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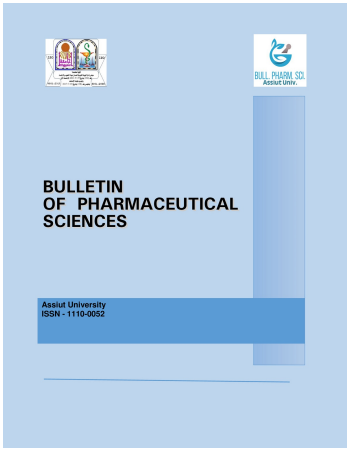

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THE EFFECT OF REPEATED COMPRESSION AND CONCENTRATION OF MALTODEXTRIN AS A BINDER ON THE PHYSICAL QUALITY OF CALCIUM LACTATE TABLET

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Objectives: *This study aims to determine the effect of recompression frequency and differences in maltodextrin concentration on the physical properties of the granule mixture and the physical properties of calcium lactate tablets, and to determine the relationship between recompression frequency and maltodextrin concentration on the physical properties of the granule mixture and the physical properties of calcium lactate tablets.* ***Material and Methods:*** *Calcium lactate was compressed into tablets with varying concentrations of maltodextrin as a binder and repeatedly compressed. Tablets were prepared using the wet granulation method. The physical properties of the powder mixture (flowability, compressibility) and the physical properties of the tablets (organoleptic, weight uniformity, active substance content, hardness, friability, and disintegration time) were tested.* ***Results:*** *The results showed that variations in maltodextrin concentration and recompression significantly affected the some of the physical properties of calcium lactate powder and tablet. Statistical analysis showed significant differences in flow rate, compressibility, tablet hardness, friability, and tablet disintegration time.* ***Conclusion:*** *Repeated compression frequency does not affect tablet hardness; and maltodextrin concentration does not affect the compressibility of the mixture and tablet hardness.*

Keywords: *Recompression, tablet excipient, physical properties of tablet*

INTRODUCTION

In the pharmaceutical industry, a stable and validated tablet manufacturing process can ensure the achievement of tablet products with consistent results over time. However, in the routine tablet production process, sometimes problems can occur that cause the product to be out of specification. After considering the advantages and disadvantages, reworking or reprocessing is usually carried out so that the tablet meets quality requirements and can be produced[1]. In this reworking or reprocessing, although carried out using the same procedure, tablet products often have different characteristics from the tablet product before undergoing reworking or reprocessing.

Likewise, after considering several aspects of tablet manufacturing, it is decided to undergo repression when a tablet does not meet quality requirements. Products resulting from the repression process often have different properties. This is a challenge, as reprocessed products are still required to meet quality control standards before being released to the public.

One key factor in the success of tablet preparations is the excipients used in the tablet formula. The ability of excipients to maintain the properties of the tablet product after undergoing several reprocessing processes will affect the product's character. Several studies have shown that binders are one of the excipients that play a significant role in

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maintaining tablet properties during reprocessing, for example, PVP K-30[2]. It shows different concentrations of PVP K-30 on the physical properties of the mixture (flow rate, compressibility, and compactibility of the mix) and the physical properties of paracetamol tablets[1]. Binders play an important role in tablet formulation, they can increase flowability by increasing particle size, which increases particle cohesiveness[3,4]. Tablet hardness is one of the physical properties of tablets that can be used to observe the binder's ability to maintain its function when the tablet undergoes repeated compression. Repeated compression often leads to an increase in the hardness of the resulting tablet[2]. However, there is currently no complete data on the ability of various binders to maintain tablet character when the tablet undergoes repeated compression in the reworking process. One of them is Maltodextrin, which is a polysaccharide often used as a binder in tablet formulations. It has several advantages, such as good solubility in water, the ability to increase the compressibility of powder mixtures, and compatibility with various active ingredients[5]. In some formulas, Maltodextrin as a binder could increase hardness, reduce friability, extend disintegration time, extend wetting time, and reduce the water absorption ratio[6].

