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Regulations, characteristics and feasibility of partitioning oral solid drugs according to current Brazilian legislation

Regulamentações, características e viabilidade da partição dos medicamentos sólidos orais segundo a legislação brasileira vigente

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ABSTRACT

Introduction: The difficulty in swallowing solid oral dosage forms is collectively reported by patients; however, this form of medication is still the most frequently prescribed. **Objective:** To investigate the format, dimension and viability of partitioning drugs in solid forms most frequently sold in Brazil and evaluate the regulations and the dissemination of this information to the population. **Method:** The shape and size of solid oral forms were obtained from the collection, analysis and measurement of 470 drugs. The feasibility of partitioning was verified by the presence or absence of grooves and by reading their respective package inserts. A bibliographic survey of current regulations was carried out and the format, size and partition data found were debated in terms of these regulations. **Results:** Pills with the same type and dose of the active pharmaceutical ingredient showed size differences related to the classification of the drug (reference, generic and similar) and pharmaceutical laboratory. Generic drugs, in general, had larger dimensions than similar and reference drugs. The difference in volume (mm3) of tablets of the same classification and different pharmaceutical laboratories reached 66.00%. Considering the information on the package inserts, 90.00% of the drugs analyzed do not have partition permission. Several drugs do not present information about partition consistent with Anvisa RDC nº 47. **Conclusions:** Disclosure of the format and size of medications in package inserts and/or packaging can help patients with dysphagia. For greater security, partitioning of medications should not be based on the groove present in them, and it is necessary to consult the package leaflet.

KEYWORDS: Drugs; Active Principle; Collective Health; Diseases; Solid Oral Dosage Form; Tablet Partition

RESUMO

Introdução: A dificuldade de deglutição de formas farmacêuticas sólidas orais é coletivamente relatada por pacientes, no entanto, esta forma de medicamento ainda é a mais frequentemente prescrita. **Objetivo:** Investigar o formato, a dimensão e a viabilidade de partição dos medicamentos em formas sólidas mais frequentemente comercializados no Brasil e avaliar as regulamentações e a divulgação destas informações para a população. **Método:** A dimensão e o formato das formas sólidas orais foram obtidos a partir da coleta, análise e medição de 470 medicamentos. A viabilidade de partição foi verificada pela presença ou não de sulcos e pela leitura de suas respectivas bulas. Um levantamento bibliográfico das atuais regulamentações foi realizado e os dados de formato, dimensão e partição encontrados foram debatidos em função destas regulamentações. **Resultados:** Os comprimidos com o mesmo tipo e dose do insumo farmacêutico ativo apresentaram diferenças de dimensão relacionadas com a classificação do medicamento (referência, genérico e similar) e o laboratório farmacêutico. Os medicamentos genéricos, em geral, apresentaram dimensões maiores do que os similares e os de referência. A diferença de volume (mm^3) encontrada nos comprimidos de mesma classificação e laboratórios farmacêuticos diferentes foi de

66,00%. Considerando as informações das bulas, 90,00% dos medicamentos analisados não possuem permissão de partição. Diversos medicamentos não apresentam informações sobre a partição condizente com a RDC nº 47, de 8 de setembro de 2009, da Anvisa. **Conclusões:** A divulgação do formato e da dimensão dos medicamentos nos bulários e/ou embalagens podem auxiliar os pacientes com disfagia. Para maior segurança, a partição dos medicamentos não deve ser feita com base no sulco presente nos mesmos, sendo necessário consultar a bula.

PALAVRAS-CHAVE: Medicamentos; Princípio Ativo; Saúde Coletiva; Doenças; Forma Farmacêutica Sólida Oral; Partição de Comprimido

INTRODUCTION

Within a global context marked by intense urbanization, industrialization of food, increased incidence of stress, sedentary lifestyles, intensification of pollution, among other factors, there has been an increase in the number of diseases and disorders in the population[1].

The pharmacological approach is one of the main means of treatment for numerous physical or psychological pathologies, and the prescription and administration of drugs are common during the population's health treatment[1,2].

According to Law No. 9.787 of February 10, 1999, medicines in Brazil are classified as reference, generic, and similar medicines[3].

