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Research Article

Optimization of Temperature and Drying Time in the Process of Making Paracetamol Tablets Using PVP K-25 as a Binder

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ABSTRACT

Wet granulation is a crucial technique in tablet manufacturing since it improves the physical properties of the formulation, such as the flowability and compressibility of paracetamol. One of the critical stages in this process is drying the granules using oven heating. This study aims to optimize the drying temperature and time and evaluate their effects on the physical properties of paracetamol granules and tablets. PVP K-25 was selected as a binder due to its ability to enhance tablet compactness. A full factorial experimental design was used with two factors and two levels, optimizing drying temperature (°C) and drying time (hours) based on the physical properties of granules and tablets. Data were analyzed using ANOVA and Design Expert 13 software to determine the optimal formulation. The results showed that drying temperature, drying time, and their interaction significantly affected the physical characteristics of granules and tablets. The optimal formulation was achieved at 55°C for 4 hours. Formula A (40°C, 6 hours) and Formula B (60°C, 3 hours) demonstrated the best results in producing tablets with desirable physical properties. Thus, optimizing drying temperature and time can enhance the quality of paracetamol granules and tablets.

INTRODUCTION

Oral drug administration is the most widely used method in clinical practice, primarily in the form of tablets. As a solid dosage form, tablets must remain visually and functionally intact. However, despite technological advancements, tablet defect during production remains a challenge and may even worsen due to the complexity of the manufacturing process and the stringent quality standards required (Ardiansyah *et al*., 2022; Zaman & Sopyan, 2020). Tablet manufacturing can be done using three main methods: wet granulation, dry granulation, and direct compression. In this study, the wet granulation method was used to produce paracetamol tablets because it enhances compactibility and flow properties with the help of a binder (Abimanyu *et al*., 2023; Sudarsono *et al*., 2021). The tablet formulation must consider excipients such as fillers, disintegrants, binders, lubricants, and glidants. One commonly used binder is polyvinylpyrrolidone (PVP), specifically PVP K-25, due to its good flow properties, ability to produce compact tablets, and inert and stable nature. PVP K-25 also has high solubility in various solvents and good compatibility with many types of drugs (Direktorat Jenderal Kefarmasian dan Alat Kesehatan, 2020; Cahyani *et al.,* 2023).

In the wet granulation method, the drying process determines the moisture content of the granules, which affects tablet hardness. The drier the tablet, the lower its porosity, resulting in stronger interparticle bonds. Longer drying times and higher temperatures increase water evaporation, producing drier granules, but this can also increase tablet friability (Maskuriah *et al*., 2021).

METHODS

Materials

Paracetamol (active ingredient), polyvinylpyrrolidone PVP K-25 (binder), magnesium stearate and talcum (lubricants), corn starch (disintegrant), and distilled water (solvent).

Equipment

Glassware, analytical balance (OHAUS Pioneer PA213), mixer (Erweka AR-401), sieves No. 12 and 14 (Patraproduk), oven (MEMERT BE 500), moisture balance (Kern MLS 50-3C), flowability tester (Erweka AR 401), volumenometer (HY-100B), rotary tablet press (Shanghai Develop Machinery ZP-5B), caliper 0.05mm (NRT-PRO), attrition tester (ATMI), hardness tester (Pharmas Test PTB 302), and disintegration tester (Develop BJ-2).

Preparation of PVP K-25 solution

This study used one concentration as a binder, which was 3% w/w. The solution was made by dissolving PVP K-25 powder in aquadest as a solvent.

Wet granulation method

Paracetamol, lactose, magnesium stearate, talc, and corn starch are weighed according to the specified amounts (Table 1). Paracetamol and lactose powders are mixed using a mixer until homogeneous. The mixture is transferred to a plastic tray, and the PVP K-25 solution is gradually added as a wetting agent until a damp granulation mass is formed. Then, a small amount of corn starch is added to the granulation mixture and stirred until homogeneous. The granulation mass is sieved through a 12-mesh sieve, and the weight of the wet granules is measured. The granules are then dried at 40°C and 60°C for 3 and 6 hours using an oven.

