

# Quality control of aromatic drugs reported in *European Pharmacopoeia* 3rd edition<sup>☆</sup>

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## Abstract

The apparent current explosion of interest and commercial activity in the area of herbal products should be followed by accurate quality control. In this work, the authors carried out the specific quality assays of all the aromatic drugs reported in *European Pharmacopoeia*. For each drug, several samples of different brands were bought in pharmacies, herbalist's shops, or supermarkets. The worst results were obtained in the assay for the essential oil content and this is very negative as the medicinal activities of these drugs are ascribed to their essential oil content. The samples of different brands yielded very different results from a qualitative point of view. In most cases, the analyzed samples were very far from the acceptable qualitative standards that they definitely lacked any health benefits. © 2001 Éditions scientifiques et médicales Elsevier SAS

**Keywords:** Quality control; Aromatic drugs; *European Pharmacopoeia*

## 1. Introduction

Over the last decade, the consumption of medicinal plants has almost doubled in Western Europe. This trend is certain to continue in view of the widespread interest in 'green' medicine. Consequently, the number of official drugs of plant origin reported in the official Pharmacopoeias of many countries has noticeably increased, such as the commerce in plant drugs.

Recently, there has been a renewed interest in an ancient and particular branch of natural medicine, the 'aromatherapy', which uses volatile oil drugs and their essential oils, in both therapeutic and cosmetic fields. In this particular therapy, essential oils are absorbed by the skin or by inhalation.

Following this success, the last edition of *European Pharmacopoeia* (EP) [1] increased the number of aromatic drugs with respect to the previous edition. Today, 14 monographs concerning essential plant drugs are reported: *Absinthii herba*, *Anisi fructus*, *Anisi stellati fructus*, *Boldi folium*, *Carvi fructus*, *Caryophylli flos*,

*Chamomillae romanae flos*, *Cinnamomi cortex*, *Foeniculi amari fructus*, *Foeniculi dulcis fructus*, *Matricariae flos*, *Menthae piperitae folium*, *Salviae officinalis folium* and *Thymi herba*.

International regulations have established that all manufacturers are required to complete a thorough technical appraisal of their products and to provide evidence on the quality, safety and efficacy of their drugs.

The evaluation of a crude drug, which is available on the commercial market is obviously of considerable importance. This operation involves the identification of the material and the determination of its quality. The quality of a crude drug is established by reference to the description of it given in the Pharmacopoeia of the country concerned; in fact, every Pharmacopoeia provides monographs of quality standards (numerical values) for all herbs commonly used in the preparation of botanical drugs.

In this work, we carried out the quality assays reported in each monograph of all essential plant drugs of EP [1]; the tests were performed on commercial samples bought in the market. The aim of this work was the control of quality of the essential oil drugs of commerce and a comparison among the results ob-

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tained and the general quality criteria for aromatic drugs requested by EP [1].

## 2. Material and methods

The analyses were carried out on the 14 essential oil drugs reported in EP [1]. For each drug, several samples coming from different manufacturers, represented by capital letters in the tables, were bought in pharmacies, herbalist's shops, or supermarkets.

On each sample, all the quality tests reported in EP were performed [1], where the exact conditions for carrying out such tests are described in individual monographs. The EP [1] sets quantitative standards for the majority of the essential oil herbs in terms of acceptable limits for the determination of essential oil, foreign matter, total ash, ash insoluble in hydrochloric acid, and determination of water content.

## 3. Results

In this section, the analyzed essential oil drugs are treated one by one and in alphabetical order.

In the tables, the relative results obtained are reported as mean percentage  $\pm$  standard deviation. The values are expressed as means of at least three determinations.

- *Absinthii herba* (Table 1): For this essential oil drug, EP reports the following tests: stems thicker than 5 mm (S), other foreign matter (OFM), bitter value (BV), total ash (TA), ash insoluble in hydrochloric acid (AH), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).
- *Anisi fructus* (Table 2): For this essential oil drug, EP reports the following tests: foreign matter (FM), total ash (TA), ash insoluble in hydrochloric acid (AH), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).
- *Anisi stellati fructus* (Table 3): For this essential oil drug, EP reports the following tests: foreign matter (FM), total ash (TA), water content (WC), essential oil content (EO), and acceptable limit of EP (EP).