Reference medicines are innovative products, pioneered by a pharmaceutical industry. Their quality, efficacy, and safety are proven through the analysis of clinical trials (for new products) or through a bibliographic review of their use in different population subgroups (in the case of traditionally used products)[3,4,5]. They are registered with the federal agency responsible for health surveillance and marketed in the country under a commercial name (brand)[4,5]. In general, this brand name is well-established and widespread, which is why reference medicines are also known as "branded" medicines[4].

In Brazil, patent applications for these drugs are filed and analyzed by the Brazilian National Health Surveillance Agency (Anvisa) and, when granted, the company has exclusive rights to produce, use, and market them for a period of 20 years[3,4,5,6].

After the patent or other exclusive right to sell expires or is waived, other pharmaceutical companies can market the same product in the form of similar and generic products[3,4,5].

Similar drugs have the same active ingredient, concentration, pharmaceutical form, route of administration, posology, and therapeutic indication as the reference drug. They are marketed under a different trade name to the one used for the reference drug[3,4,5].

Similar medicines may differ in some characteristics (size and shape of the product; excipients and vehicles; packaging; label and expiry date), however, their efficacy, safety, and quality should be similar to those of reference and generic medicines[3,4,5].

Generics have the same active pharmaceutical ingredient (substance that produces the therapeutic effects), the same dose, the same pharmaceutical form and route of administration as the drugs manufactured by the innovator company[3,4,5]. However, they do not have a trade name, are sold by the name of the active ingredient, and must bear the words "Generic drug - Law 9.787/99"[3,5] on their packaging.

The use of generic drugs has increased in recent years, mainly due to their lower cost, which is usually 20%-90% cheaper than the original equivalents[4].

The quality, efficacy, and safety of generic and similar drugs in relation to the reference drug (interchangeability) are proven through pharmaceutical equivalence and bioequivalence tests. Pharmaceutical equivalence is an *in vitro* test which proves that the generic and/or similar drug has the same formulation as the reference drug[5]. The bioequivalence test is applied to drugs that need to be absorbed by the gastrointestinal tract. It consists of *in vivo* tests, also called relative bioavailability, to prove that the generic and/or similar drug has the same absorption and distribution in the bloodstream as the reference drug[5].

In order to facilitate use and/or obtain the desired therapeutic effect, reference, generic or similar drugs are commercially available in various pharmaceutical forms (solid, liquid, semi-solid, and gaseous) and routes of administration[7,8].

Among the most common routes of administration, parenteral administration is restricted to use in hospitals and/or by health professionals[9]; topical and introductory administration (such as rectal and/or vaginal) are more restricted to dermatological, gynecological, and/or ophthalmological areas, and inhalation is generally the route used to treat respiratory diseases. Oral administration, in liquid or solid form, is the one that extends to the most diverse areas of treatment[7,8].

Although oral liquid pharmaceutical forms are indicated for adult use, they are more commercially available in concentrations for pediatric use[10]. Thus, solid oral forms are the most widely prescribed, produced, marketed, and administered[11].

The pharmaceutical challenge today is to find suitable solid forms for patients with difficulty or inability to swallow, especially pediatric patients and the elderly[11].

A study published in the scientific journal *Pediatrics* showed that 20%-40% of children are unable to swallow standard-sized tablets or capsules[12]. This difficulty, however, is not directly

related to age, since young people have the same blockage and it is usually motivated by negative associations with medicines[12,13,14].

Adults also have difficulty swallowing solid pharmaceutical forms, even if they don't have a blockage when swallowing food or liquids[13,14,15,16,17,18]. According to an American survey, 40% of adults have this difficulty, with 8% relating this blockage to the fact that they don't like the sensation of the medication sticking in their throat, 48% to the bad taste it leaves in their mouth, and 32% to the fact that they choke during the swallowing process[13,15].

Data from a study carried out in Germany showed that 37.4% of participants had experienced difficulties in swallowing medication in solid form. Of these, 24.2% reported that the situation occurred frequently and, in 70.4% of these cases, the problem was not reported to the doctor or its cause was not detected[14,16].

