

## Analysis of some parameters of herbal products commercialized in Teresina-PI in accordance with Brazilian legislation

## Análise de alguns parâmetros de produtos de plantas comercializados em Teresina-PI de acordo com a legislação brasileira

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### RESUMO

Medicamentos fitoterápicos são aqueles obtidos exclusivamente de extratos de plantas, de acordo com a legislação brasileira. No entanto, muitos produtos à base de plantas são vendidos no mercado em desacordo com a Lei. O objetivo desse trabalho foi realizar um estudo exploratório dos produtos fitoterápicos comercializados em farmácias, supermercados e drogarias na cidade de Teresina, no Estado do Piauí, Nordeste do Brasil. Para a obtenção dos dados foram visitadas duas grandes redes de farmácias, dois supermercados e farmácias, totalizando 21 lojas. As informações foram descritas a partir dos produtos presentes nas prateleiras. Dados relativos à nomenclatura, forma farmacêutica, inscrição na bula de indicação/ contra indicação terapêutica e a designação “medicamento fitoterápico” foram avaliados. No total, 363 produtos fitoterápicos foram avaliados, desses 294 (81,0%) encontravam-se na forma farmacêutica sólida, 52 (14,3%) na líquida e 17 (4,7%) na semi-sólida. Considerando a nomenclatura na caixa do medicamento, 120 continham somente o nome científico, 25 somente o nome popular e 69 ambos os nomes. Ainda, menos da metade dos produtos avaliados (151) continham a designação “medicamento fitoterápico”. A avaliação das bulas demonstrou que 69 produtos apresentavam as indicações terapêuticas e que 79 apresentavam contra-indicação. É interessante destacar que a maioria dos produtos avaliados não se mostraram dentro das normas tanto na modalidade de indicações e contra-indicações, quanto na designação “medicamento fitoterápico”.

**Palavras-Chave: Medicamentos fitoterápicos; Produtos fitoterápicos.**

### ABSTRACT

Phyto-therapeutic medicines are products obtained exclusive with plant extract, accordance with Brazilian legislation. However, many phyto-based products are sold in the market in disagreement with the law. The aim of this work was to conduct an exploratory study of herbal products commercialized in the city of Teresina, Piauí State, Northeast of Brazil. Data were obtained from those over the counter products from stores of a great drugstores chain, two supermarkets and drugstores, comprising 21 shops. The observed parameters were relative to pharmaceutical formulation and those registered in the labeling and package leaflet, including “phyto-therapeutic medicine” designation, absence or presence of therapeutic indications and contraindications. A total of 363 herbal products were recorded, among then 81.0% were sold in solid formulation, 14.3% in liquid and 4.7% in the semi-solid. In relation to the nomenclature in the package label, 120 products showed only the scientific name, 25 only the popular name and 69 both names. Besides, less than half of the products showed the designation “phyto-therapeutic medicine”. Considering those phyto-therapeutic medicines with package leaflet, 69 presented therapeutic indication and 79 showed contraindications. It is interesting to note that the most of phyto-therapeutic medicines available in the Teresina market are in disagreement with the Brazilian legislation regarding to therapeutic indications and contraindications as well as the phyto-therapeutic medicine designation.

**Keywords: Phytotherapeutic drugs; Herbal products.**

## INTRODUCTION

The therapeutic use of medicinal plants is recorded since antiquity by great civilizations as China, India, Egypt and Greece. The medicinal use of *Artemisia annua* L. for the treatment of malaria was first described in the "52 prescriptions" that was written during the Mawangdui Han Dynasty who reined in China from 206 BC – 220 AD. (CUNHA, 2003; ALVES, 2013).

The major sources of biodiversity are tropical forests located in developing countries, like Brazil, that accounts for about one third of the world's Flora (CARNAVAL, 2009; KLEIN, 2010).

Phyto-therapeutic medicines are products obtained exclusive with plant extract accordance with Brazilian National Health Surveillance (ANVISA). The knowledge of the effectiveness and risks of their use, as well as the reproducibility and consistency of its quality characterize the phyto-therapeutic medicines. It is very important to note that it is not considered phyto-therapeutic medicines those that in its composition includes isolated active compounds or the combination of isolated compounds with plant extracts (NETTO, 2006; ANVISA 2010).

