed to the products were converted into percentage values. The sensory profile of the samples was determined by Quantitative Descriptive Analysis (STONE and SIDEL, 1993), and the conservation aspect was also analyzed. In the present study, the appearance of the teas was evaluated based on two parameters: characteristic color of caramelized sugar (caramel color) and Degree of opacity of the solution in which there is no light transmission (turbidity). The data were collected and later statistically evaluated in a computer program.

3 RESULTS AND DISCUSSION

Of the 25 samples evaluated, only 12% had labels. The contents of the teas and leaves were in transparent plastic bags (Fig. 1). The packaging of medicines has a predominant role. In addition to being part of the product, the packaging must be seen as a means of providing a certain presentation, protection, identification, information and use of the product (DEAN and PACKAGING, 2002). Thus, the packaging represents an object of direct contact between the product and the user and, in addition to fulfilling technical, aesthetic and informational functions, it must comply with current legislation and ethical and moral concepts, in order to contribute to efficiency and safety in the use of the medication. However, in the samples analyzed, only 12% contained some information, such as expiration date and no information on proper conservation, forms of use, whether it was recommended for adults or children or both (Fig. 2).

When analyzing the frequency of the data legally required on herbal labels, all samples had the identification of the commercial name, 12% informed the expiration date and had a bar code. Only 8% of herbal medicines had a scientific name, weight specification and company logo with CNPJ data, botanical nomenclature, state inscription (Table 1).

Information on SAC number, acronym and number at the Ministry of Health, package insert and technical responsible were not included in the product packaging. This information is necessary for the correct conservation of the product by the establishment that sells it and by the customer. Sudden changes in temperature and humidity of the vegetable favor the action of fungi, bacteria and enzymes, which can lead to loss of

material quality due to alteration and / or destruction of the active principles responsible for the pharmacological action and, also, the production of substances toxic. The labeling of drug packaging is important, due to its formal character, its power of information and influence with the user (PETROVICK, et al., 2003). This demonstrates that RDC No. 333/03 (ANVISA, 2003) is not clear as to the mandatory nature of this item in medicines of plant origin. It was found that 100% of the surveyed products are not registered with the Ministry of Health and are therefore considered illegal before ANVISA.

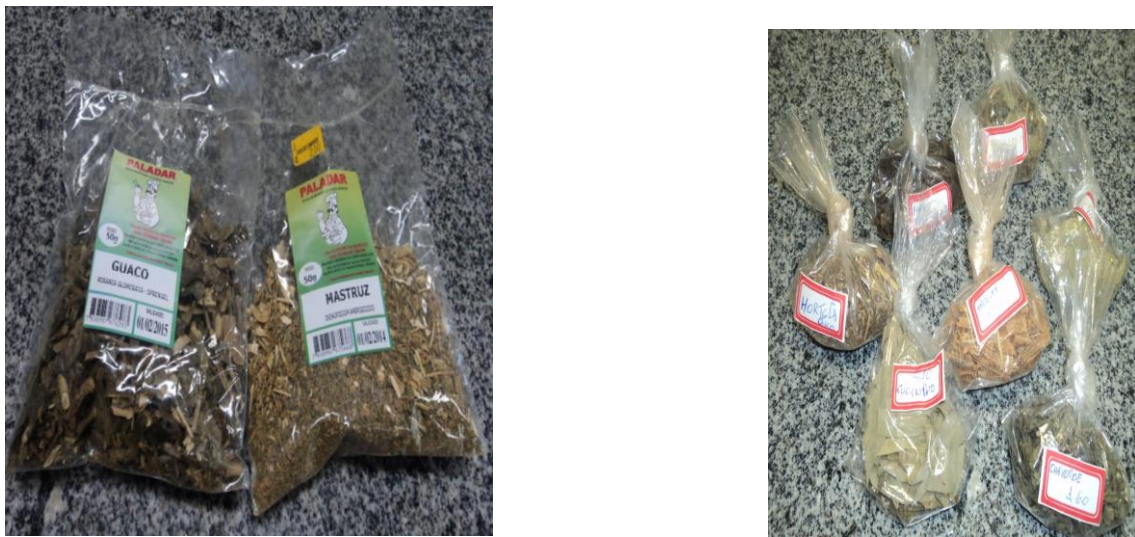


Fig 1. Samples subjected to analysis of labels, package inserts and appearance.