In Brazil, studies show that difficulty swallowing this type of medication is more common among women, children, young adults, and the elderly, with the size of the medication being the main reason[16,17,19].

Various blockages are related to the problem of swallowing solid oral pharmaceutical forms, including anxiety, hypersensitivity, and physiological reasons such as gastrointestinal reflux disorder, scleroderma (a type of scar that can weaken the lower ring of the esophagus), as well as the fear of choking and aversion to the taste of the medication, as previously rep orted[12,13,14,15,16,17,18,19]. In addition, the physical characteristics of medicines - including size (74.6%), type of surface (70.5%), shape (43.5%), and taste (22.1%) - are also associated with the problem[15,18].

Difficulty and limitations in swallowing medication are extremely important and serious factors, as they lead to inappropriate and early discontinuation of treatment when another pharmaceutical form of the drug is not commercially available[12,18,19,20]. Studies have also shown that swallowing solid medication in patients with stroke-induced dysphagia increases the risk of laryngeal penetration and laryngotracheal aspiration[18].

An alternative often used by patients when it is difficult to swallow is to partition or dissolve solid medicines in some kind of liquid, such as water, milk, juice, etc. However, due to the specific release profile of each drug, which defines how the drug should be absorbed by the body, partitioning and/or dissolving can alter or nullify its pharmacological response[16,21,22,23].

Although Collegiate Board Resolution (RDC) No. 47, of September 8, 2009, improved the form and content of package leaflets for medicines marketed in Brazil, in order to guarantee access to and interpretation of information in a safe and appropriate way for the population and health professionals[24], some information of great relevance to public health, such as the shape and size of oral solid pharmaceutical forms, is still missing.

The aim of this study was to survey the regulations and the format, size, and partitioning feasibility of the oral solid forms regulated by Anvisa and frequently prescribed and marketed in Brazil.

METHOD

For the development of this study, surveys were initially carried out on the main diseases affecting the Brazilian population and the drugs most prescribed for these diseases. This survey was carried out at a national level by consulting documents from the Ministry of Health and the Brazilian Institute of Geography and Statistics[25,26,27].

The pharmaceutical forms currently available for each of these drugs were checked using the Anvisa portal[28,] and drugs that are available exclusively in tablet and capsule form were considered for this study.

Once the aforementioned surveys and definitions had been carried out, the collection of medicines began, through collaborations with users and public and private health institutions.

The medicines collected were catalogued according to their Anatomical Therapeutic Chemical classification, type, and dose of the active pharmaceutical ingredient.

Subsequently, the dimensions and shape (in the case of tablets) were defined based on their geometric shapes. For oblong and oval-shaped drugs, for example, the height, width, and length were considered, and for round ones the height and diameter were measured[29].

For capsules, the size was obtained by following the standard measurement procedure for this type of pharmaceutical form and relating it to their numbering[29,30]. According to this procedure, the measurement should be made by uncoupling the two parts (called cap and body) and measuring them separately. Each part has a specific dimension and together they generate the size of the capsule (size 000 to 4), as shown in Figure 1.

All measurements were taken using a 150 mm stainless steel caliper (LEE Tools, Sandro André, SP).

Information on the feasibility of splitting all the drugs was gathered by checking for grooves in the tablets and also by consulting the information contained in the package leaflets, available on the Electronic Bulletin Board of the Anvisa portal[31].

RESULTS AND DISCUSSION

According to the National Health Survey 2019[25] and the National Health Plan 2020-2023[27], in recent decades there has been a change in the illness and death profile of the Brazilian population, with a decrease in communicable diseases and an increase in chronic non-communicable diseases (CNCDs). Studies of the Global Burden *of Disease (*GBD) for Brazil showed that of the

Body (mm)		22.2	20.22	18.44	16.61	15.27	13.59	12.19
Cap (mm)		12.95	11.74	10.72	9.78	8.94	8.08	7.21
Volume (mL)		1.40	0.95	0.68	0.37	0.30	0.21	0.13

Source: Adapted by the authors[29].

Figure 1. Representation of capsule sizes and respective body and cap dimensions.

total burden of morbidity, CNCDs accounted for approximately 85% of the total years lived with disability[25].