Table 1  
*Absinthii herba*<sup>a</sup>

Brands	S <sup>a</sup>	OFM <sup>b</sup>	BV <sup>c</sup>	TA <sup>d</sup>	AH <sup>e</sup>	WC <sup>f</sup>	EO <sup>g</sup>
F			22 400	6.68 $\pm$ 0.41	0.52 $\pm$ 0.02	5.31 $\pm$ 0.40	0.15 $\pm$ 0.01
G	0.90 $\pm$ 0.20	0.34 $\pm$ 0.43	18 640	4.91 $\pm$ 0.10	0.49 $\pm$ 0.03	2.58 $\pm$ 0.15	0.13 $\pm$ 0.09
H	1.10 $\pm$ 0.18	0.44 $\pm$ 0.20	14 000	7.00 $\pm$ 0.64	0.63 $\pm$ 0.02	7.14 $\pm$ 0.60	0.26 $\pm$ 0.06
EP <sup>h</sup>	not more than 5.0%	not more than 2.0%	not less 10 000	not more than 12.0%	not more than 1.0%	not more than 10.0%	not less than 0.2%

<sup>a</sup> S, stems thicker than 5 mm.

<sup>b</sup> OFM, other foreign matter.

<sup>c</sup> BV, bitter value.

<sup>d</sup> TA, total ash.

<sup>e</sup> AH, ash insoluble in hydrochloric acid.

<sup>f</sup> WC, water content.

<sup>g</sup> EO, essential oil content.

<sup>h</sup> EP, acceptable limit reported in EP.

Table 2  
*Anisi fructus*<sup>a</sup>

Brands	FM <sup>a</sup>	TA <sup>b</sup>	AH <sup>c</sup>	WC <sup>d</sup>	EO <sup>e</sup>
A	3.10 $\pm$ 0.85	5.74 $\pm$ 0.03	0.33 $\pm$ 0.04	7.12 $\pm$ 0.15	1.70 $\pm$ 0.06
B	1.96 $\pm$ 0.04	5.78 $\pm$ 0.03	0.16 $\pm$ 0.01	5.43 $\pm$ 0.10	2.07 $\pm$ 0.11
C	3.50 $\pm$ 0.76	5.85 $\pm$ 0.15	0.32 $\pm$ 0.03	4.99 $\pm$ 0.12	2.00 $\pm$ 0.03
D	1.46 $\pm$ 1.01	6.77 $\pm$ 0.12	0.40 $\pm$ 0.02	5.82 $\pm$ 0.09	2.21 $\pm$ 0.02
E	3.30 $\pm$ 0.47	7.66 $\pm$ 0.01	0.75 $\pm$ 0.07	7.42 $\pm$ 0.12	1.93 $\pm$ 0.20
EP <sup>f</sup>	not more than 2.0%	not more than 12.0%	not more than 2.5%	not more than 7.0%	not less than 2.0%

<sup>a</sup> FM, foreign matter.

<sup>b</sup> TA, total ash.

<sup>c</sup> AH, ash insoluble in hydrochloric acid.

<sup>d</sup> WC, water content.

<sup>e</sup> EO, essential oil content.

<sup>f</sup> EP, acceptable limit reported in EP.

Table 3  
*Anisi stellati fructus*<sup>a</sup>

Brands	FM <sup>a</sup>	TA <sup>b</sup>	WC <sup>c</sup>	EO <sup>d</sup>
B	1.65 ± 0.14	3.05 ± 0.14	7.43 ± 0.10	4.67 ± 0.01
D	1.06 ± 1.59	2.59 ± 0.09	8.22 ± 0.09	6.46 ± 0.02
F	1.71 ± 0.86	3.46 ± 0.27	12.86 ± 0.3	4.13 ± 0.01
G	0.22 ± 0.17	2.4 ± 0.01	6.14 ± 0.20	7.73 ± 0.01
EP <sup>e</sup>	not more than 2.0%	not more than 4.0%	not more than 10.0%	not less than 7.0%

<sup>a</sup> FM, foreign matter.

<sup>b</sup> TA, total ash.

<sup>c</sup> WC, water content.

