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Article

Determination and evaluation of unofficial or complementary tests of rosemary extract tablets (as a finished product)

Determinación y evaluación de las pruebas no oficiales o complementarias de comprimidos de extracto de romero (como producto terminado)

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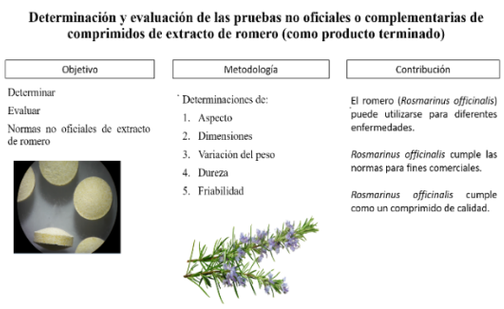
Abstract

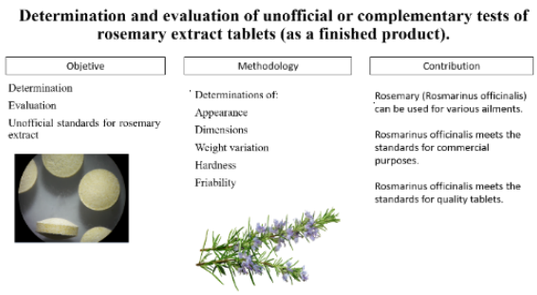
Rosemary (Rosmarinus officinalis) is a plant rich in active ingredients, it generates a tonic and stimulating action on the nervous, circulatory and heart systems, in addition to being choleretic, cholagogue, antispasmodic, diuretic, emmenagogue and antigodanotropic. The objective was to carry out unofficial tests in the production of rosemary tablets as a finished product. The appearance, hardness, weight variation and friability of the tablets were determined. The results show an appearance with irregular edges and faint yellow spots, the diameter of the tablets shows a P-value of 0.408, a thickness with a P-value of 0.458, and a tablet weight of a lower P-value. at 0.050, in hardness a P-value of .942, while in the friability tests values less than 1 were obtained. These results show acceptable values for the production of rosemary extract tablets, which can have commercial use.



Rosmarinus officinalis, Rosemary extract, Tablets

Resumen

El Romero (Rosmarinus officinalis) es una planta rica en principios activos, genera una acción tónica y estimulante sobre el sistema nervioso, circulatorio y corazón, además de ser colerético, colagogo, antiespasmódico, diurético, emenagogo y antigodanotrópico. El objetivo fue realizar las pruebas no oficiales en la elaboración de comprimidosde romero como producto terminado. Se determinó el aspecto, la dureza, la variación de peso y la friabilidad de las tabletas. Los resultados nos muestran un aspecto con bordes irregulares y manchas tenues de color amarillo, el diámetro de los comprimidos arroja un P-value de 0.408, un espesor con valor de P-value de 0.458, un peso de tabletas de un P-value menor a 0.050, en dureza un P-value de .942, mientras que en las pruebas de friabilidad se obtuvieron valores menor de 1. Estos resultados muestran valores aceptables para la elaboración de comprimidos de extractos de romero, lo cual puede tener uso comercial.



Rosmarinus officinalis, Extracto de romero, Comprimido

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Introduction

Rosemary (Rosmarinus officinalis) is a Mediterranean plant whose term is derived from the Greek "(rhops and myrinos)" which means "marine shrub" due to its growth near the coast (Alonso, 2004). It is generally found wild in rocky and sandy areas near the sea, but due to its adaptability and low demand for cultivation, it reproduces easily in other areas.

Rosemary belongs to the Lamiaceae family (Labiatae Labiadas), it is a shrubby plant with prismatic stems, the leaves are narrow, acute and small, they are shaped like bright greenspikes with revolute margins and woody andbranched stems (Sotelo et al. , 2002 and Sardans et al., 2005).

Various chemical compounds have been reported in the plant, which have been generally grouped by various authors into phenolic acids, flavonoids, essential oil, triterpenic acids and triterpenic alcohols (Caribe and Campos, 1991; Botsaris, 1995 and Atti-Santos, 2005). Rosemary essential oil is the most qualitatively studied component.