NCDs encompass a range of diseases, with hypertension, diabetes, cholesterol, chronic respiratory and kidney diseases, cardiovascular diseases, cancer, depression, stroke, and musculoskeletal disorders constituting a major public health problem in Brazil[25,27].

For the treatment of these diseases, various medicines are described in the National List of Essential Medicines (Rename) 2022 and on the Medicines Consultation Portal. These medicines have different compositions (single active pharmaceutical ingredient or combinations of several active ingredients) and different pharmaceutical forms and routes of administration[26,28].

According to the Anatomical Therapeutic Chemical Classification of Rename 2022, for some active pharmaceutical ingredients, oral solid forms are predominant. Considering the digestive system and metabolism and the musculoskeletal system, more than 44% of the drugs described are exclusively in this pharmaceutical form. For the nervous system and the cardiovascular system, these percentages are over 58% and 77%, respectively[26].

Characteristics of the solid medicines evaluated

The collection carried out in this study totaled 470 medicines, 41.00% of which were generics and the rest reference and/or similar.

The chemical therapeutic classification of the medications obtained - systemic hormonal preparations; digestive system and metabolism; and musculoskeletal, genitourinary, nervous, and cardiovascular systems (Chart 1) - corroborates data from the Brazilian Institute of Geography and Statistics (IBGE) and the Ministry of Health, which describe CNCDs (e.g., hypertension, diabetes, cholesterol, and depression) as the main diseases in the Brazilian health system[25,27].

Of the medicines obtained, 90.00% have the same type and at least one dose of the active pharmaceutical ingredients included in Rename 2022, such as: omeprazole (10 and 20 mg), atenolol (50 and 100 mg), atorvastatin calcium (20, 40 and 80 mg), and simvastatin (10, 20 and 40 mg).

For all the active pharmaceutical ingredients and their respective doses, it was possible to obtain drugs from different pharmaceutical laboratories, as shown in Chart 1.

Formats and dimensions of solid medicines

Regarding the shapes and sizes of medicines, Law No. 9.787/1999 and RDC No. 16, of March 2, 2007[3,32], define that the generic must be similar to the reference medicine that it intends to be interchangeable with, without clearly recommending that it be allowed to vary in size and shape in relation to the reference medicine. In the case of similar drugs, Laws No. 9.787/1999 and No. 13.235, of December 29, 2015, clearly state that these drugs can differ in size and format from the reference drug[3,33].

Of the 470 medicines analyzed in this study, it was found that 41.85% of the generic medicines and 32.59% of the medicines analyzed did not have the same size and shape as their respective reference medicine.

The shapes of the tablets were round, oblong, oval, square, drop, hexagonal, triangular, and semi-round (Figure 2). Among these shapes, round was predominant, followed by oblong and oval, totaling 98.90% of the drugs analyzed.

Studies have shown that, compared to round tablets, oblong and oval tablets are better swallowed by adult patients and present a lower risk of laryngotracheal penetration and aspiration

Chart 1. Active pharmaceutical ingredients analyzed in this study and their respective therapeutic indications.