Moisture content

After drying, the granules undergo moisture content testing using a moisture balance with a sample weighing 1 gram. Moisture content can be calculated using the following formula:

$$\%MC = \frac{weight\ of\ wet\ granules - weight\ of\ dry\ granules}{weight\ of\ wet\ granules}\ x\ 100\%$$

The optimal moisture content for granules is 1%–5% (Mariyani *et al.,* 2016). The dried granules are then sieved again using a 14-mesh sieve.

Lubrication method

The dried granules are placed into a mixer, and the remaining corn starch is added and mixed. Then, magnesium stearate and talcum are incorporated into the mixture and blended until homogeneous.

Flow time

Granule flow time testing is performed using a flowability tester. A hundred grams of granules are placed into the funnel, and the flow time is measured until all the granules pass through. The result is recorded in seconds, with the standard ≤10 seconds (Noval *et al*., 2021).

Angle of repose

The angle of repose test is conducted by weighing 100 grams of granules and placing them into a flow funnel. As the granules flow, the angle of repose is determined by measuring the steepness of the pile formed. The angle of repose is determined using a formula (United States Pharmacopeia Convention, 2024a) :

$$\text{Tan } \alpha = \frac{h}{r}$$

The angle of repose is classified into several levels: excellent (25-30°), good (31-35°), fair (36-40°), passable (41-45°), poor (46-55°), very poor (56-65°), and extremely poor (>66°) (Taylor and Aulton, 2022).

Table 1. Formulation, Temperature, and Granule Drying Time of Paracetamol Tablets

Ingredients	Formula (mg/tablet)			
	F1	Fa	Fb	Fab
Paracetamol	500	500	500	500
Lactose	320	320	320	320
PVP K-25 3%	3.6	3.6	3.6	3.6
Corn starch	20	20	20	20
Talc	6.5	6.5	6.5	6.5
Magnesium stearate	6.5	6.5	6.5	6.5
Temperature for drying (°C)	40	60	40	60
Drying time (hours)	3	3	6	6

Compressibility index

The compressibility index test for granules was conducted using a volumeter. First, 40 grams of granules were weighed and placed into a 100 mL graduated cylinder, and the initial volume of the granules was recorded. The graduated cylinder was then mounted on the volumeter and tapped 500 times, after which the final volume of the granules was recorded. A good compressibility index for granules ranges from 5-16% or <20% and an optimal Hausner ratio falls between 1.12-1.18. The compressibility index is calculated using the following equation:

$$Compressibility\ Index = 100\ x\ \left(\frac{V_1 - V_2}{V_1}\right)$$

Notes:
V1 : Initial volume
V2 : Final tapped volume

Tablet Manufacturing

The mixed granules are then compressed into tablets using a single-punch tablet machine. After compression, the physical properties of the tablets are tested to evaluate their quality.

Evaluation of Granule Characteristic
Organoleptic test

Organoleptic testing is the initial step in achieving maximum objectivity in tablet evaluation. This test involves visually observing the tablets using human senses, including color, odor, shape, and surface texture (Syukri, 2018].

Weight Variation Test

Ten tablets are individually weighed with precision. The active ingredient content in each tablet is determined and expressed as a percentage of the labeled amount. The obtained assay results from each tablet are then used to calculate the acceptance value according to the established criteria. The acceptance value for weight uniformity is met if L1 = 15.0 and L2 = 25.0 (Direktorat Jenderal Kefarmasian dan Alat Kesehatan, 2020).

Tablet hardness test

Using a hardness tester, tablet hardness testing is used as a reference to determine whether tablet meets the required standards. Ten tablets are used as test samples, each placed in the center of the hardness tester in a vertical position. The device then applies pressure until the tablet breaks. The acceptance criterion for tablet hardness is 4-8 kg for oral tablets (Rori *et al*., 2016).