The use of medicinal plants is expanding and constitutes a promising market worldwide, representing approximately \$ 22 billion per year. Therefore, this market has been increasingly attracting the interest of developed countries. For example herbal products handled about \$ 6.5 billion in 2000 in the USA and \$ 8.5 billion in Europe. Germany is the world's largest market for herbal medicines (NASCIMENTO, 2005).

Currently, there is an increase in the use of herbal medicines by the Brazilian population. Some factors that could explain the increased rate of use is the scientific advances in the herbal research, that are allowing the development of safe and effective phyto-therapeutic medicines, as well as a strong tendency to search less aggressive therapies aimed at primary health care (RIBEIRO, 2005).

Another interesting point that should to be mentioned is the marketing about herbal medicine. Many companies that commercialize herbal products in Brazil offer then to prevent or cure every kind of disease. Besides, the offer of herbal products is not restricted to pharmacies or drugstores in Brazil. These products can also be found in supermarkets, in open-air markets or herbalists. (NASCIMENTO, 2005).

This paper aimed to conduct an exploratory study of herbal products commercialized in the city of Teresina, Piauí State, Northeast of Brazil.

## MATERIALS AND METHODS

The research was conducted in June and July 2012, in Downtown, North, South and Southeast of city of Teresina, Piauí State, Brazil. Data were collected from the package label and package leaflet of herbal products sold in stores of a great drugstores chain, two supermarkets and drugstores, comprising 21 shops. Information data were collected from those over the counter products.

The observed parameters for each product were: (a) plant name (popular and scientific); (b) pharmaceutical formulation (solid, liquid, semi-solid); (c) phyto-therapeutic medicine designation; (d) absence or presence of therapeutic indications; (e) contraindications.

Each product was considered as one unit and the repeated information were not recorded. The overall score of the products was made with the brand name of the product. Thus, if two products with different brands names obtained with the same plant, then the plant count is taken as one and the product as two.

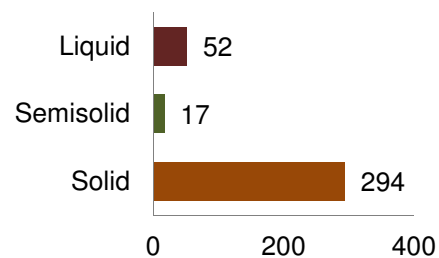
It was not possible quantify the exactly number of the plants since the same popular name can refer to different plant species.

Once the intention was to verify the quality of the information, the plants scientific names were transcript identical to the written in the labels, even that containing errors of spelling or nomenclature.

## RESULTS AND DISCUSSION

It was possible to register 363 herbal products in the investigated stores (21). Among then 294 (81.0%) were sold in solid pharmaceutical formulation, 52 (14.3%) were in liquid formulation and 17 (4.7%) were in the semi-solid formulation (Figure 1).

**Figure 1 – Pharmaceutical formulations**

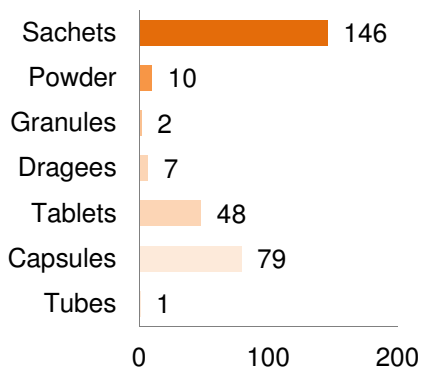


It can be observed in the figure 2 that the main available solid formulation regard to sachets (49.6%), followed by capsules (26.9%) and then pills (16.3%). It was also registered dragees,

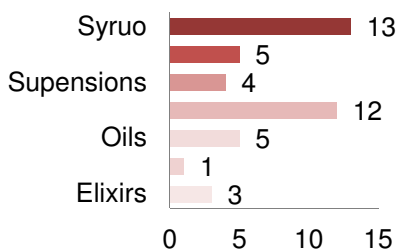
granules, powders and tubes. The large percentage of the dosage form in sachet is due in all the visited supermarkets this was the only solid dosage form found.

Figure 3 shows that the products in liquid form are mainly presented in the syrups (25.0%), followed by solutions (24.0%). Drop-shaped were registered with lower percentages (1.9%).