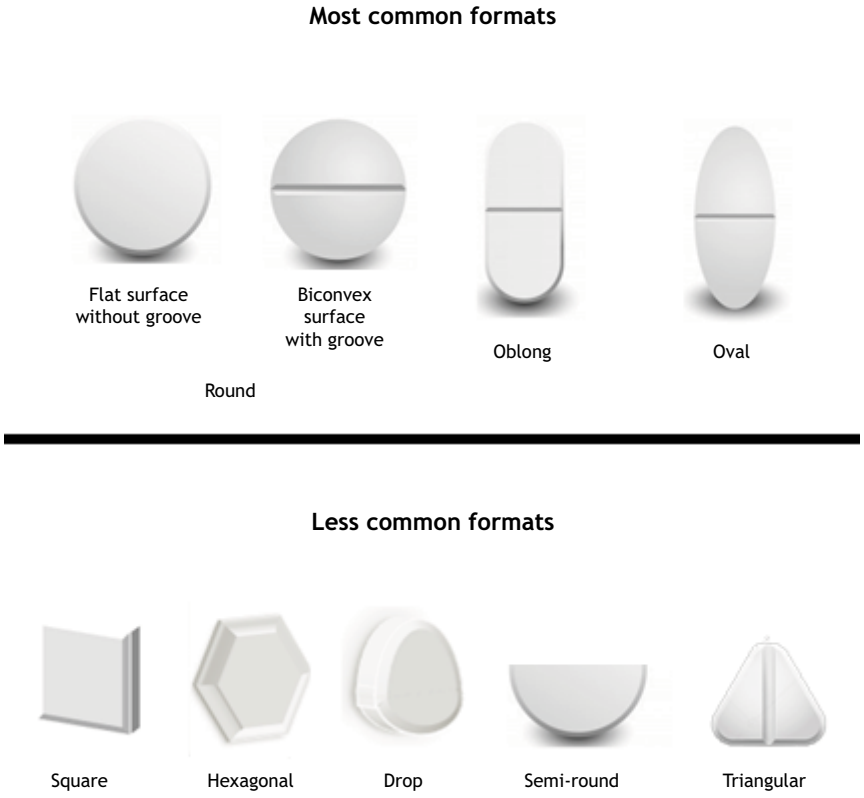
Anatomical classification chemical therapy	Active pharmaceutical ingredient	Pharmaceutical laboratory1
Metabolism	Metformin hydrochloride	MT, RP, RE, WR
	Glibenclamide	CA, BW, MT, EU, IN, MC
	Gliclazide	LS, MC, AB, PH, RA
Systemic hormone preparation	Prednisone	BW, UJ, FQ, RE, MT, KZ, OF
Musculoskeletal system	Alendronate sodium	UA, FQ, MT, FW
	Cyclobenzaprine hydrochloride	LJ, ZL, NI, MT, IX
	Tramadol hydrochloride	ZL, HP, XP
	Diclofenac sodium	VY, IX, OF, XP
	Naproxen	FW, AP, OJ
	Nimesulide	QS, VL
	Tenoxicam	BW, MT, CR, QO
Digestive system	Bromopride	AB, OJ, MC
	Thiamine hydrochloride	OV, FW
	Domperidone	VL, MT, ZL
	Esomeprazole magnesium	PL, OJ
	Omeprazole	FW, RE, GY, FQ, MT, IU, CA, AP
	Pantoprazole	OF, SG, QS
Genitourinary system	Cyproterone acetate	OV, AP, QV
	Tamsulosin hydrochloride	FQ, RB, FW
	Finasteride	HL, GX, FW, WR, VL
	Norfloxacin	CD, SG
Nervous system	Nifedipine	OV, MT, CA
	Alprazolam	IX, MT, IP
	Lithium carbonate	VL, GY, IP
	Amitripline hydrochloride	UJ, FW, FQ, MT, WR
	Fluoxetine hydrochloride	UJ, VL, FW, MC
	Paroxetine hydrochloride	VC, MJ
	Sertraline hydrochloride	MT, VC, PL, HG
	Venlafaxine hydrochloride	FQ, VL, HG
	Gabapentin	IN, ZL, EU
	Quetiapine hemifumarate	MP, SG, NI
Cardiovascular system	Atenolol	XE, RE, FQ, MP, SG, AB
	Anlodipine Besylate	MP, UJ, QS, CA, MT, SG, IP, NI
	Captopril	FQ, FW, MT, QS, IN, NI, KZ
	Carvedilol	NM, OF, ZL
	Ciprofibrate	IX, OF, HG, HC, MP, CA, FQ
	Sildenafil citrate	ZL, DV, OF
	Hydralazine hydrochloride	JL, UJ, OF, XE
	Propafenone hydrochloride	XE, DV, UL, QS, HL, HC
	Ethofibrate	GA, ZA
	Genfibrozil	MP, MT, FQ
	Hydrochlorothiazide	SN, VL, SG
	Methyldopa	KZ, LJ, WR, MV
	Simvastatin	MT, AB, KZ, JI, SG, UJ, OJ

Continue

Continuation

Cardiovascular system	Atorvastatin calcium	MT, GA, OS, IN
	Spironolactone	MT, EU
	Losartan potassium	CA, OF, FQ, EU, RE, VL
	Enalapril maleate	QS, EU, BW, XE, NI, CD

Source: Prepared by the authors, 2023.
[1] Acronyms adopted by the authors at random in order to preserve the disclosure of the names of drug manufacturers.