Tablet friability test

Friability, a parameter used to measure the tablet's surface resistance to friction during packaging and transportation, is measured using a friabilator. Ten tablets, cleaned of dust, are weighed and recorded before being placed in the testing device, which operates at a speed of 25 rpm for 4 minutes. The tablets are then cleaned and reweighed to determine the weight loss. The acceptance criterion for tablet friability is less than 1% weight loss from the total tablet mass (United States Pharmacopeia Convention, 2024a). The acceptance results are calculated using the formula in the following equation:

$$F = \frac{W_1 - W_2}{W_1}\ x\ 100\%$$

Notes:
F : Friability percentage
W1 : Initial tablet weight
W2 : Final tablet weight

Disintegration time test

The disintegration test is an essential tablet evaluation with specific requirements to ensure rapid therapeutic effects. The test is conducted using a disintegration tester, where six tablets are placed in each tube of the device. Water at a temperature of 37°±2°C is used as the medium, and the testing duration is 15 minutes. At the end of the test, all tablets are observed to ensure complete disintegration, and the disintegration time is recorded. If one or two tablets fail to disintegrate completely, the test is repeated with an additional 12 tablets. The disintegration time requirement is met if at least 16 out of 18 tested tablets disintegrate. The acceptance criterion for uncoated tablets is a disintegration time of less than or equal to 15 minutes (Direktorat Jenderal Kefarmasian dan Alat Kesehatan, 2020).

Data Analysis

The data were analyzed using the Shapiro-Wilk test in SPSS 23 (IBM Corp., Chicago, USA). Based on the data, the factorial design equation was calculated using the formula ($Y = \beta_0 + \beta_1.X_A + \beta_2.X_B + \beta_{12}.X_A.X_B$), where Y represents the observed response, X_A and X_B represent the levels, and β_0, β_1, β_2, and β_{12} are coefficients. The goal is to determine the optimal formulation of drying temperature and time for granules. Data with a normal distribution were then analyzed using Design Expert 13 (free trial) to obtain

ANOVA values and determine the optimal formulation.

RESULTS AND DISCUSSION

A total of 720 respondents participated in our Table 2 presents the results of the physical properties test of paracetamol granules. Analysis using Design Expert software with the factorial design method indicates that the physical properties of paracetamol granules and tablets were obtained under optimal drying conditions. The contour plot in Figure 1 (a), (b), (c) and (d) illustrates the relationship between drying time and temperature on the physical properties of paracetamol granules.

Table 2. Results of Evaluation of Paracetamol Granule Characteristic

Granule Quality Control	F1	Fa	Fb	Fab
Moisture Content (%)	4.931 ± 0.003	2.430 ± 0.0045	3.267 ± 0.0030	1.107 ± 0.0046
Flow Time (s)	3.8 ± 0.7	2.43 ± 0.9	2.9 ± 0.7	1.56 ± 0.5
Angle of Repose (°)	34.71 ± 1.47	30.39 ± 1.07	31.40 ± 1.14	27.45 ± 1.80
Compressibility index	9.907 ± 3.214	7.508 ± 2.516	8.411 ± 2.516	6.911 ± 3.055

Note for temperature and drying time respectively:
Formula 1: 40°C and 3 hours.
Formula a: 60°C and 3 hours.
Formula b: 40°C and 6 hours.
Formula ab: 60°C and 6 hours.