Different research works affirm that depending on the geographicallocation where plants grow under conditions of soil type, climate and height above sea level, they generate different changes in the quantity and type of bioactive molecules present (Al-Sereiti et al., 1999 and Guerrero et al., 2007).

Tablets are one of the most used pharmaceutical forms. It is estimated that today, half of themedications are administered in this pharmaceutical form (Vanaclocha, 2003).

The advantages of this pharmaceutical form are that they allow precision in dosage, they are easy to use, they allow the formulation of poorly soluble active ingredients and they can be manufactured on a scale with the consequent reduction in costs, durability of the physicalcharacteristics for extended periods of storage, excellent physical, chemical, pharmaceutical and pharmacological stability and great ease of handling during the packaging and packaging processes (Vanaclocha, 2003 and Miranda, 2006).

Methodology

Aspect

5 tablets were placed in the Carl Zeiss Stemi DV 4 stereoscope to observe the tablets' regularedges, homogeneous color and absence ofstains (EUHU, 2000 and Játiva, 2009).

Dimensions

5 samples of 10 tablets were taken and the diameter and thickness of each tablet in millimeters were measured with the caliper, vernier or caliper, and the average of each sample was calculated (EUHU, 2000 and Játiva, 2009).

Weight variation

5 samples of 10 tablets taken at random from the sample to be analyzed were weighed, they were weighed individually, trying not to touch them directly with the hand using gloves or tweezers to prevent the fat that is on the fingers of the hands from increasing the weight of the tablet, and all the decimals shown on the analytical balance were recorded (EUHU, 2000 and Játiva, 2009).

Hardness

Five samples of 10 tablets each were taken and the hardness was measured with the HELMER brand durometer of each tablet. (EUHU, 2000 and Játiva, 2009).

Friability

10 samples of 10 tablets each were analyzed, first the 10 tablets were weighed together taking into account all the decimals of the analytical balance reading (initial weight), then they were subjected to the Roche equipment (friabilizer) for approximately 5 minutes (i.e. say 100 blows), after said time the tablets were weighed again (final weight), and with these weights the percentage of friability (EUHU, 2000 and Játiva, 2009):

Results

Aspect

The rosemary extract tablets, as can be seen in Figure 1, show irregular edges and faint yellow spots, with slight porosity.

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Box 1

Figure 1

Morphological observation of rosemary extract tablets (Pharmacy Laboratory, Chemical Sciences, UAZ, 2016).

Own elaboration

Diameter

As seen in Figure 2, the diameter of 5 samples of 10 tablets each was measured with a verniercaliper or caliper.

Box 2

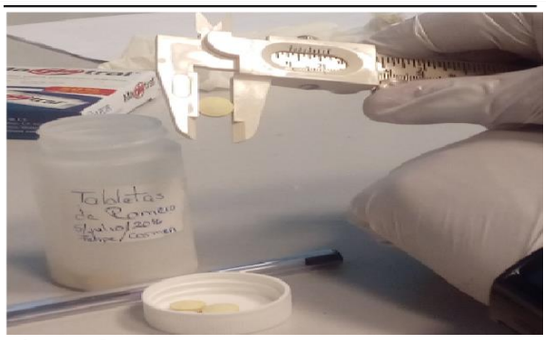

Figure 2

Measurement of the diameter of rosemary tablets (Laboratory of Pharmacy, Chemical Sciences, UAZ, 2016).

Own elaboration

The results of measuring the diameter of the rosemary extract tablets were tabulated in Table1.

Box 3

Table 1

Diameter of rosemary extract tablets

Tablets	M-1 (cm)	M-2 (cm)	M-3 (cm)	M-4 (cm)	M-5 (cm)
1	1.05	1.0	1.05	1.0	1.0
2	1.05	1.0	1.05	1.0	1.05
3	1.0	1.0	1.04	1.05	1.0
4	1.0	1.05	1.05	1.0	1.0
5	1.0	1.05	1.05	1.0	1.0
6	1.0	1.0	1.04	1.0	1.0
7	1.0	1.05	1.05	1.0	1.0
8	1.0	1.0	1.05	1.0	1.0
9	1.0	1.0	1.05	1.0	1.05
10	1.0	1.0	1.05	1.0	1.0
x̄	1.01	1.015	1.048	1.005	1.01
S	0.02108	0.02415	0.00421	0.01581	0.02108
C.V.	2.087	2.3793	0.4017	1.5731	2.0871

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M-1, M-2, M-3, M-4, M-5 = Samples 1 to 5, x = average, s = standard deviation and C.V. = Variation Coefficient.