Source: Prepared by the authors, 2023.

Figure 2. Shapes, surface, and groove found on the drugs analyzed in this study.

in patients with dysphagia[13,18,20,34]. Although the round shape was the most commonly observed in the drugs analyzed, the predominance of oblong and oval shapes over other shapes indicates a favorable outlook for patients with swallowing difficulties.

In addition to the variety of shapes, two types of surfaces were found on the tablets (flat or biconvex), both with the presence or absence of grooves, as shown in Figure 2.

When it came to the size of the medicines analyzed, four standard capsule sizes were identified, with size 4 being the predominant one (32.40%), followed by sizes 3 and 2 (24.30% each), 1 (10.80%), and 0 (8.20%). For medicines containing the same type and dose of pharmaceutical ingredient, the size of the capsules tended to be standardized for the different classifications (reference, generic, and similar) and pharmaceutical laboratories.

For tablets with the same type and dose of the active pharmaceutical ingredient, however, statistically significant differences were found (*t-student*, $p < 0.05$, 95% confidence), considering the volume in mm^3.

These differences were related both to the classification of the drug (reference, generic, and similar) and to the pharmaceutical laboratories that manufactured it.

In terms of classification, generic drugs were generally larger than similar and reference drugs. For tablets of the active ingredient simvastatin at a dose of 40 mg, for example, the difference in volume (mm^3) of the reference drug was 20.00% less than the similar drug from the AB laboratory and 38.00% less than the generic drug from the SG laboratory (Chart 2).

Chart 2. Comparison of the drug Simvastatin, at a dose of 40 mg, from different pharmaceutical laboratories.

Pharmaceutical laboratory[1]	Format	Grooved	Dimensions (mm)[a]	Volume (mm^3)
UJ	Round	No	9.7 x 4.7	347.15
MT	Oval	No	19.0 x 8.0 x 4.6	365.91
SG	Oval	No	14.7 x 7.4 x 9.8	557.90
AB	Round	No	11,2 x 4,4	433.27
KZ	Oval	No	14.4 x 4.9 x 8.4	310.18

Source: Prepared by the authors, 2023.
[a] Measurements expressed as external diameter x height for round-shaped measurements and length x width x height for oval-shaped measurements.
[1] Acronyms adopted by the authors at random in order to preserve the disclosure of the names of drug manufacturers.

The variations found in the dimensions of the solid pharmaceutical forms analyzed may be due to the pharmaceutical equivalence adopted for generic and similar drugs, which requires the use of the same active substance (salt or ester of the therapeutic molecule) present in the reference drug, but without determining the origin and polymorphism of the raw material used[35].

It may also be related to the fact that the excipients used in generic and similar drugs do not necessarily have to be identical to those used in the reference drugs, as long as their functions are well established.

Depending on the manufacturing process of the active substance and the type of excipient, the molecules of these inputs can be spatially organized in different ways, generating crystals with different characteristics. Macroporous crystals tend to be more difficult to compact than more compact polycrystals, which tend to aggregate more easily during the drug manufacturing process[36].

Due to the Brazilian pharmaceutical sector's dependence on imported raw materials and the cost of these, the use of active substances and excipients with the same characteristics is not always feasible during the production of generic and similar medicines[37].

Among the solid oral forms analyzed, tablets of the same classification but from different pharmaceutical laboratories also showed differences in size. For captopril, at a dose of 25 mg, the volume of the tablets varied from 75.9 to 224.0 mm^3, which corresponds to an increase in size of around 66.00% between the medicines.

Larger tablets and capsules can compromise the patient's acceptability and tolerance of the drug and, consequently, the success of the pharmacological treatment. Data from the literature shows that 80.00% of elderly people consider tablets to be well swallowable when they have volumes of up to 166.4 mm^3. For younger patients, this acceptability is for tablets with up to 330.2 mm^3 of volume[18,34].