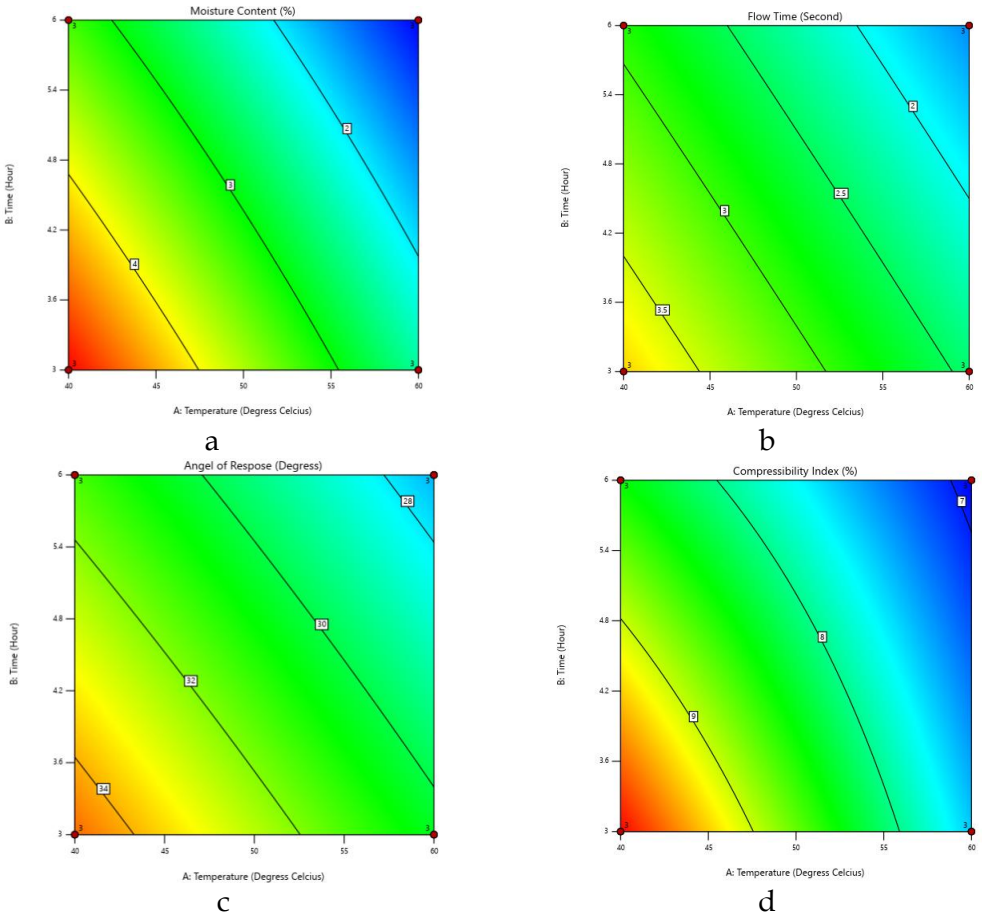

Figure 1. Contour plot of granule test response (a) moisture content; (b) powder flow; (c) angle of repose; and (d) compressibility index.

Table 3. Effect of Temperature, Time, and Interaction on Moisture Content

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	-2.3305	70.6282	<0.0001	<0.0001 (Significant)
Time	-1.4935	28.9932	<0.0001	
Interaction	0.1705	0.3780	<0.0001	

Table 4. Effect of Temperature, Time, and Interaction on Powder Flow

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	-1.35	45.935	0.0114	0.0293 (Significant)
Time	-0.88	19.666	0.0649	
Interaction	0.015	0.007	0.9688	

The Effect of Temperature and Drying Time on the Physical Properties of Granule

Moisture content

Table 2 shows that all formulations meet the moisture content requirement of 1-5% (Noval, dkk., 2021). Formula ab has the lowest moisture content (1.107%) compared to formula a, b and formula 1 (respectively 2.430%, 3.267% and 4.931%) due to the higher drying temperature of 60ºC. Figure 1(a) supports this finding with a contour plot, where red shading indicates high moisture content and blue shading indicates low moisture content. Higher temperatures accelerate the evaporation of the binding liquid during the drying process. The factorial equation predicts moisture content using $Y = 12.279 - 0.142100X_A - 0.7818X_B + 0.00568X_AX_B$, where Y represents the moisture content response, X_A represents temperature, X_B represents time, and X_AX_B represents the interaction between temperature and time.

The analysis results show that all factors significantly influence the moisture content (p-value < 0.0001). Temperature is the most dominant factor with a contribution of 70.6282%, followed by drying time at 28.9932%. Although the interaction between temperature and drying time is statistically significant, its contribution is very small (0.3780%), so its influence can be practically ignored. The negative effect values for temperature and drying time indicate that increasing these two factors tends to decrease the moisture content (Table 3).

Flow time

The fastest flow time value was found in Fab (1.56±0.5 s), followed by Fa (2.43±0.9 s), then Fb (2.9±0.7 s), and the slowest in F1 (3.8±0.7 s). This shows that Fab granules have the best flow properties, while F1 has the least good flow properties.

According to Table 4, the analysis results show that only the temperature factor has a significant effect on the powder flow (*p*-value = 0.0114 < 0.05), with a contribution of 45.935%. The time factor, although having a relatively moderate contribution (19.666%), does not show statistical significance (*p*-value = 0.0649), so its effect on the powder flow is inconsistent. Meanwhile, the interaction between temperature and drying time has no significant effect (*p*-value = 0.9688) with a very small contribution (0.007%). Thus, the powder flow variation is mainly controlled by temperature changes.