Calcium is essential in various physiological functions, including bone and tooth formation, muscle contraction, nerve transmission, and blood clotting. Insufficient calcium intake can lead to various health problems, such as osteoporosis, especially in the elderly and postmenopausal women. Therefore, calcium supplementation is required to meet daily needs. Unfortunately, lactate tablets contain relatively small quantities of elemental calcium, so relatively large numbers of tablets may need to be given[7]. Calcium lactate is widely made in tablet form, due to its ease of use, accurate dosing, and stability. However, calcium lactate is hygroscopic and quickly absorbs water molecules from the surroundings[8]. This presents a challenge in the process of making calcium lactate tablets.

In this research, calcium lactate is a drug model in the tablet preparations because it has flow properties and compressibility indices included in the fair category. This study used calcium lactate as a model of active ingredients with maltodextrin as a binder. After being compressed into tablets and tested for physical properties, the tablets were crushed and recompressed 2 times. The physical properties of the tablets between the first, second, and third compressions were then compared to analyze the ability of the binder to maintain tablets with stable physical properties, especially seen in the hardness of the tablets. The aims of this research are :

1. To determine the effect of recompression frequency and differences in maltodextrin concentration on the physical properties of the granule mixture and the physical properties of calcium lactate tablets.
2. To determine the relationship between recompression frequency and maltodextrin concentration on the physical properties of the granule mixture and the physical properties of calcium lactate tablets.

MATERIALS AND METHODS

Research materials include calcium lactate (pharmaceutical grade; Sigma-Aldrich), lactose monohydrate (Kerry Ingredients India, pharmaceutical grade), maltodextrin (pharmaceutical grade), croscarmellose sodium (DYC Hangzhou Dingyan Chem), magnesium stearate (Faci Asia Pasific, Singapore, pharmaceutical grade), talcum (Takehara Plant, Japan, pharmaceutical grade), hydrochloric acid (pharmaceutical grade), sodium edetate (pharmaceutical grade), sodium hydroxide (pharmaceutical grade), blue indicator hydroxy naphthol P (proanalysis grade), and aquades.

The tools used in this study include glassware (Pyrex), analytical balance (OHAUS Pioneer PA213), mortar and stamper, sieve, oven (Memmert), moisture analyzer (OHAUS MB35 Halogen H2-027), flowability tester (Erweka, GmbH AR 401), compressibility tester (Erweka SVM-22), single punch tablet machine (Korsch Maschinenfabrik Berlin), hardness tester (Pharma Test PTB 302), tablet friability tester (Lorderan CS-2), disintegration tester (Develop BJ-2), and UV-Vis spectrophotometer (UVmini-1240 Shimadzu®).

The tablet formulation used in this study was modified from the standard formula and was presented in **Table 1**. The variations tested were the concentration of maltodextrin as a binder (4% and 6%) and the number of times it was compressed.

Table 1: Formula calcium lactate tablet @300mg.

Ingredients	Amount of each ingredient (mg/tablet)	
	Formula 1	Formula 2
Calcium Lactate	300	300
Maltodextrin	24	36
Lactose	240	228
Croscarmellose Sodium 2,5%	15	15
Magnesium stearate 1,5%	9	9
Talcum 2%	12	12
Total	600	600

Notes :

- Formula 1 : formula with 4% maltodextrin concentration
- Formula 2 : formula with 6% maltodextrin concentration

Tablet Manufacturing Procedure

The weighed maltodextrin was formed into a wet mass with distilled water. Lactose monohydrate, and 1/3 croscarmellose sodium were mixed in a cube mixer and stirred at a speed of 135 rpm for 15 minutes. The mixed materials were gradually given maltodextrin, which had been formed into a wet mass. The granules formed from the mixing process were sieved with a mesh number of 12 and dried at 50°C in an oven. After being dried for 24 hours, the humidity of the granules was checked using a moisture analyzer until it met the humidity requirements. It was sieved again with a mesh number of 14. The mixing process is carried out again with the most significant weight of calcium lactate, talc, and 2/3 of croscarmellose sodium put into the previous cube mixer, which already contains dry granules and stirred for 5 minutes. Magnesium stearate is added to the cube mixer to be stirred with the previous granules for 5 minutes. The powder mixture is then compressed using a tablet machine with a upper punch scale of 4 mm, and a bottom punch scale of 7 mm is selected.