Considering the drugs analyzed in this study, those with a low dose of active ingredient, such as captopril at a dose of 25 mg, had dimensions compatible with what the elderly and young adults consider to be well swallowable. For drugs containing higher doses of active ingredient, however, the size of the tablets tends to exceed these dimensions[18,34]. This is the case with metformin hydrochloride tablets, which have volumes ranging from 192.8 to 781.5 mm^3 for the 500 mg dose and from 550.7 to 915.6 mm^3 for the 850 mg dose.

Partitioning feasibility of solid medicines

The partitioning of oral solid drugs is a routine procedure among patients and hospital units around the world, as a measure to make the dose more flexible, reduce the cost of treatment and facilitate swallowing. This practice may not significantly affect the release mechanism of the active pharmaceutical ingredient or its release kinetics, however, the irregularity of the active ingredient in the parts obtained by partitioning can result in uncertainty about the dose administered[23,38].

Studies have shown that during the splitting of a drug, a deviation of more than 10%-20% is obtained in the weights of the parts. The loss of active substance due to fragmentation and contamination of the drug during partitioning has also been considered a risk factor for patients[23,38].

Partitioning is generally guided by the markings (grooves) present on the tablets but these grooves only indicated the feasibility of partitioning before the development of extended-release drugs and special coatings. Nowadays, grooves are present on tablets to promote greater mechanical resistance, for aesthetic reasons, or due to the configurations of the manufacturing machines, not to ensure the viability and safety of the partitioning process[39]. Therefore, the partitioning of a drug must be subject to the information specified in the package leaflet.

In 2009, new rules for drug package leaflets were recommended by Anvisa's RDC No. 47/200924. According to its guidelines, they must contain the item "6. How should I use this medicine?", with the information that coated and modified-release tablets and capsules cannot be split, opened, or chewed. Other medicines in which the manufacturing process is unreliable regarding partitioning must also bear the information: "This medicine must not be split, opened, or chewed"[24].

This study compared the markings (grooves) on the drugs analyzed with the information contained in their respective package leaflets. It was found that 27.80% of the tablets evaluated have

grooves but the package leaflet describes the non-viability of partitioning, confirming that the grooves do not ensure the viability and safety of the partitioning process.

Particularly for drugs in the nervous and cardiovascular system disorders class, it was also observed that the information on partitioning was not in line with RDC 47/2009. The most frequently found irregularities were: phrases outside the standard or the established item and absence of information on the non-viability of partitioning for coated and modified release tablets and capsules. This is possibly due to the fact that the pharmaceutical company has not yet adopted the package leaflet model recommended by RDC No. 47/2009, since a large number of package leaflets were found with the standard defined by RDC No. 140, of May 29, 2003, and/or their own standardization[40]. In the latter case, the use of technical language that is difficult for patients to understand and comprehend has already been reported in other studies in the literature[41,42].

Considering the rules established in RDC No. 47/2009 for coated and modified-release tablets and capsules, 90.00% of the drugs analyzed in this study do not have partitioning permission.

CONCLUSIONS

It can be concluded that there are significant differences in the dimensions of oral solid pharmaceutical forms containing the same active pharmaceutical ingredient and dose, but different manufacturers. Therefore, the disclosure of this information in the package leaflets and/or packaging of these medicines could help in the choice of formats and dimensions that are more pertinent to each patient, especially those with dysphagia problems.

Regarding the feasibility of partitioning, the grooves on many drugs do not match the information described in the package leaflets, corroborating data published in the literature that grooves do not currently guarantee the possibility of partitioning the pharmaceutical form. For this conduct, it is necessary to consult the package leaflet to obtain more precise and reliable information.

Finally, the harmonization and guidelines for package leaflets, regulated by RDC 47/2009, have not been fully adopted by pharmaceutical laboratories, especially regarding the use of language, font size, allocation of items on the leaflet, and lack of information.

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Authors' Contribution

Clava F, Medeiros VB - Analysis, data interpretation, and writing of the work. Colombo R - Conception, planning (study design), analysis, data interpretation, and writing of the work. All the authors approved the final version of the work.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.