<sup>d</sup> EO, essential oil content.

<sup>e</sup> EP, acceptable limit of EP.

Table 4  
*Boldi folium*<sup>a</sup>

Brands	LS <sup>a</sup>	OFM <sup>b</sup>	TA <sup>c</sup>	WC <sup>d</sup>	EO <sup>e</sup>	A <sup>f</sup>
B	1.14 ± 0.10	0.68 ± 0.25	13.3 ± 0.09	7.71 ± 0.08	2.00 ± 0.06	0.16 ± 0.01
C	5.04 ± 0.20	3.87 ± 0.14	11.0 ± 0.09	6.43 ± 0.05	2.10 ± 0.17	0.21 ± 0.02
D	4.90 ± 0.30	5.28 ± 0.12	12.5 ± 0.10	8.59 ± 0.09	1.17 ± 0.15	0.23 ± 0.02
H	1.25 ± 0.09	0.69 ± 0.08	12.3 ± 0.24	8.12 ± 0.08	1.67 ± 0.15	0.19 ± 0.03
EP <sup>g</sup>	not more than 4.0%	not more than 2.0%	not more than 13.0%	not more than 10.0%	not more than 1.50%	not less than 0.1%

<sup>a</sup> LS, lignified stems.

<sup>b</sup> OFM, other foreign matter.

<sup>c</sup> TA, total ash.

<sup>d</sup> WC, water content.

<sup>e</sup> EO, essential oil content. EP reports: 'not more than 2.0% for whole leaves and not more than 1.50% for broken leaves'. All samples analyzed in this work were constituted by broken leaves.

<sup>f</sup> A, alkaloids.

<sup>g</sup> EP, acceptable limit reported in EP.

Table 5  
*Carvi fructus*<sup>a</sup>

Brands	FM <sup>a</sup>	TA <sup>b</sup>	WC <sup>c</sup>	EO <sup>d</sup>
B	0.52 ± 0.07	5.16 ± 0.04	7.47 ± 0.08	3.97 ± 0.07
D	0.40 ± 0.03	5.28 ± 0.07	3.49 ± 0.09	1.93 ± 0.09
G	0.18 ± 0.04	4.85 ± 0.05	8.29 ± 0.02	2.30 ± 0.00
H	0.05 ± 0.02	5.66 ± 0.01	7.14 ± 0.10	3.60 ± 0.08
EP <sup>e</sup>	not more than 2.0%	not more than 7.0%	not more than 10.0%	not less than 3.0%

<sup>a</sup> FM, foreign matter.

<sup>b</sup> TA, total ash.

<sup>c</sup> WC, water content.

<sup>d</sup> EO, essential oil content.

<sup>e</sup> EP, acceptable limit reported in EP.

- *Boldi folium* (Table 4): For this essential oil drug, EP reports the following tests: lignified stems (LS), other foreign matter (OFM), total ash (TA), water content (WC), essential oil content (EO) (EP reports: 'not more than 2.0% for whole leaves and not more than 1.50% for broken leaves' and all the samples analyzed in this work were constituted by broken leaves), alkaloids (A), and acceptable limit reported in EP (EP).

- *Carvi fructus* (Table 5): For this essential oil drug, EP reports the following tests: foreign matter (FM), total ash (TA), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).
- *Caryophylli flos* (Table 6): For this essential oil drug, EP reports the following tests: peduncles, stems and fruits (PSF), altered flower-buds (AFB), other foreign matter (OFM), total ash (TA), essential oil

Table 6  
*Caryophylli flos*<sup>a</sup>

Brands	PSF <sup>a</sup>	AFB <sup>b</sup>	OFM <sup>c</sup>	TA <sup>d</sup>	EO <sup>e</sup>
A	1.77 ± 1.20	1.78 ± 1.55	2.94 ± 1.06	2.15 ± 0.03	8.63 ± 0.05
B	1.16 ± 0.40	9.48 ± 0.54	8.23 ± 2.21	3.44 ± 0.09	7.42 ± 0.03
F	1.42 ± 0.79	4.48 ± 3.17	1.90 ± 0.75	2.45 ± 0.09	8.00 ± 0.02
G	1.98 ± 1.47	2.79 ± 0.54	2.93 ± 1.35	2.30 ± 0.03	8.17 ± 0.05
EP <sup>f</sup>	not more than 4.0%	not more than 2.0%	not more than 0.5%	not more than 7.0%	not less than 15.0%

<sup>a</sup> PSF, peduncles, stems and fruits.