Evaluation of Physical Properties of Powder Mixtures

Organoleptic

Granules were visually observed for form, color, and odor.

Moisture Content

Testing the water content of the granules is done using a Moisture Analyzer—approximately 1 gram of mixed granules that have been dried for about 20 hours. The lid on the device is then closed, and the percentage of water content will appear on the device screen. The water content that is stated as good is 1-5%[9,10].

Flow Properties

100 g of granules were put into the funnel of the flowability tester through the edge. The measurement is started by pressing the F1 button indicating start so that the granule comes out and the speed results are recorded. A good flow rate value is more than 10 g/s, which indicates the flow time of 100 grams of granules is less than 10 seconds[11].

Compressibility

The mixture was weighed equivalent to 100 mL of volume, then put into a 100 mL measuring cup until the volume reached 100 mL, and the volume was recorded as V_0. Then, the measuring cup was attached to the tapped density volumeter, and the device was turned on. As many as 10, 500, and 1250 beats were determined. Then, the volume is read on the 10th, 500th, and 1250th beat to the nearest unit of the measuring cup. If the difference between V_{500} and V_{1250} is less than or equal to 2 mL, then V_{1250} is the constant fixation volume and is recorded as V_f. If the difference between V_{500} and V_{1250} is more than 2 mL, the determination must be repeated for 1250 beats, until the difference in measurement volume is less than or equal to 2 mL[12].

$$\text{Compressibility Index} = 100 \text{ x } \frac{\text{Vo} - \text{Vf}}{\text{Vo}}$$

notes :

Vo= Mix volume before testing (mL)
Vf= Mix volume after testing (mL)

Evaluation of Tablet Physical Properties
Organoleptic
Tablets were visually observed for color, odor, taste, shape, and surface

Weight Uniformity
The weight variability test was carried out by weighing one tablet at a time, as many as 10 calcium lactate tablets of each formula, using an analytical balance, and the results were recorded. Then, the average weight value and the values X_1, X_2, ..., X_{10} are used to predict the content of the tested tablet unit. The value can be used in determining the M value, which is a reference value based on the average value of $\bar{X}$. Weight diversity testing can be said to be qualified if the acceptability value of the first 10 tablets is not less than or equal to L1%. If the acceptability value is greater than L1%, then it is necessary to redo the weight diversity test on 20 additional tablets. The following formula can calculate the acceptability value of weight diversity[12].

$$NP = |M - \bar{X}| + k\,s$$

notes:
NP: acceptance value
M: reference value
$\bar{X}$: average tablet weight
k: acceptability constant
s: standard deviation

Tablet Hardness
Tablet hardness was tested using a digital hardness tester (Pharma Test PTB 302) by placing tablet in the center of the tester. The button is pressed, and the tool moves to break the tablet. The tablet hardness value appears on the display, and the test results are recorded. Tablet hardness is good if it meets the tablet hardness requirements of 4-8 kg[2].

Tablet Friability
Tablets were taken and cleaned from particles and dust using a vacuum. Then, the tablets were weighed, the results were recorded, and the tablets were put into the friability tester tool and cleaned from particles. Furthermore, the tool was operated at a rotation speed of 25 rpm with a rotation frequency of 100 times. After the tool stops, the tablet is removed and cleaned of fine particles using a vacuum, and then the tablet is weighed, and the final weight is recorded. Tablets are said to be good if they meet the requirements of tablet friability, namely, the percentage of friability is less than 1%[13].

Tablet Disintegration Time
A tablet disintegration test is a test conducted to determine the time required for a tablet to disintegrate in a liquid medium. The tool used is a disintegration tester. This test is performed by inserting one tablet into each of the six tubes of the basket. Then, the disintegrator is turned on, the tube is raised and lowered in a water medium at 37±2°C, and the tablet disintegration time is measured using a stopwatch. When the last tablet disintegrates, the time is recorded as the tablet disintegration time. If 1 or 2 tablets do not disintegrate completely, repeat the test with 12 other tablets, and no less than 16 of the 18 tablets tested must disintegrate completely[12].