The analysis of variance carried out on the results of the diameter of the rosemary extract tablets shows a P-value of 0.408, which indicates that there are no significant differences in the diameter of the rosemary tablets.

Thickness

Figure 3 shows how the thickness of the rosemary tablets was measured with a vernier caliper or caliper in 5 samples of 10 tablets.

Box 4

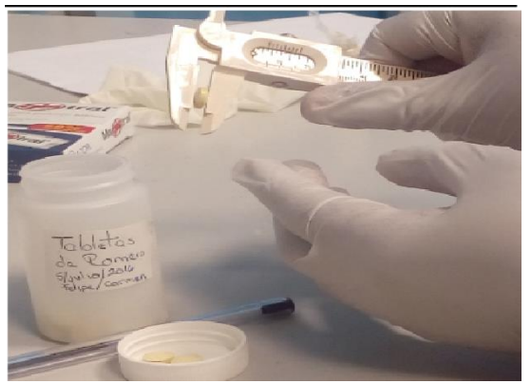

Figure 3

Measurement of the thickness of rosemary extract tablets (Pharmacy Laboratory, Chemical Sciences, UAZ, 2016

Own elaboration

The results of measuring the thickness of the rosemary tablets were tabulated in Table 2.

Box 5

Table 2

Diameter of rosemary extract tablets

Tablets	M-1 (mm)	M-2 (mm)	M-3 (mm)	M-4 (mm)	M-5 (mm)
1	4.8	4.8	4.5	4.7	4.8
2	4.5	4.8	4.5	4.7	4.8
3	4.8	4.8	4.8	4.8	4.8
4	4.8	4.8	4.7	4.8	4.8
5	4.8	4.7	4.8	4.8	4.8
6	4.8	4.8	4.8	4.8	4.8
7	4.8	4.8	4.8	4.8	4.8
8	4.8	4.8	4.8	4.8	4.8
9	4.5	4.8	4.8	4.8	4.8
10	4.8	4.7	4.8	4.7	4.8
x̄	4.74	4.78	4.73	4.77	4.8
S	0.1264	0.0421	0.1251	0.0483	0
C.V.	2.6666	0.8807	2.6448	1.0125	0

Thickness of rosemary extract tablets. M-1, M-2, M-3, M-4, M-5 = Samples 1 to 5, x = the average, s= standard deviation and C.V. = Variation Coefficient.

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Weight variation

As shown in figure 4, 5 samples of 10 tablets were weighed with tweezers on an analytical balance, recording all the decimals of the balance reading

Box 6

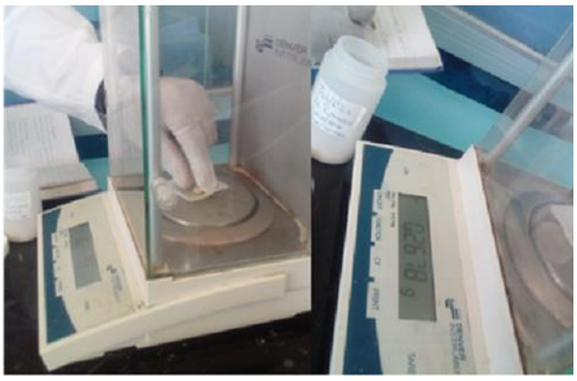

Figure 4

Weight of rosemary extract tablets (Laboratory of Pharmacy, Chemical Sciences, UAZ, 2016).

Table 3 shows the results of the weights of the 5 samples of 10 tablets each taken at random.