**Figure 2 – Solid pharmaceutical formulation**

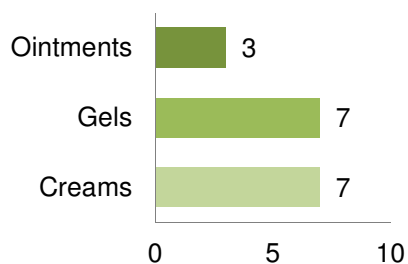


**Figure 3 – Liquid pharmaceutical formulation**



It is demonstrated in figure 4 that products in semi-solid form are mainly presented in gels and creams (41.2%), and in minor amounts ointments (17.6%).

**Figure 4 – Semi-solid pharmaceutical formulation**



Plants with their scientific name, as registered in the label, are listed in table 1.

The Brazilian regulation for phyto-therapeutic medicines (ANVISA, 2010) determines

that all products must have the appropriate botanical scientific nomenclature (family, genus, species, variety and taxonomist). It was possible to register 52 irregularities and 65 regularities (detached lines) regarding the botanical nomenclature (Table 1). Besides, 120 products showed only the scientific name, 25 only the popular name and 69 both names (Tables 2 and 3). Considering the 69 citations, 21 of them have the correct scientific name, including botany family.

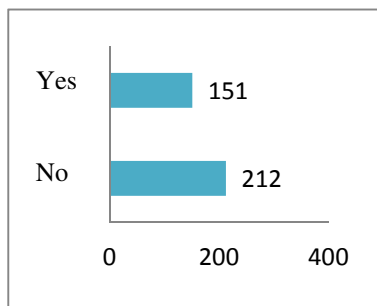
Since a popular name can refer to many different plant species, those with only popular names represent a serious risk to the population's health. For instance, in Brazil, "capimsanto", "capimlimão", "capimcidreira" and "capimcidirão" are common designation for *Cymbopogon citratus* Stapf. And *Melissa officinalis* L. The same problem can occur with "maracujá" that is a popular name for different species of the genus *Passiflora*. (*P. alata*, *P. edulis*, *P. incarnata*) (NASCIMENTO, 2004). By this mean it is very important that a phyto-therapeutic medicine has the correct botanical designation, in accordance with Brazilian National Health Surveillance (ANVISA, 2010).

Brazilian regulation for phyto-therapeutic medicines (ANVISA, 2008a) allowed the register of 34 different plants that have safety and efficacy of use. It facilitates the register of phyto-therapeutic medicines produce with these 34 plants. This study showed more than 34 plant products that are commercialized in Teresina. So, for example, phyto-therapeutic medicines containing *Caesalpinia ferrea* Martius, *Cocos nucifera* L. and *Myroxylon balsamum* (L.) Harms. must be registered at ANVISA including production reports with, among other data, those of safety and efficacy of use (also pre-clinic and clinical toxicological reports) (MOREIRA, 2013). If the product fills the Brazilian Health Ministry (BMH) demand it can be registered at this Ministry. Otherwise this kind of product cannot be registered at BMH. This is a huge problem in Brazil. Since the products do not have requirements of the BMH they can be registered at the Ministry of Agriculture as a food supplement (as the sachets that are commercialized in the supermarkets in Teresina). In this case they cannot be classified as phyto-therapeutic medicine (MOREIRA, 2013). By this reason many plant-products are commercialized without the BMH authorization and cannot receive phyto-therapeutic medicine designation. Regarding to this subject, less than half of the products (151) commercialized in Teresina showed the designation **phyto-therapeutic medicine** (41.6%) (Figure 5). In accordance with BMH this designation must be used, otherwise the herbal

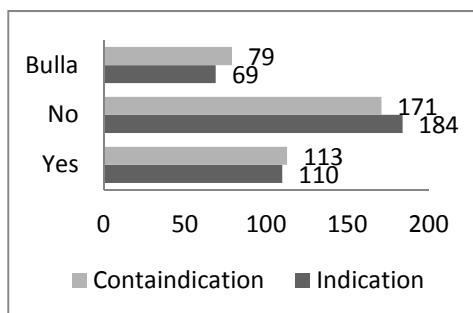
product cannot be considered as phyto-therapeutic medicine. It can just be designed as herbal product and cannot be registered in the BMH (ANVISA, 2008b; ANVISA, 2009). So, 212 (58.4%) herbal products cannot be named as **phyto-therapeutic medicine** and by this mean cannot be legally used for treatment, prevent or cure any disease.