Crushing
The tablets tested for overall physical properties are crushed again using a mortar and stamper until they become granules/powder. The powder is sieved using a sieve with a mesh number of 12. Crushing is done repeatedly, namely twice for each formula.

Re-Compression
After the re-crushing process, the powder/granules sieved are pressed again using a rotary tablet punch press machine using the same pressing method as the first pressing stage. Repeated pressing will be done twice for each formula.

Statistical Analysis
The test data were statistically analyzed using a two-way analysis of variance (ANOVA) with a confidence level of 95% to determine the effect of different binder concentrations and repeated compression on the physical properties of powder and tablet mixtures. Test type of Statistical Test was used to compare differences between treatment groups. The significance level used was $p < 0.05$.

RESULTS AND DISCUSSION

This study evaluates the effect of repeated pressing and variation in maltodextrin concentration as a binder on the quality of calcium lactate tablets. The results showed that both factors significantly affected various tablet quality parameters. The variation of

maltodextrin concentration in tablet formulation had different effects on the physical properties of the powder mixture and the tablets produced. An increase in maltodextrin concentration generally increased the flow rate of the powder blends. The mechanism of action of maltodextrin as a binder can explain this. Maltodextrin increases the cohesiveness between powder particles by forming liquid bridges during the wet granulation and solid bridges after drying. This increased cohesiveness facilitates better powder flow, reduces internal friction, and minimizes segregation during the filling in tablet machine[14]. These results are consistent with previous studies showing that adding binders can improve the flow properties of powder blends.

Characteristic of Granule Before Lubrication

Organoleptic

The results of the organoleptic observation of granules before lubrication are presented in **Table 2**. In general, the granules of all formulas showed a white color and the typical odor of calcium lactate. There was no significant difference in organoleptic between formulas with different maltodextrin concentrations.

Moisture Content

Table 2 presents the measurement results of granule moisture content. The moisture content of the granules ranged around 1.3%. There was no difference in moisture content between formulas with different maltodextrin concentrations. This range of moisture content is considered optimal for the tablet tempering process.

Physical Properties of Powder Mixture

Flow Properties of the Powder

The measurement results of the flow properties of the powder blend after lubrication are presented in **Table 3**. The flow rate of the mixture in Formula 1 is higher than that of Formula 2. Significant differences can be observed in the initial mix (M1) and the mixture of crushed tablets after the compression (M2 and M3) ($p < 0.05$). Differences in maltodextrin concentration cause the difference in flow rates produced by the two formulas. In general, an increase in binder concentration tends to increase the flow rate of the powder blend because the greater the cohesiveness of the powder, the larger the size[2]. A good powder flow rate will need to get the proper quality of tablet because it would ensure uniformity of the filling into the die hole in the tablet machine.

Table 2: The results of the granule inspection test before lubrication.

	Formula 1	Formula 2
Organoleptic	White, flat round, odorless	White, flat round, odorless
Moisture content (%)	1,32 ± 0,1	1,38 ± 0,15

Notes :

- Formula 1 : formula with 4% maltodextrin concentration
- Formula 2 : formula with 6% maltodextrin concentration

Table 3: The results of the granule physical properties test before lubrication.

	Formula 1			**Formula 2**		
	M1	**M2**	**M3**	**M1**	**M2**	**M3**
Flow rate (g/s)	16,2 ± 1,0	33,3 ± 4,5	33,3 ± 0,6	14,3 ± 0,4	27,3 ± 1,2	28,7 ± 9,1
Compresibility index (%)	11,1 ± 0,2	9,6 ± 0,2	9,4 ± 0,2	11,0 ± 1,6	7,7 ± 0,1	7,4 ± 1,2

Notes :

- Formula 1 : formula with 4% maltodextrin concentration
- Formula 2 : formula with 6% maltodextrin concentration
- M1 : initial mixture
- M2 : the mixture of crushed tablets from the first compression
- M3 : the mixture of crushed tablets from the first re-compression