Angle of repose

The smallest angle of repose value was found in Fab (27.45±1.80°), followed by Fa (30.39±1.07°), then Fb (31.40±1.14°), and the largest in F1 (34.71±1.47°). This result indicates that Fab granules have the best flow (freer), while F1 tends to be more cohesive.

Based on Table 5, the analysis results showed that temperature (*p* = 0.0009) and drying time (*p* = 0.0049) significantly influenced the angle of repose, contributing 53.1982% and 30.3351%, respectively. Meanwhile, the interaction between temperature and drying time was not significant (*p* = 0.8254) and had a very small contribution (0.1063%). The negative effect values for both main factors indicated that increasing temperature and drying time tended to decrease the angle of repose value. Thus, the angle of repose variation was primarily controlled by temperature and drying time factors independently.

Table 5. Effect of Temperature, Time, and Interaction on Angle of Repose

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	-4.135	53.1982	0.0009	0.0016 (Significant)
Time	-3.125	30.3351	0.0049	
Interaction	0.185	0.1063	0.8254	

Table 6. Effect of Temperature, Time, and Interaction on Compressibility Index

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	-1.949	74.564	<0.0001	<0.0001 (Significant)
Time	-1.047	21.491	<0.0001	
Interaction	0.449	3.960	<0.0001	

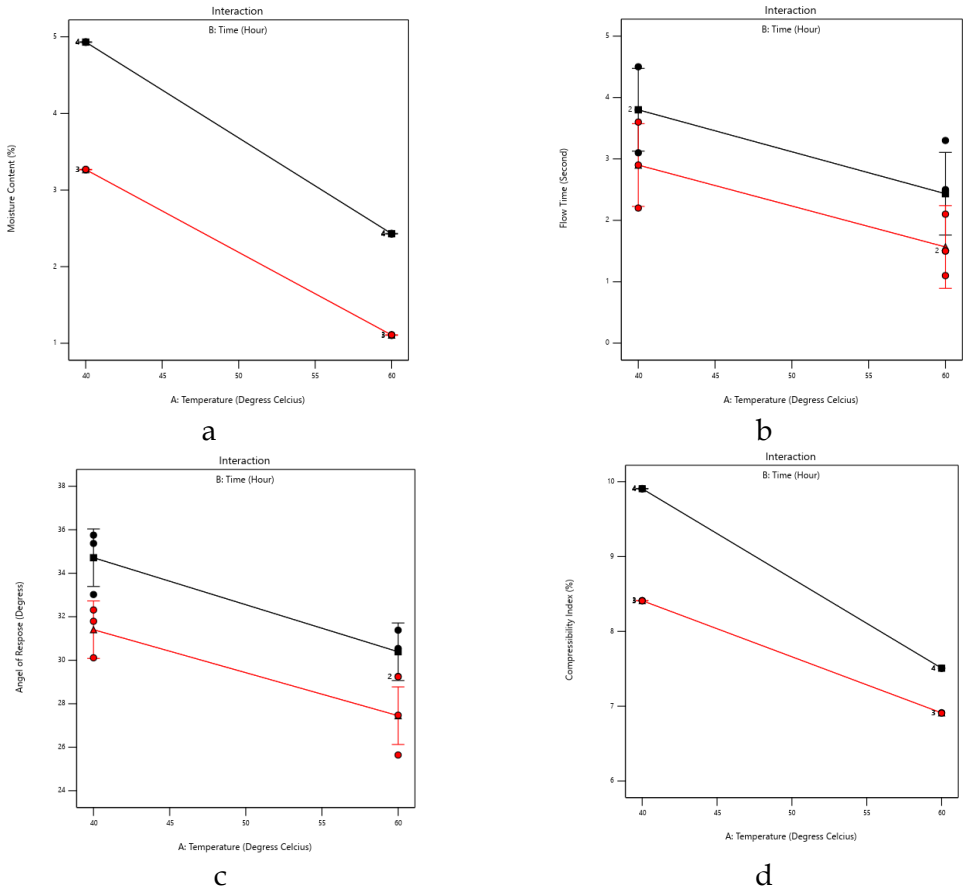

Figure 2. Interaction of Drying Temperature and Time on (a) Moisture Content; (b) Powder Flow Response; (c) Angle of Repose Response; and (d) Compressibility Index Response.