Figure 6 shows that the greatest number of products contains no indications and contraindications. These specifications are law requirements (ANVISA, 2008b; ANVISA, 2009). The lack of information for indications and contraindications may lead to misuse of the herbal product and risk to patient's health. This problem is not restricted to the city of Teresina. Leite and Branco (2010) analyzed 12 packages leaflet of *Ginkgo bilobaphyto-therapeutic* medicine from different parts of Brazil. Their results showed that all packages leaflet were in disagreement with ANVISA legislation.

**Figure 5 – Phyto-therapeutic medicine designation**



**Figure 6 – Indications and contraindications**



## CONCLUSIONS

Our research found that herbal medicines commercialized in the city of Teresina are greater in solid pharmaceutical formulation (81%) and most of them are in disagreement with Brazilian regulation (ANVISA) for phyto-therapeutic medicines, regarding plant name, phyto-therapeutic medicine designation, indications and contraindications. It is very important that the local sanitary vigilance supervise the market in order to

notify companies that produce those herbal products in disagreement with the legislation, since these products can bring serious damage to the population's health.

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**Table 1 - Products with scientific plant name as registered in the label**

|  |                                     |                                      |
|--|-------------------------------------|--------------------------------------|
| <i>Aconitum napellus</i> , L.          | <i>Echinodorus grandifloru</i>      | <i>Pérsia gratissima</i>             |
| <i>Aesculus hippocastanum</i>          | <i>Erythrina mulungu</i> Martius    | <i>Peumus boldus</i> Molina.         |
| <i>Aesculus hippocastanum</i> L.       | <i>Eucaliptus globulos</i>          | <i>Phyllanthus niruri</i> Linné.     |
| <i>Allium sativum</i> L.               | <i>Foeniculum vulgare</i> , Mill.   | <i>Physalis angulata</i> , Linné.    |
| <i>Ananas comosus</i>                  | <i>Ginkgo biloba</i> L.             | <i>Pimpinella anisum</i>             |
| <i>Arnica montana</i>                  | <i>Glycine max</i>                  | <i>Piptadenia colubrina</i>          |
| <i>Arnica montana</i> , L.             | <i>Glycyrrhiza glabra</i> L.        | <i>Plantago ovata</i> Forsk          |
| <i>Atropa beladona</i> , L.            | <i>Hamamelis virginiana</i> L.      | <i>Plumeria lancifolia</i> , Muller. |
| <i>Baccharis genistelloides</i>        | <i>Hedera helix</i>                 | <i>Polygala senega</i>               |
| <i>Baccharis genistelloides</i> ,L.    | <i>Hibiscus sabdariffa</i> L.       | <i>Polygala senega</i> L.            |
| <i>Borago officinalis</i>              | <i>Hyoscyamus niger</i> , L.        | <i>Polypodium vacciniifolium</i>     |
| <i>Bowdichia major</i> Mart, L.        | <i>Hypericum perforatum</i>         | <i>Prunus serotina</i> , Ehrh.       |
| <i>Caesalpineia ferrea</i> , Martius.  | <i>Ilex paraguariensis</i>          | <i>Pyrus malus</i>                   |
| <i>Camelia sinensis</i>                | <i>Lantana camara</i> , L.          | <i>Rhamnus purshiana</i> D.C.        |
| <i>Camellia sinensis</i> (L.) Kuntze.  | <i>Linum usitatissimum</i> L.       | <i>Rheum palmatum</i>                |
| <i>Canduous marianus</i>               | <i>Linum usitatissimum</i>          | <i>Rhodiola rosea</i> L.             |
| <i>Carapa guianensis</i>               | <i>Malpighia glabra</i> , L.        | <i>Ribes nigrum</i>                  |
| <i>Caryophyllus aromaticus</i> L.      | <i>Malva sylvestris</i> , L.        | <i>Roripa nasturtium</i> , Linné.    |