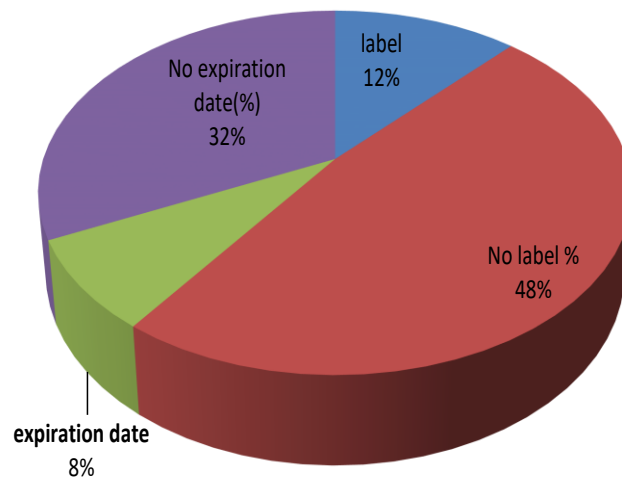


Fig 2. Results of analysis of labels and package inserts.

Table 1. Frequency of data legally required on herbal labels.

REQUIRED DATA	FREQUENCY %
Commercial name	100%
Botanical nomenclature	8%
Genre	8%
Species	8%
Content	0%
Company logo	8%
“PHYTOTHERAPIC MEDICINE”	0%
Use (adult and / or pediatric)	0%
Manufacturer name	8%
Full address	8%
CNPJ	8%
"BRAZILIAN INDUSTRY"	0%
Acronym and registration number in MS	0%
SAC	0%
Technical manager	0%
Lot	8%
Manufacturing	0%
Due date	12%
Reactive ink	0%
Seal Seal	8%
Barcode	12%
"Technical information to the patient: See package insert"	0%
"Store the product at room temperature and protected from light and moisture"	0%
"Every medicine must be kept out of the reach of children"	0%
"Please follow the way of use. If symptoms persist, seek medical attention"	0%

All evaluated samples had the characteristic flavor of the species. The characterization of the sensory quality of teas depends on the volatile compounds that give rise to quality indexes. Regarding the sweetness parameter, most of the species evaluated (77%) had a weak sweet taste and 23% strongly sweetened (Fig.3). The boldo tasted bitter and slightly acrid as required by the Brazilian Pharmacopoeia 5th edition (Fig. 4). The chamomile sample exhibited an aromatic and slightly bitter taste as required by the Brazilian Pharmacopoeia 4th edition. In relation to cinnamon powder and stick and fennel teas both had a sweet taste, the carqueja bitterness flavor, the espinheira santa flavor slightly bitter and astringent, melissa pleasant aromatic and slightly bitter taste, a little astringent, while the sene one had a bitter and astringent taste (Fig. 4). All these flavors found agree with those mentioned in the Brazilian Pharmacopoeia 5th edition. 80.77% of the analyzed samples showed no acidity (Fig. 3).

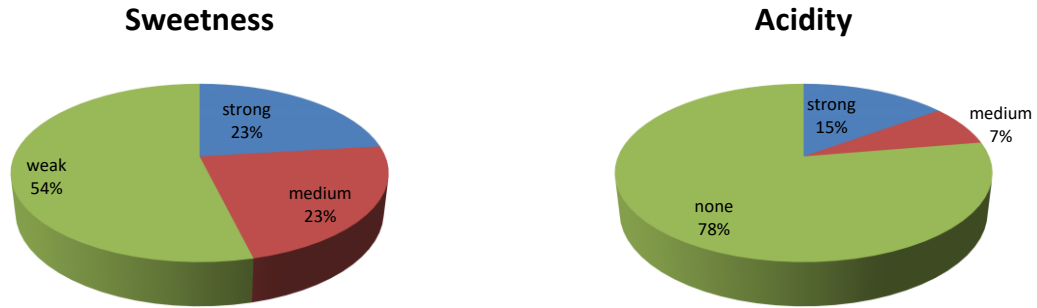


Fig. 3. Results of the Sensory Analysis of the taste of teas from 25 samples of species of medicinal use, regarding sweetness and acidity.