Compressibility index

The lowest compressibility index value was found in Fab (6.911±3.055%), followed by Fa (7.508±2.516%), then Fb (8.411±2.516%), and the highest was in F1 (9.907±3.214%). This indicates that Fab granules have the best flow and compaction capabilities, while F1 has the least good.

According to Table 6, the analysis results showed that all factors significantly influenced the response (*p*-value < 0.0001). However, based on the percentage contribution, temperature was the most dominant factor in explaining response variability (74.564%), followed by time (21.491%), while the interaction effect was relatively small (3.960%). This indicates that

compressibility index is primarily controlled by temperature of drying.

Figure 2(a) illustrates the interaction between temperature and time by two non-parallel lines, one red and one black. The interaction is minimal since the lines do not intersect or touch. The graph indicates that higher temperatures and longer drying times reduce granule moisture content (Hiremath *et al*., 2019 ; Elisabeth *et al*.., 2018). Based on the graph in Figure 2(b), the non-parallel red and black lines represent an interaction between temperature and drying time. Increasing temperature from 40°C to 60°C reduces granule flow time, indicating improved flow properties (United States Pharmacopeia Convention, 2024a; Elisabeth *et al*., 2018). Figure 2(c) shows that as the drying temperature increases from 40°C to 60°C, the angle of repose of the granules tends to decrease, both at 3 hours (black line) and 6 hours (red line). This decrease in the angle of repose suggests that higher temperatures enhance granule flow properties, making the granules easier to flow at higher temperatures (Elisabeth *et al*.., 2018). Figure 2(d) demonstrates that increasing the temperature from 40°C to 60°C significantly reduces the compressibility index. The black line represents a drying time of 3 hours, while the red line represents a drying time of 6 hours. Granules are more sensitive to temperature at shorter drying times, whereas the effect of temperature becomes more moderate with longer drying times (Cahyani *et al*., 2023).

The Effect of Temperature and Drying Time on the Physical Properties of Tablet

Tablet friability

All tablet formulas meet the friability requirements, which is less than 1% (United States Pharmacopeia Convention, 2024b). Tablets with fragility values respectively from low to high are formula ab (0.55%), a (0.66%), b (0.74%) and the highest is formula 1 (0.85%).

Based on Table 8, the analysis results showed that temperature (p = 0.0001) and drying time (p = 0.0053) significantly influenced the tablet friability, contributing 68.5911% and 20.1717%, respectively. Meanwhile, the interaction between temperature and drying time was not significant (p = 0.9952) and had a very small contribution (≈0.00005%). The negative effect values for both main factors indicated that increasing temperature and drying time tended to decrease the tablet friability. Thus, the response variation was primarily controlled by temperature and time factors independently.

Tablet hardness

Table 7 indicates that all formulations meet the weight uniformity acceptance criteria within the range of 4-8 kg (Rori, dkk., 2016). Formula a and b exhibit the highest hardness, measuring 5.58 kg and 5.71 kg, respectively, while formula 1 and b show hardness values of 3.73 kg and 5.57 kg. The greater hardness observed in formula a and b is attributed to the drying temperature applied. Figure 3(a), (b), and (c) presents a contour plot of tablet friability, hardness and disintegrating time respectively, where red shading represents higher hardness, and blue shading represents lower hardness. Higher drying temperatures and longer drying times reduce the moisture content in granules, enhancing particle bonding during compression and leading to harder tablets. Conversely, excessive moisture can result in brittle tablets, while insufficient moisture reduces cohesion, making tablets prone to cracking and breaking (Maskuriah *et al*., 2021). The factorial equation predicting tablet hardness is represented as: $Y=5.90+0.191X_A+1.98X_B-0.0331X_AX_B$ where Y is the tablet hardness response, X_A denotes temperature, X_B represents drying time, and X_AX_B accounts for the interaction between temperature and time.