All data were presented in mean ± SD

Compressibility of the Powder

Table 3 presents the results of the compressibility measurement of the powder mixture for the initial mixture (M1) and after compression (M2 and M3). There is an inverse relationship between the binder concentration and percent compressibility index; the higher binder concentration can produce a smaller compressibility index[15,16]. The higher the compressibility index, the better the powder flow properties[17]. When the binder concentration is greater, the binding ability between the constituent powders will be stronger, forming increasingly solid granules with increasing numbers. These granules'form will improve the granule particles'gravity, making the particles more straightforward to arrange themselves, thereby increasing the flow rate[14]. Based on the statistical data analysis results, both types of flow properties testing didn't obtain normally distributed data, so the Kruskal-Wallis test was continued, which resulted in p-values <0.05, which concluded that the data had significant differences.

Powder compressibility tends to decrease with repeated compression. Based on the results obtained in Formula 1, there is a significant difference between the M1 (initial mixture) and M2 (the mixture after 1st compression), as well as between the M1 and M3 (the mixture after 2nd compression). However, there is no significant difference between M2 and M3. In Formula 2, there is a significant difference between the M1 and M2, and between the M1 and M3. Still, there is no significant difference between the M2 and M3. The M1 (initial mixture) has the largest compressibility index. This is due to the flow properties produced previously, which prove that the initial mix has a non-uniform particle shape and is small in size. This condition causes the mixture to fill more voids, resulting in a higher percentage of compressibility index than M2 and M3. M2 and M3 have a smaller compressibility index because the mixture produced after tablet crushing has a more uniform particle shape and size. The tablet-crushing process with constant force and speed supports the formation of a more uniform mixture in terms of particle size and shape. These results indicate that the powder blends, after crushing, have good flow properties. The results of statistical analysis showed that there were significant differences ($p < 0.05$) in compressibility between several treatment groups **(Table 3).**

Physical Characteristic of Tablet

Tablet Appearance

Table 4 presents the results of the tablet appearance observation. In general, tablets from all formulas showed a white color, biconvex shape, and smooth surface. There was no significant difference in appearance between formulas with different concentrations of maltodextrin or different amounts of compression. The tablets in the 1st compression have a greater thickness than the tablets in each repeated compression. This occurs because of changes in the upper and lower punches, which cause the weight and hardness of the resulting tablets to differ in each compression. Changes in the upper and lower punches are made to produce tablets with the desired hardness and weight and to overcome the differences in the response of each mixture when compressed with the same punch reduction.

Weight Uniformity

Table 4 presents the results of the tablet weight uniformity test. All formulas met the Indonesian Pharmacopoeia's requirements for weight uniformity[12]. This can occur because the powder mixture has good flow properties, which allow it to flow more efficiently during compression[18]. Weight variation can be affected by flow properties and particle size distribution[19]. For Formula 1, when there is recompression, it tends to increase the acceptance value (NP), although it is fulfilling the requirements.

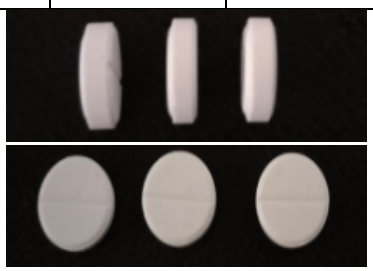
Tablet Hardness

The results of the tablet hardness test are presented in **Table 4**. The hardness of the tablets varied depending on the concentration of maltodextrin and the amount of compression used. The upper punch scale is critical in measuring tablet hardness; the greater the pressure applied, the higher the hardness produced[20]. In this study, the upper punch scale of 4 mm and the lower punch of 7 mm were used because tablets with the appropriate hardness can be produced on this scale.