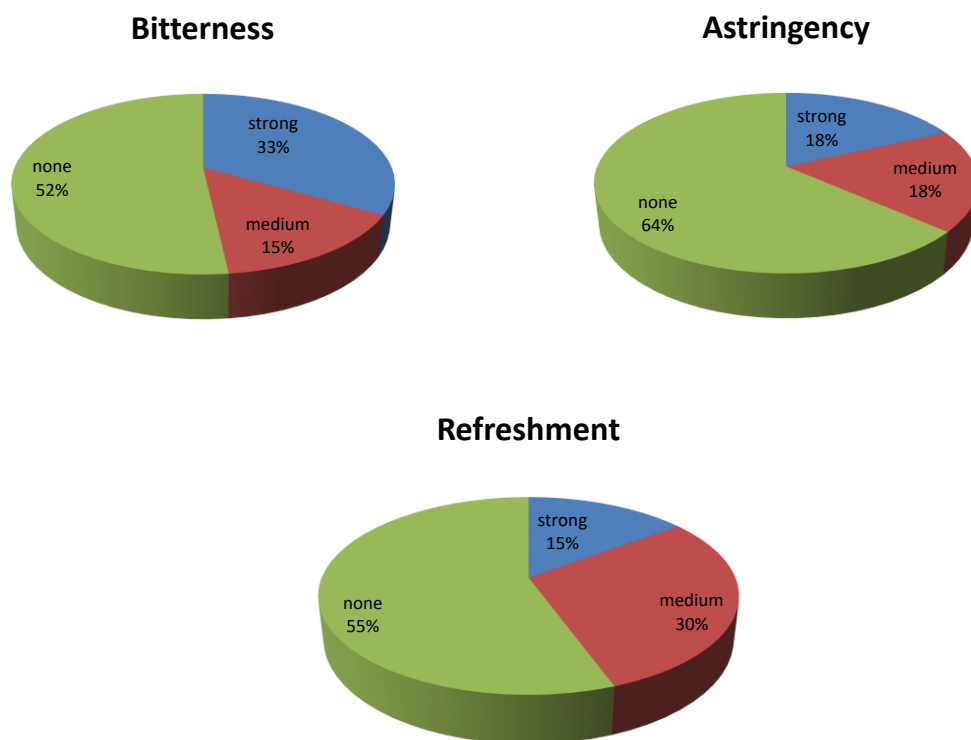


Fig 4. Results Sensory analysis of the taste of teas from 25 samples of species of medicinal use, in terms of bitterness, astringency and freshness.

Of the 25 samples analyzed, 69% of these had a pleasant, strong aromatic odor, 15% did not have a strong aromatic odor as is characteristic of the species evaluated and 16% odorless (Fig. 5). The samples that did not have the characteristic aroma of their respective species, possibly may have been due to the shape and the storage time of the samples and some really would have to be odorless as the Brazilian Pharmacopoeia 5th edition describes for its species, as is the case holy thorn. The occurrence of weak odor may be due to an inadequate drying process, in which excessive temperatures were used during the process. When preparing teas it was possible to observe that only 23.1% of the

samples had a sweet aroma and 50% did not exhibit this type of odor. During the evaluation of the aroma of the herbal teas studied, it was observed that of the 25 species evaluated, only 5% exhibited an artificial plant odor.