<sup>b</sup> AFB, altered flower-buds.

<sup>c</sup> OFM, other foreign matter.

<sup>d</sup> TA, total ash.

<sup>e</sup> EO, essential oil content.

<sup>f</sup> EP, acceptable limit reported in EP.

Table 7  
*Chamomillae romanae flos*<sup>a</sup>

Brands	AC <sup>a</sup>	CD <sup>b</sup>	TA <sup>c</sup>	WC <sup>d</sup>	EO <sup>e</sup>
B	0.69 ± 0.60	0.58 ± 0.31	5.50 ± 0.09	8.14 ± 0.09	0.88 ± 0.03
C	5.76 ± 5.68	0.59 ± 0.76	4.05 ± 0.07	8.97 ± 0.07	0.50 ± 0.05
D	2.23 ± 1.12	3.77 ± 0.98	3.66 ± 0.06	6.14 ± 0.09	0.80 ± 0.03
F		1.63 ± 0.30	3.82 ± 0.10	9.27 ± 0.10	0.77 ± 0.03
EP <sup>f</sup>	none	not more than 3.0%	not more than 8.0%	not more than 10.0%	not less than 0.7%

<sup>a</sup> AC, altered capitula.

<sup>b</sup> CD, capitula less than 8 mm in diameter.

<sup>c</sup> TA, total ash.

<sup>d</sup> WC, water content.

<sup>e</sup> EO, essential oil content.

<sup>f</sup> EP, acceptable limit reported in EP.

content (EO), and acceptable limit reported in EP (EP).

- *Chamomillae romanae flos* (Table 7): For this essential oil drug, EP reports the following tests: altered capitula (AC), capitula less than 8 mm in diameter (CD), total ash (TA), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).
- *Cinnamomi cortex* (Table 8): For this essential oil drug, EP reports the following tests: total ash (TA), essential oil content (EO), and acceptable limit reported in EP (EP).
- *Foeniculi amari fructus*: For this essential oil drug, EP reports the following tests: peduncles (P), other foreign matter (OFM), total ash (TA), water content (WC), essential oil content (EO) (it must contain not less than 60.0% of anethole, not less than 15% of fenchone, not more than 5.0% of estragole), and acceptable limit reported in EP (EP).

All the samples of fennel we bought in the market were defined by the sellers as 'sweet fennel' and, in effect, a GC/MS control [2] of their content in anethole and fenchone confirmed the sellers' assessment. Consequently, it was not possible to carry out a quality control of the drug 'bitter fennel'.

- *Foeniculi dulcis fructus* (Table 9): For this essential oil, drug, EP reports the following tests: peduncles (P), other foreign matter (OFM), total ash (TA), water content (WC), estragole (Es), fenchone (Fen), essential oil content (EO) (it must contain not less than 80% of anethole, not more than 10.0% of estragole, and not more than 7.5% of fenchone), and acceptable limit reported in EP (EP).
- *Matricariae flos* (Table 10): For this essential oil drug, EP reports the following tests: foreign matter (FM), broken flowers (BF) (the drug must pass through the sieve n° 710), total ash (TA), essential oil content (EO) and acceptable limit reported in EP (EP).

Table 8  
*Cinnamomi cortex*<sup>a</sup>

Brands	TA <sup>a</sup>	EO <sup>b</sup>
A	3.58 ± 0.07	0.58 ± 0.07
B	2.32 ± 0.09	0.53 ± 0.00
F	3.58 ± 0.06	0.75 ± 0.07
G	3.63 ± 0.23	0.84 ± 0.03
EP <sup>c</sup>	not more than 6.0%	not less than 1.2%

<sup>a</sup> TA, total ash.

<sup>b</sup> EO, essential oil content.

<sup>c</sup> EP, acceptable limit reported in EP.