In general, increased binder concentration tended to increase tablet hardness. In this research, the difference in maltodextrin concentration in the two formulas resulted in significantly different tablet hardness. This

indicates the influence of differences in binder concentration on tablet hardness. Based on the average tablet hardness data, Formula 1, containing a lower binder, produced higher hardness, while Formula 2, containing a higher binder, had lower hardness. Repeated compression also significantly affected the physical properties of calcium lactate tablets. Repeated compression significantly increased the tablet's hardness. This can be explained by increased tablet density due to the additional pressure applied during the second compression[2,9]. Tablet hardness test data were analyzed using the Shapiro-Wilk normality test. The results were $p>0.05$, so the data obtained were normally distributed. The Two-Way Anova test results obtained $p<0.05$ for the concentration variable, meaning there was a significant difference between each concentration on tablet hardness. In contrast, for the compression frequency variable and the interaction between the compression group and the formula, there was no significant difference with $p>0.05$ **(Table 5)**. This shows that when the compression process is repeated twice, statistically, maltodextrin as a binder can still maintain its function when viewed from the tablet hardness parameters.

Table 4: The results of the physical properties test of calcium lactate tablet.

Tablet's Physical Properties ($\bar{X}$ ± SD)	**Tablet**					
	Formula 1			**Formula 2**		
	KI	**K2**	**K3**	**K1**	**K2**	**K3**
Appearance						
Diameter (mm)	13,25	13,2	13,25	13,3	13,1	13,2
Thickness (mm)	4,9	4,45	3,7	4,95	3,9	3,9
Weight average (mg)	590±0,002	610±0,005	606±0,01	599±0,008	601±0,007	584±0,007
Weight uniformity (NP)	1,05	1,80	3,52	3,06	6,24	2,85
Hardness (kg)	6,24 ± 0,18	5,01 ± 0,49	6,15 ± 0,59	4,82 ± 0,34	4,52 ± 0,13	5,05 ± 0,58
Friability (%)	0,891±0,161	2,801±0,051	3,011±0,096	0,971±0,091	2,714±0,250	3,899±0,232
Disintegration time (minutes)	12,77±0,60	18,57±0,39	21,87±0,35	13,60±0,34	19,15±0,43	22,64±0,08

Notes:

- Formula 1 : formula with 4% maltodextrin concentration
- Formula 2 : formula with 6% maltodextrin concentration
- K1 : tablet for the first compression
- K2 : tablet for the second compression/first recompression
- K3 : tablet for the third compression/second recompression
- NP : Acceptance value
- $\bar{x}$: Average data of 3 repetitions
- SD : Standard deviation

Table 5*:*Two-way anova test results of tablet hardness.

Test of Between-Subjects Effects					
Dependent Variable:					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	7.776	5	1.555	3.765	.028
Intercept	505.620	1	505.620	1223.899	.000
Frequency	2.622	2	1.311	3.174	.078
Concentration	4.480	1	4.480	10.844	.006
Frequency * Concentration	.674	2	.337	.816	.465
Error	4.957	12	.413		
Total	518.354	18			
Corrected Total	12.734	17			

a. R Squared = ,611 (Adjusted R Squared = ,448).

Tablet Friability

The results of the tablet friability test are presented in **Table 4**. The friability of the tablets varied depending on the concentration of maltodextrin and the amount of compression used. Increasing the concentration of maltodextrin and the amount of compression tends to decrease the friability of the tablets. All formulas met the friability requirement, which is less than 1%[13]. Increasing the concentration of maltodextrin significantly decreases tablet friability. This is associated with increased tablet hardness, which makes the tablet more resistant to abrasion and mechanical damage during handling and packaging. Repeated compression significantly decreased the tablet's friability. The formulated tablets that use recompression have a higher percentage of friability because they can cause the formation of new particle surfaces. Therefore, the binder's capability to bind interparticles to form tablets was not optimal compared to the initial granule used to form the first pressed tablet. The results of the statistical analysis showed that there were significant differences ($p < 0.05$) in tablet friability between several treatment groups **(Table 6)**.

Tablet Disintegration Time

The results of the tablet disintegration time test are presented in **Table 4**. The tablet disintegration time varied depending on the maltodextrin concentration and the amount of compression used. Increasing the concentration of maltodextrin and the amount of compression increased the tablet disintegration time. This can be explained by the increased tablet hardness, making it difficult for water to penetrate the tablet and slowing down the disintegration process. Tablets with too high hardness may take longer to disintegrate and release the active ingredient, affecting the drug's bioavailability. Therefore, optimizing the maltodextrin concentration is important to balance tablet hardness and appropriate disintegration time. The results of statistical analysis showed that there was a significant difference ($p < 0.05$) in tablet disintegration time between several treatment groups **(Table 7)**.