| <i>Cassia Angustifolia</i>             | <i>Matricaria chamomilla</i> , L.   | <i>Rosa canina</i> , L.              |
| <i>Cassia angustifolia</i> Vahl        | <i>Matricaria recutita</i>          | <i>Rosmarinus officinalis</i> Linné. |
| <i>Cassia fistula</i>                  | <i>Matricaria recutita</i> , L.     | <i>Rubus ideaus</i> L.               |
| <i>Cassia fistula</i> L.               | <i>Maytenus ilicifolia</i>          | <i>Salix alba</i>                    |
| <i>Cassia senna</i> L.                 | <i>Melilotus officinalis</i>        | <i>Salix alba</i> L.                 |
| <i>Centella Asiática</i>               | <i>Mentha arvensis</i> L.           | <i>Salvia hispanica</i> L.           |
| <i>Cereus peruvianus</i> (L.), Miller. | <i>Mentha crisper</i>               | <i>Sambucus nigra</i> L.             |
| <i>Chicorium intybus</i> , L.          | <i>Mentha piperita</i> L.           | <i>Schinus terebinthifolius</i>      |
| <i>Chondodendron platyphyllum</i>      | <i>Mikania glomerata</i>            | <i>Schinus terebinthifolius</i>      |
|  |                                     | Raddi.                               |
| <i>Cimicifuga racemosa</i>             | <i>Mikania glomerata</i> , Sprengel | <i>Senna alexandrina</i>             |
| <i>Cinchona calisaya</i>               | <i>Mikania hirsutissima</i> DC.     | <i>Senna alexandrina</i> Miller.     |
| <i>Cinnamomum zeylanicum</i>           | <i>Morinda citrifolia</i>           | <i>Silybum marianum</i>              |
| <i>Citrus aurantium</i> , L.           | <i>Myrospermum erytroxilon</i>      | <i>Solanum melongena</i>             |
| <i>Citrus limmonia</i> , Osbeck.       | <i>Myroxylon balsamum</i> (L.)      | <i>Stevia rebaundiana</i> , Bert.    |
|  | Harms                               |                                      |
| <i>Citrus limonium</i> , Risso.        | <i>Ocotea pretiosa</i> Mez          | <i>Symphytum officinale</i> L.       |
| <i>Citrus sinensis</i> , L.            | <i>Oenothera biennis</i> L.         | <i>Tamarindus indica</i> L.          |
| <i>Cocos nucifera</i> L.               | <i>Panax ginseng</i>                | <i>Trifolium pratense</i> L.         |
| <i>Crataegus oxyacantha</i>            | <i>Passiflora alata</i>             | <i>Uncaria tomentosa</i>             |
| <i>Crataegus oxyacantha</i> L.         | <i>Passiflora incarnata</i>         | <i>Vaccinium myrtillus</i> L.        |
| <i>Cymbopogan citratus</i> (D.C.)      | <i>Passiflora incarnata</i> L.      | <i>Valeriana officinalis</i> L.      |
| Stapf                                  |                                     |                                      |
| <i>Cymbopogon citratus</i>             | <i>Paullinia cupana</i> Kunth,      | <i>Vitis vinifera</i>                |
| <i>Cynara scolymus</i> , L.            | <i>Peltodon radicans</i>            | <i>Zingiber officinale</i>           |

Legend: Detached lines indicate regular scientific botanical nomenclature.

**Table 2- Products with only the popular plant name as registered in the package label:**

|                   |                           |
|-------------------|---------------------------|
| Açaí              | Chá verde                 |
| Alho              | Coco                      |
| Ameixa            | Colágeno e algas marinhas |
| Amendoas doce     | Guaraná                   |
| Andiroba          | Linhaça                   |
| Arnica            | Maça                      |
| Berinjela         | Maçã                      |
| Cajú              | Maracujá                  |
| Cânfora           | Prímula                   |
| Cártamo           | Rosa canina               |
| Castanha da Índia | Soja                      |
| Centelhaasiática  | Unha-de-gato              |