Table 9  
*Foeniculi dulcis fructus*<sup>a</sup>

Brands	P <sup>a</sup>	OFM <sup>b</sup>	TA <sup>c</sup>	WC <sup>d</sup>	Es <sup>e</sup>	Fen <sup>f</sup>	EO <sup>g</sup>
D	1.12 ± 0.10	1.47 ± 0.15	7.34 ± 0.37	6.02 ± 0.05	0.43 ± 0.01	0.99 ± 0.09	1.52 ± 0.03
E	0.42 ± 0.12	0.60 ± 0.10	7.95 ± 0.38	7.79 ± 0.02	93.91 ± 0.20	2.44 ± 0.10	1.30 ± 0.17
G	0.95 ± 0.16	1.13 ± 0.30	8.14 ± 0.76	5.42 ± 0.09	5.42 ± 0.23	3.46 ± 0.12	1.68 ± 0.06
H	1.01 ± 0.31	1.33 ± 0.15	8.32 ± 0.49	6.67 ± 0.03	2.87 ± 0.09	1.37 ± 0.08	1.50 ± 0.00
L	1.59 ± 0.20	1.87 ± 0.30	7.19 ± 0.18	3.47 ± 0.10	83.79 ± 0.19	2.74 ± 0.09	1.23 ± 0.03
M	0.94 ± 0.09	0.83 ± 0.20	7.59 ± 0.41	7.02 ± 0.09	67.10 ± 0.20	6.93 ± 0.22	1.50 ± 0.10
EP <sup>h</sup>	not more than 1.5%	not more than 1.5%	not more than 10.0%	not more than 8.0%	not more than 10.0%	not more than 7.5%	not less than 4.0%

<sup>a</sup> P, peduncles.

<sup>b</sup> OFM, other foreign matter.

<sup>c</sup> TA, total ash.

<sup>d</sup> WC, water content.

<sup>e</sup> Es, estragole.

<sup>f</sup> Fen, fenchone.

<sup>g</sup> EO, essential oil content. It must contain not less than 80% of anethole, not more than 10.0% of estragole, not more than 7.5% of fenchone.

<sup>h</sup> EP, acceptable limit reported in EP.

Table 10  
*Matricariae flos*<sup>a</sup>

Brands	FM <sup>a</sup>	BF <sup>b</sup>	TA <sup>c</sup>	EO <sup>d</sup>
A		8.18 ± 0.99	7.65 ± 0.01	0.20 ± 0.03
B	0.68 ± 0.21	2.36 ± 0.05	7.94 ± 0.06	0.39 ± 0.05
C	0.10 ± 0.99	23.96 ± 1.20	7.76 ± 0.03	0.30 ± 0.05
F	0.10 ± 0.11	38.98 ± 1.25	8.12 ± 0.10	0.25 ± 0.02
EP <sup>e</sup>	not more than 2.0%	not more than 25.0%	not more than 13.0%	not less than 0.4%

<sup>a</sup> FM, foreign matter.

<sup>b</sup> BF, broken flowers. The drug must pass through the sieve n° 710.

<sup>c</sup> TA, total ash.

<sup>d</sup> EO, essential oil content.

<sup>e</sup> EP, acceptable limit reported in EP.

Table 11  
*Menthae piperitae folium*<sup>a</sup>

Brands	S <sup>a</sup>	OFM <sup>b</sup>	PML <sup>c</sup>	TA <sup>d</sup>	AH <sup>e</sup>	WC <sup>f</sup>	EO <sup>g</sup>
D	0.22 ± 0.20	0.73 ± 0.53		7.76 ± 0.10	1.27 ± 0.39	8.89 ± 0.10	0.58 ± 0.03
F				8.23 ± 0.09	0.56 ± 0.06	7.96 ± 0.09	1.45 ± 0.09
G	6.14 ± 0.98	7.63 ± 5.30	5.13 ± 2.20	19.12 ± 1.24	0.50 ± 0.04	5.86 ± 0.15	0.27 ± 0.03
H		0.07 ± 0.10		6.92 ± 0.08	0.39 ± 0.01	6.73 ± 0.09	1.28 ± 0.03
EP <sup>h</sup>	not more than 5.0%	not more than 2.0%	not more than 8.0%	not more than 15.0%	not more than 1.5%	not more than 11.0%	not less than 1.2%

<sup>a</sup> S, stems with diameter not longer than 1.5 mm.