Table 7. Results of Evaluation of Paracetamol Tablet Characteristics

Parameter	F1	Fa	Fb	Fab
Weight Variation Test NP	2.93	6.66	7.03	7.94
Tablet Hardness (kg) $\bar{X}$ ± SD	3.73±0.48	5.58±0.40	5.71±0.53	5.57±0.60
Tablet Friability (%) $\bar{X}$ ± SD	0.85±0.05	0.66±0.03	0.74±0.03	0.55±0.05
Disintegration Time (min) $\bar{X}$ ± SD	2±1	6.67±1.52	3±1	7.33±1.52

SD, standard deviation.

Table 8. Effect of Temperature, Time, and Interaction on Tablet Friability

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	-0.1872	68.5911	0.0001	0.0004 (Significant)
Time	-0.1015	20.1717	0.0053	
Interaction	0.0002	5.43886E-05	0.9952	

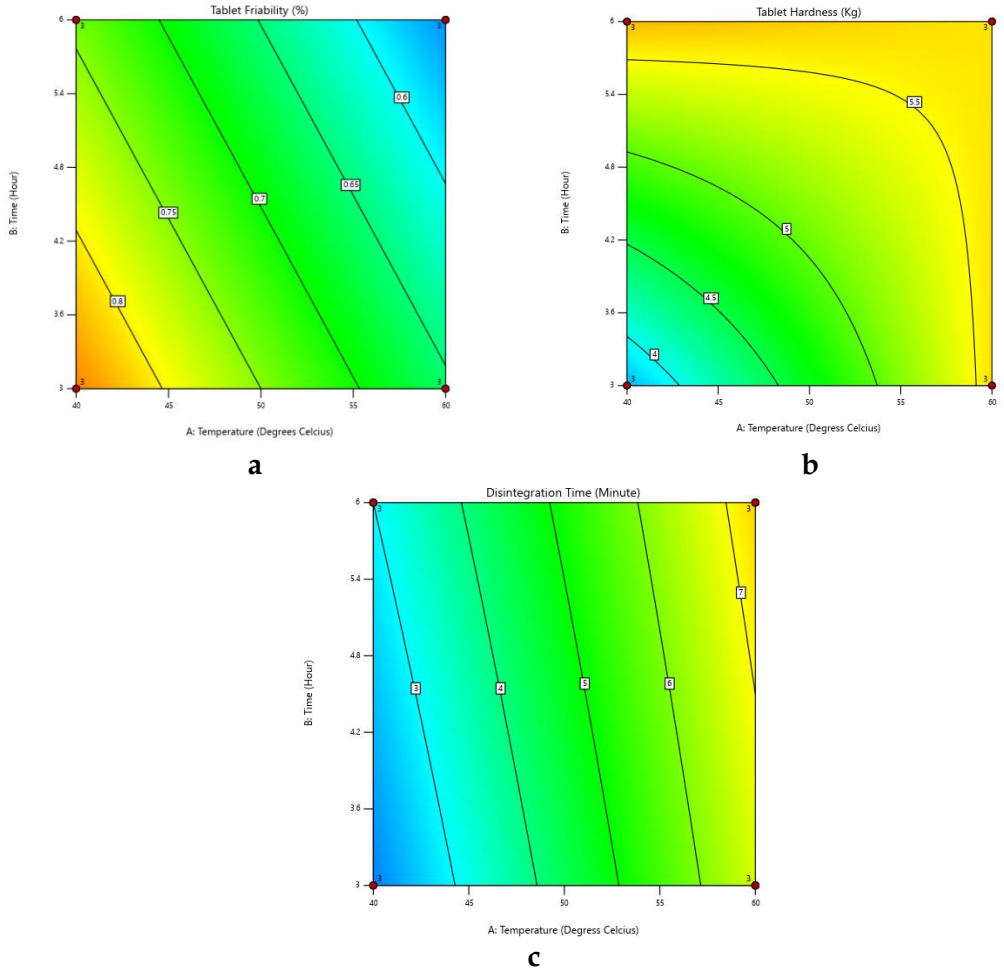

Figure 3. Contour Plot of Tablets Test Response (a) Hardness Tester; (b) Flowability Tester; and (c) Disintegration Time.