Table 6: Two-way anova test results of tablet friability.

Test of Between-Subjects Effects					
Dependent Variable:					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	21.592[a]	5	4.318	159.352	.000
Intercept	102.050	1	102.050	3765.724	.000
Frequency	20.387	2	10.194	376.152	.000
Concentration	.389	1	.389	14.342	.003
Frequency * Concentration	.816	2	.408	15.057	.001
Error	.325	12	.027		
Total	123.967	18			
Corrected Total	21.917	17			

a. R Squared = ,976 (Adjusted R Squared = ,966).

Table 7: Two-way anova test results of tablet disintegration.

Test of Between-Subjects Effects					
Dependent Variable:					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	254.577	5	50.915	325.165	.000
Intercept	5897.342	1	5897.342	37662.642	.000
Frequency	252.144	2	126.072	805.144	.000
Concentration	2.383	1	2.383	15.222	.002
Frequency * Concentration	.050	2	.025	.159	.855
Error	1.879	12	.157		
Total	6153.798	18			
Corrected Total	256.456	17			

a. R Squared = ,993 (Adjusted R Squared = ,990).

Conclusion

1) Repeated compression frequency affects the physical properties of the mixture (flow properties, compressibility) and the physical properties of the tablet, such as fragility and disintegration time of 300 mg calcium lactate tablets. However, repeated compression frequency does not affect tablet hardness.
2) There is an effect of maltodextrin concentration as a binder on the physical properties of the mixture (flow properties and compressibility) and the physical properties of 300 mg calcium lactate tablets (fragility, and disintegration time). However, maltodextrin concentration does not affect the compressibility of the mixture and tablet hardness.
3) There is a relationship between repeated compression frequency and maltodextrin concentration levels on the physical properties of the mixture (flow properties, compressibility) and the physical properties of the tablet, as shown by the fragility of 300 mg calcium lactate tablets.

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نشرة العلوم الصيدلية
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أثر تكرار الضغط وتركيز المالتودكسترين كمواد رابطة على الجودة الفيزيائية لأقراص لاكتات الكالسيوم

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الهدف

تهدف هذه الدراسة إلى تحديد تأثير كلٍّ من تكرار الضغط واختلاف تراكيز المالتودكسترين على الخصائص الفيزيائية لمزيج الحبيبات وعلى الخصائص الفيزيائية لأقراص لاكتات الكالسيوم، وكذلك لتوضيح العلاقة بين تكرار الضغط وتركيز المالتودكسترين مع هذه الخصائص.

المواد والطرق

جرى ضغط لاكتات الكالسيوم في هيئة أقراص باستخدام تراكيز مختلفة من المالتودكسترين كمادة رابطة، مع إعادة الضغط بشكل متكرر .تم تحضير الأقراص بطريقة التحبيب الرطب .جرى اختبار الخصائص الفيزيائية لمزيج المسحوق) قابلية الجريان، والانضغاطية (إضافة إلى الخصائص الفيزيائية للأقراص) الفحص الحسي، توحيد الوزن، محتوى المادة الفعّالة، الصلابة، الهشاشة، وزمن التفكك).

النتائج

أظهرت النتائج أن اختلاف تراكيز المالتودكسترين وتكرار الضغط أثّرا بشكل ملحوظ على بعض الخصائص الفيزيائية لكل من مسحوق لاكتات الكالسيوم والأقراص .كما بيّن التحليل الإحصائي وجود فروق معنوية في معدل الجريان، والانضغاطية، وصلابة الأقراص، والهشاشة، وزمن التفكك.

الاستنتاج

لا يؤثر تكرار الضغط على صلابة الأقراص؛ كما أن تركيز المالتودكسترين لا يؤثر على كل من انضغاطية المزيج وصلابة الأقراص.