<sup>b</sup> OFM, other foreign matter.

<sup>c</sup> PML, leaves with reddish brown sporangia of *Puccinia menthae*.

<sup>d</sup> TA, total ash.

<sup>e</sup> AH, ash insoluble in hydrochloric acid.

<sup>f</sup> WC, water content.

<sup>g</sup> EO, essential oil content.

<sup>h</sup> EP, acceptable limit reported in EP.

- *Menthae piperitae folium* (Table 11): For this essential oil drug, EP reports the following tests: stems with diameter not longer than 1.5 mm (S), other foreign matter (OFM), leaves with reddish brown

sporangia of *Puccinia menthae* (PML), total ash (TA), ash insoluble in hydrochloric acid (AH), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).

- *Salviae officinalis folium* (Table 12): For this essential oil drug, EP reports the following tests: stems (S), other foreign matter (OFM), total ash (TA), water content (WC), essential oil content (EO) (EP reports: 'not less than 1.5% for whole leaves and not less than 1.0% for broken leaves' and all the analyzed samples were constituted by broken leaves), and acceptable limit reported in EP (EP).
- *Thymi herba* (Table 13): For this essential oil drug, EP reports the following tests: peduncles with diameter 1 mm and not longer than 15 mm (S), total ash (TA), ash insoluble in hydrochloric acid (AH), water content (WC), essential oil content (EO), and acceptable limit reported in EP (EP).

#### 4. Discussion

The publication of the results of quality studies on present-day botanical products has been severely limited by fear of litigation. The limited number of studies that have appeared in the literature emanate principally from large organizations devoted to consumer interests [3] and from government agencies [4]. A few of these

studies, which originated in university laboratories, demonstrated that different brands of herbs varied greatly in quality and, consequently, in potency [5].

From the point of view of essential oil drugs, this work demonstrated that:

- several commercial samples are so far from the acceptable qualitative standards that they definitely lack any health benefits;
- aromatic drugs from different brands are very different from a qualitative point of view.

In many cases, the analyzed samples did not agree with the acceptable values required by EP [1], especially for the foreign matter and above all, for the essential oil content. In fact, not even one drug presented all samples with acceptable essential oil content. The worst drugs we analyzed were *Caryophylli flos*, *Cinnamomi cortex*, and *Foeniculi dulcis fructus*: in the case of the first drug, EP [1] gives an essential oil yield not lower than 15% and the samples we analyzed varied from a minimum of 7.42 to a maximum of 8.63%; for the second one, the limiting value is not less than 1.2% and the analyzed samples varied from a minimum of 0.53 to a maximum of 0.84%; for sweet fennel, the limiting value is not less than 4% and all the results for the

Table 12  
*Salviae officinalis folium*<sup>a</sup>

Brands	S <sup>a</sup>	OFM <sup>b</sup>	TA <sup>c</sup>	WC <sup>d</sup>	EO <sup>e</sup>
D	30.87 ± 1.25	0.50 ± 0.10	9.14 ± 0.80	8.48 ± 0.07	0.30 ± 0.00
F	3.05 ± 0.89	0.13 ± 0.12	6.18 ± 1.06	9.12 ± 0.09	1.47 ± 0.15
G		0.18 ± 0.03	6.64 ± 0.62	6.64 ± 0.07	1.30 ± 0.15
H		0.15 ± 0.15	13.11 ± 0.35	7.79 ± 0.15	1.13 ± 0.23
EP <sup>f</sup>	not more than 3.0%	not more than 2.0%	not more than 10.0%	not more than 10.0%	not less than 1.0%

<sup>a</sup> S, stems.

<sup>b</sup> OFM, other foreign matter.

<sup>c</sup> TA, total ash.

<sup>d</sup> WC, water content.

<sup>e</sup> EO, essential oil content. EP reports: 'not less than 1.5% for whole leaves and not less than 1.0% for broken leaves'. All analyzed samples were constituted by broken leaves.

<sup>f</sup> EP, acceptable limit reported in EP.