**Table 3- Products with popular and scientific plant name as registered in the package label:**

|   |  |
|---|--|
| Acônito - <i>conitumnapellus</i> L.               | Estévia - <i>Steviarebaundiana</i>               |
| Agoniada - <i>Plumerialancifolia</i>              | Eucalipto - <i>Eucaliptusglobulos</i>            |
| Agrião - <i>RoripaNasturtium</i> , L.             | Framboesa - <i>Rubusideaus</i> L.                |
| Alcachofra - <i>Cynarascolymus</i> , L.           | Gengibre - <i>Zingiberofficinale</i>             |
| Alho - <i>Alliumsativum</i> L.                    | Groselha negra - <i>Ribesnigrum</i>              |
| Andiroba - <i>Carapaguaianensis</i>               | Guaco - <i>Mikaniaglomerata</i>                  |
| Aroeira - <i>Schinusterebinthifolius</i>          | Guaraná - <i>Paullinia cupana</i>                |
| Aveia- <i>Avena sativa</i>                        | Hamamélis - <i>Hamamelis virginiana</i> , L.     |
| Bálsamo - <i>Myroxylonbalsamum</i> L.             | Hibisco - <i>Hibiscussabdariffa</i>              |
| Boldo - <i>Peumusboldus</i>                       | Hortelã - <i>Menthapiperita</i> , L.             |
| Cambará - <i>Lantanacamara</i> , L.               | Ipecacuanha - <i>Cephaelis ipecacuanha</i>       |
| Camomila - <i>MatricariaChamomilla</i> , L.       | Jucá - <i>Caesalpineafferrea</i>                 |
| Canela - <i>Cinhamomumzeylanicum</i>              | Laranja - <i>Citrussinensis</i> , L.             |
| Capim cidreira - <i>Cymbopogoncitratus</i>        | Limão - <i>Citruslimonium</i>                    |
| Carqueja - <i>Baccharistrimera</i>                | Linhaçadourada - <i>Linumusitatissimum</i> l, L. |
| Cáscara sagrada - <i>Rhamnuspurshiana</i>         | Maça - <i>Pyrusmolus</i> , L.                    |
| Castanha da Índia - <i>Aesculushippocastanum</i>  | Malva - <i>Malva sylvestris</i> , L.             |
| Catuaba - <i>Trichiliacatigua</i> Juss            | Maracujá - <i>Passiflora alata</i>               |
| Guaraná - <i>Paullinia cupana</i>                 | Menta - <i>Menthapiperita</i>                    |
| Catuaba- <i>Trichilacatigua</i>                   | Mistilo - <i>Vacciniummyrtillus</i>              |
| Cereja - <i>Prunusserotina</i>                    | Muirapapuama - <i>Ptychopetalumolacoides</i>     |
| Chá verde - <i>Camelliasinensis</i>               | Muirapuama - <i>Ptychopetalumolacoides</i>       |
| Chapeu de couro - <i>Echinonodorusgradiflorus</i> | Noni - <i>MorindaCitrifolia</i>                  |
| Chicória - <i>Cichoriumintybus</i> L.             | Óleo-vermelho - <i>MyrospermumErytroxilon</i>    |
| Cidreira- <i>Cymbopogocitratus</i> (DC) Staph     | Pitanga - <i>Eugenia uniflora</i> L.             |
| Cipó cabeludo- <i>Mikaniahirsutissima</i>         | Polígola - <i>Polygalasenega</i> L.              |
| Cipó cravo - <i>Tynanthusfasciculatus</i>         | Psyllium - <i>Plantagoovata</i>                  |
| Coco - <i>Cocos nucifera</i> L.                   | Rosa silvestre - <i>Rosa canina</i> , L.         |
| Copaíba - <i>Copaíferareticulata</i>              | Ruibarbo - <i>Rheumpalmatum</i>                  |
| Erva-doce - <i>Foeniculumvalgare</i>              | Sassafrás - <i>Ocoteapretiosa</i>                |
| Erva-doce - <i>Pimpinellaanisum</i>               | Silimarina - <i>Silybummarianum</i>              |
| Erva-doce - <i>Pimpinellaanisum</i> , L.          | Sucupira - <i>Bowdichiamajor</i>                 |
| Erva-silvina - <i>Polypodiumvaccinifolium</i>     | Tamarindo - <i>Tamarindusindica</i>              |
| Espinheira santa - <i>Maytenusilicifolia</i>      | Trigo - <i>Triticumsativum</i>                   |
|   | Unha de gato - <i>Uncariatomentosa</i>           |