The results of measuring the thickness of the rosemary tablets were tabulated in Table 2

Box 7

Table 3

Weigh of rose mary extract tablet

Tablet	M-1 (g)	M-2 (g)	M-3 (g)	M-4 (g)	M-5 (g)
1	0.2667	0.2772	0.2676	0.2671	0.2701
2	0.2783	0.2777	0.2683	0.2654	0.2700
3	0.2624	0.2694	0.2624	0.2701	0.2717
4	0.2745	0.2698	0.2745	0.2700	0.2700
5	0.2825	0.2707	0.2625	0.2699	0.2699
6	0.2628	0.2717	0.2630	0.2701	0.2699
7	0.2581	0.2699	0.2599	0.2699	0.2701
8	0.2838	0.2674	0.2592	0.2699	0.2703
9	0.2691	0.2688	0.2688	0.2702	0.2697
10	0.2542	0.2701	0.2701	0.2702	0.2702
X	0.2692	0.2712	0.2656	0.2692	0.2701
S	0.0102	0.0034	0.0049	0.0016	0.0005
C.V	3.7890	1.2684	1.8637	0.6129	0.2057

M-1, M-2, M-3, M-4, M-5 = Samples 1 to 5, x = average, s = standard deviation and C.V. = Variation Coefficient.

The results of measuring the thickness of the rosemary tablets were tabulated in Table 2.

By subjecting the thickness data to an analysis of variance, a P-value of 0.458 is obtained, which indicates that there is no significant difference in thickness between each of the tablets in the sample.

The analysis of variance of the tablet weight samples shows a P-value less than 0.050, which suggests a difference between the weight of each of the tablets of the five samples.

Hardness

As shown in Figure 5, the 5 samples of 10 tablets were measured in a durometer.

Box 8

Figure 4

Measurement of hardness of rosemary extract tablets (Laboratory of Pharmacy, Chemical Sciences, UAZ, 2016).

Table 4 shows the hardness results of the 5samples of 10 rosemary extract tablets.

Box 9

Table 4

Hardness of rosemary extract tablets

Tablets	M-1 (N)	M-2 (N)	M-3 (N)	M-4 (N)	M-5 (N)
1	70	80	75	90	75
2	75	90	80	70	90
3	68	80	85	80	90
4	80	70	90	85	80
5	80	75	70	85	80
6	85	75	80	75	80
7	70	80	70	80	80
8	80	80	80	80	80
9	80	80	85	80	75
10	80	85	80	80	80
$\bar{x}$	76.8	79.5	79.5	80.5	81
S	5.692	5.5025	6.4334	5.5025	5.1639
C.V.	7.4114	6.9213	8.0918	6.8354	6.3751

M-1, M-2, M-3, M-4, M-5 = Samples 1 to 5, x = average, s = standard deviation and C.V. = Coefficient of Variation, N = Newton.

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According to the variance analysis carried out on the hardness of the tablets in Newton, it indicates that there are significant differences inthe hardness test since it showed a P-value of .942, however, this test passes since the allowedrange of hardness is from 70 to 90 Newton.

Friability

Figure 6 shows the evaluation of the friability of the rosemary extract tablet samples in the friabilizer.

Box 10

Figure 6

Determination of the friability of rosemary extract tablets (Laboratory of Pharmacy, Chemical Sciences,UAZ, 2016).

As shown in table 5, the friability percentage ofthe rosemary tablets is less than 1, which indicates that they have acceptable friability.

Box 11

Table 5

Friability of rosemary extract tablets

Samples	Friability (%)
1	0.209
2	0.310
3	0.290
4	0.340
5	0.337
x̄	0.2984
s	0.03736
C.V.	12.5201

x = average, s = standard deviation and C.V. = VariationCoefficient

Table 6 shows the averages of the 5 samples of the diameter, thickness, weight, hardness and friability of the total rosemary extract tablets.