Table 13  
*Thymi herba*<sup>a</sup>

Brands	S <sup>a</sup>	TA <sup>b</sup>	AH <sup>c</sup>	WC <sup>d</sup>	EO <sup>e</sup>
D	0.63 ± 0.15	6.87 ± 0.35	1.12 ± 0.08	5.97 ± 0.20	1.08 ± 0.07
E	1.03 ± 0.21	6.26 ± 0.33	1.04 ± 0.07	7.67 ± 0.31	1.59 ± 0.02
G	2.20 ± 1.31	7.96 ± 0.07	1.68 ± 0.10	8.36 ± 0.28	0.64 ± 0.04
H		11.48 ± 0.68	2.97 ± 0.10	6.65 ± 0.30	1.55 ± 0.06
EP <sup>f</sup>	not more than 10.0%	not more than 15.0%	not more than 3.0%	not more than 10.0%	not less than 1.2%

<sup>a</sup> S, peduncles with diameter 1 mm and not longer than 15 mm.

<sup>b</sup> TA, total ash.

<sup>c</sup> AH, ash insoluble in hydrochloric acid.

<sup>d</sup> WC, water content.

<sup>e</sup> EO, essential oil content.

<sup>f</sup> EP, acceptable limit reported in EP.

samples were lower than half of this value, varying from 1.23 to 1.68%.

For other drugs, for example, *Anisi fructus* and *Chamomillae romanae flos*, the results showed that only one of the samples analyzed agreed with limit values required by EP [1].

These are very negative results as the medicinal activities of these drugs are ascribed to their essential oil content. As is well known, a vast range of factors exist, which in the course of aromatic plant production, can have a decisive impact on the quality of the final products. The essential oil yields can be influenced by climatic and environmental conditions, hour and season of collection, age of the plants, care in the preparation of the commercial material, etc. Besides, the low essential oil content could be due to the age of the samples, which widely influences the yield; an old sample contains less essential oil, especially if it is kept in incorrect storage conditions, e.g. open container, exposure to light, excessive temperature, etc.

In order to have a sure and safe product, ideally the exact geographical source of a herbal material should be known and the condition under which it has been grown, harvested, dried, and stored, as well as any chemical treatments, such as pesticides or fumigants, to which it may have been subjected. Unfortunately, several standards giving a quality assurance, such as permitted levels of microbial contamination, toxic elements, pesticides, mycotoxins, fumigants, or radioactive residues, are not defined in the individual monographs. In addition, the knowledge of all this data in many cases is not possible, since plant drugs are obtained from varied geographical and commercial sources. The appropriate level of testing, in addition to the monograph criteria, should therefore be carefully assessed, based on various factors, including the nature of the material and knowledge of its complete history.

Besides, several standards need to be changed because they are acceptable for several drugs, but not for all. For example, the actual legislation permits botanical drugs to be sold for three years from the date of manufacture; this period could be appropriate for several drugs, but not for aromatic drugs, which, in such a long time, would surely lose high quantities of essential oil.

The serious situation concerning the quality and the efficacy of medicinal herbs was urged not only by specialists in the study of medicinal and aromatic plant materials [6,7], but also by the governing bodies. In USA, a legislation enacted in 1994 permitted botanical drugs to be sold as dietary supplements without being subjected to the costly drug approval process [5].

However, Committees of Pharmacopoeial Convention in USA and a special committee in the European Union are working diligently to establish quality standards for the most popular botanicals; the aims of these organizations are to advance the status of herbal medicines throughout the world and to assist with the harmonization of their regulatory status. New homogeneous rules will be determined by extensive consultation with the industry, medical herbalists, and academicians to arrive at what is realistic control specification that assures quality without excluding perfectly satisfactory commercial material. For this reason, it is very important to have good agricultural and manufacturing guidelines outlining medicinal plant growing and handling conditions because they are an intrinsic part of any quality assurance system or plant-based health care program [8,9].

The results obtained in this work demonstrated the difficult situation and the lack of quality control in aromatic plant drugs, many of which are also very commonly used. Adequate quality control is the basic point of departure by which the public may rest assured that the medicinal herbs that they demand will function efficiently and will not contain ingredients that may be toxic or have different therapeutic actions. Establishment and enforcement of quality standards are required urgently to remedy this serious situation.

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