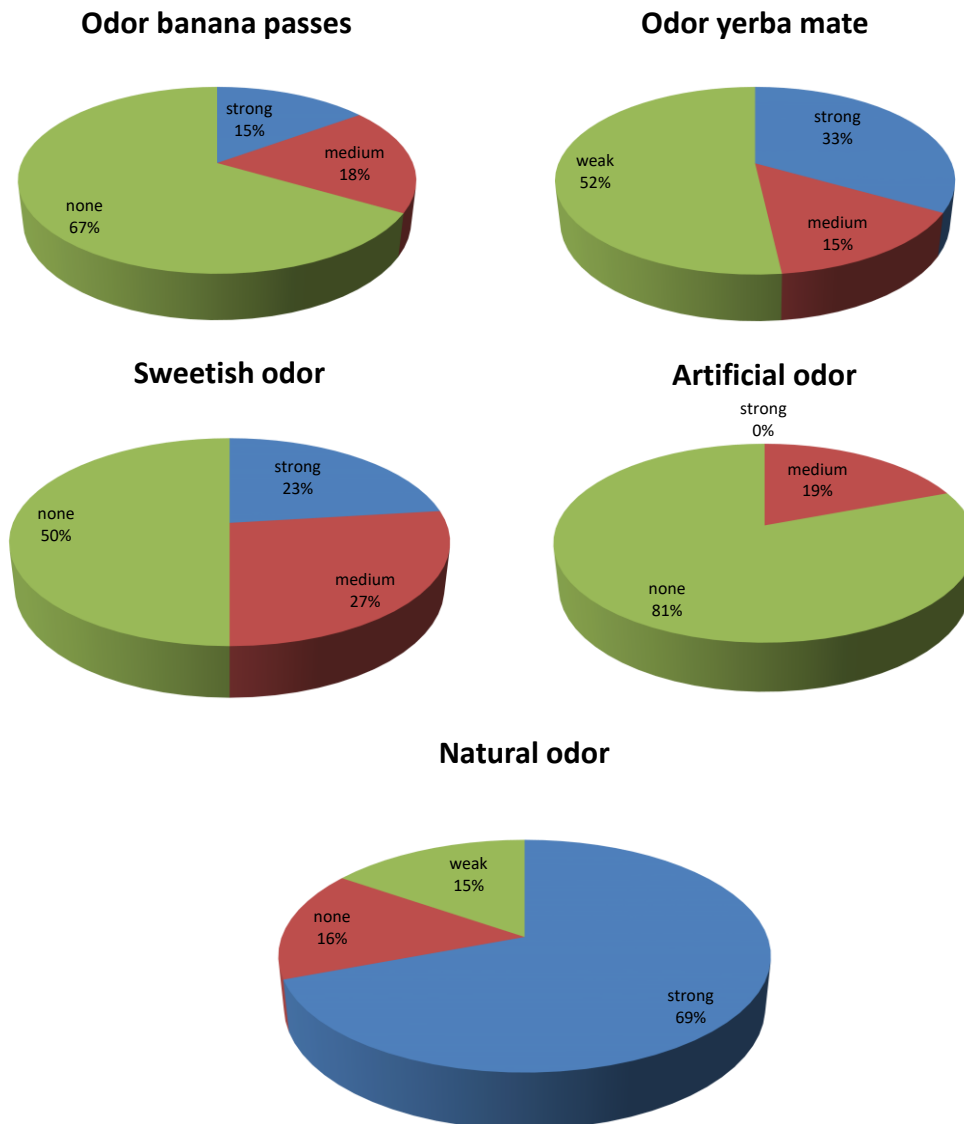


Fig. 5. Results of the aroma analysis of the samples.

All the samples observed were adequate for the color that characterizes the species, with no disagreement regarding the characteristics described in the current standard for this analysis. The classification of teas by color corresponds to different manufacturing processes and results in white, green, yellow, red, blue and black teas - 6 different colors. This classification refers to the colors of the leaves after the infusion. In most Western countries, the colors used for teas are white, green and black. Like any

other vegetable, tea leaves contain oxidizing enzymes, the molecules responsible for the color change in autumn. As soon as they are harvested, oxidation of pigments and tannin begins, and it is this phenomenon that determines the color of the tea. In the present study, most of the samples analyzed belong to the group of yellow teas.

Of the 25 samples evaluated, 57.7% had a strong caramel color, 38.46% a weak color and 4% an intermediate appearance to these two parameters. There was a significant difference ($p \leq 0.05$) between the samples for the caramelized shade of color. As for turbidity, most samples (81%) did not show any indication of this parameter (Fig. 6). As for the conservation aspect, although the packages do not contain instructions on how to preserve the samples and are transparent (to avoid exposure to light), the natural products were within the standards. All samples were sold dry, in the form of powder or in shells and regardless of the form of commercialization, and all showed a color similar to when they are fresh.