Box 12

Table 6

Averages of non-pharmacopoeial or complementary trials of Rosmarinus offisinalis extract tablets

Averag eof samples	Diamete rin cm	Thicknes sin mm	Weigh tin grams	Hardnes sin Newton	Friabilit y(%)
M-1	1.01	4.74	0.2692	76.8	0.209
M-2	1.015	4.78	0.2712	79.5	0.310
M-3	1.048	4.73	0.2656	79.5	0.290
M-4	1.005	4.77	0.2692	80.5	0.340
M-5	1.01	4.8	0.2701	81.0	0.337
x̄	1.0176	4.764	0.2690	79.46	0.2972
S	0.01735	0.0288	0.0021	1.6226	0.0534
C.V.	1.7049	0.6047	0.7813	2.0420	17.9712

M-1, M-2, M-3, M-4, M-5 = Samples 1 to 5, x = average, s = standard deviation and C.V. = Variation Coefficient

In Figure 7 you can see the correlation that exists between the variables diameter, thickness, weight, hardness and friability of the rosemary extract tablets, where a) represents the correlation coefficient, b) the P-value and C) the number of samples.

Box 13

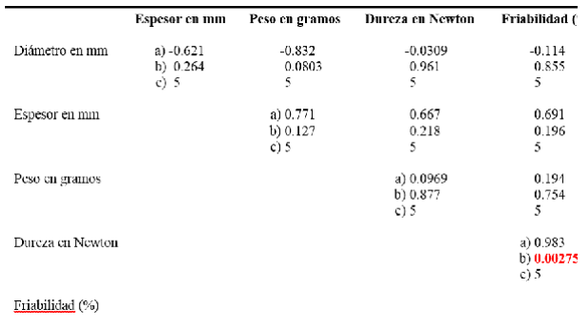

Figure 7

Correlation between unofficial or complementary tests

It can be seen in the previous figure (figure 7), that there is only a difference between Friability and Hardness, because it shows a P-value of 0.00275, while no significant difference is observed in the other variables.

Figure 8 shows that there is only a correlation between the hardness and friability of the rosemary extract tablets, since the higher thehardness the tablets have greater friability, which means that they are more resistant to wear or breakage during packaging and packaging. shipment of the medication.

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Box 14

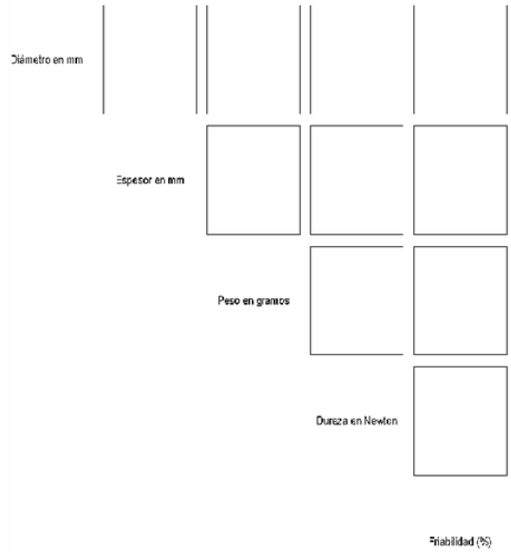

Figure 8

Correlation between the averages of the 5 samples of diameter, thickness, weight, hardness and friability

Conclusions

Rosemary (*Rosmarinus officinalis*) is a medicinal plant that can be used for different purposes. Rosemary extract is very important for its health benefits, since it has several pharmacological effects that can improve people's quality of life. If it is of good quality, it can be used as an active ingredient to make tablets of the same extract.

The medicine (*Rosmarinus officinalis* extract tablets) has the desired physical and organoleptic characteristics and/or properties, which guarantee that when official and unofficial tests are evaluated, it can be used for commercial purposes. The appearance, dimensions, weight variation, hardness and friability are unofficial tests in the production of rosemary extract tablets that determine a quality tablet.

Declarations

Conflict of interest

The authors declare that they have no conflicts of interest. They have no known conflicting financial interests or personal relationships that could have influenced the article presented in this paper.

Author contribution

Orta-Martínez, Felipe: Contributed to the development of the experiments for the determinations of the unofficial tests of rosemary.

Hernández-Salas, Claudia: Contributed to the analysis of the data and the writing of this article.

Regalado-Barrera, José David: Contributed to the translation of this article.

Fores-Treviño, Nora Elia: Contributed to the laboratory experiments for this research.

Availability of data and materials

For this research, open databases wereaccessed, platforms such as Google Scholar, Scopus, served as the basis for said work

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Abbreviations

Not applicable

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Antecedents

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