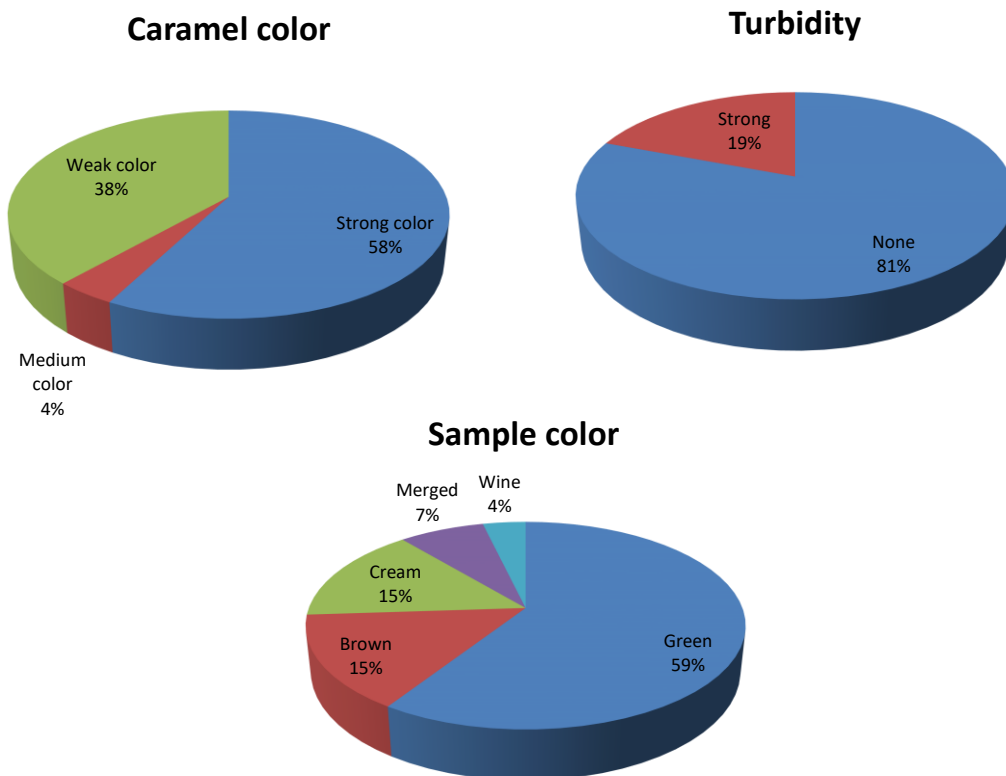


Fig. 6. Results of the analysis of the tea appearance of the samples.

4 CONCLUSION

It is noticed that many companies overlook the care with the labeling of their products, leaving important information missing for patients, which can lead to misuse of the product and consequent inefficiency. Despite the existence of laws that regulate this process, the market is still provided with examples that do not meet this requirement. Finally, this type of activity proves to be useful for monitoring the market and providing diagnoses of existing problems, a fact that encourages such data to be passed on to the health inspection bodies, charged with monitoring and regulating the sector.

The flavor evaluation performed agreed with the results of the Quantitative Descriptive Analysis, in relation to the six parameters considered. It was possible to realize that it is necessary to include some of the medicinal species analyzed here in the next editions of the Brazilian Pharmacopeia, to provide subsidies for quality control, aiming to ensure the safety of the products. After carrying out the taste analysis of the samples, in comparison to the pharmacopoeic parameters, it was found that the species already registered had corresponding characteristics.

The aroma analysis performed agreed with the results of the Quantitative Descriptive Analysis, in relation to the five parameters considered. With the present study it was possible to realize that it is necessary to include some of the medicinal species evaluated here in the next editions of the Brazilian Pharmacopoeia, to provide subsidies for quality control, aiming to ensure the safety of the products. After carrying out the aroma analysis of the samples, in comparison to the pharmacopoeic parameters, it was found that the species already registered had corresponding characteristics.

The color analysis carried out on the analyzed samples agreed with the results of the Quantitative Descriptive Analysis, in relation to the appearance, caramel color and turbidity characteristics characteristic of the evaluated species.

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