According to Table 9, temperature, drying time, and their interaction significantly affect tablet hardness, with *p*-values <0.05 for each factor. Temperature has an effect value of 0.085 and contributes 21.61% to tablet hardness, whereas drying time has an effect value of 0.98 with a contribution of 28.50%. Drying time has a more significant influence compared to temperature. These results indicate that the combination of both factors has a more significant impact than each factor individually.

Tablet disintegration time

Based on Table 7, tablets with disintegration time respectively from low to high are formula 1 (2minutes), b (3 minutes), a (6.67 minutes) and the highest is formula ab (7.33 minutes). Table 10 shows that temperature significantly affects tablet disintegration time, with a p-value of 0.0003 and a contribution of 79.67%. Drying time has a minor influence (2.73%) and is not statistically significant (*p*-value 0.2960). Meanwhile, the interaction between temperature and time contributes 0.11% with a *p*-value of 0.8287, which is not statistically significant. Therefore,

Table 10. Effect of Temperature, Time, and Interaction on Tablet Disintegration Time

Factor	Effect Value	%Contribution	*p*-value	*p*-value Equation
Temperature	4.5	79.6721	0.0003	0.0021 (Significant)
Time	0.8333	2.7322	0.2960	
Interaction	-0.1666	0.1092	0.8287	

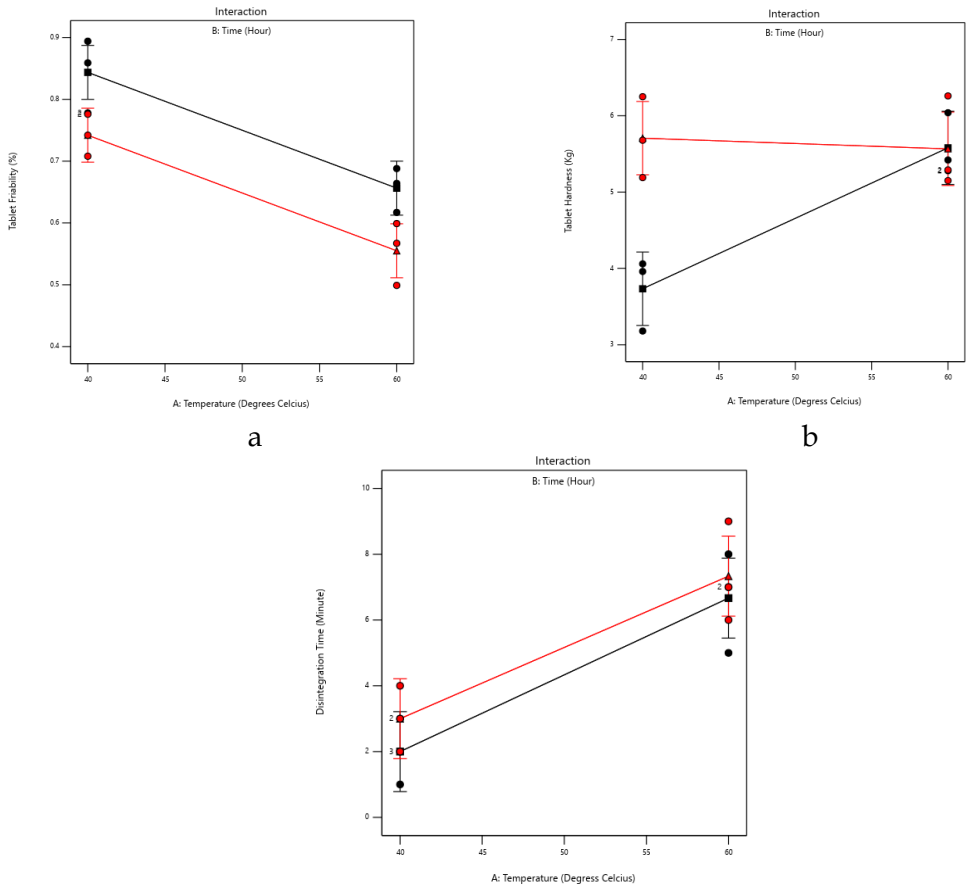

Figure 4. Interaction of Drying Temperature and Time on (a) Friability Tester; (b) Hardness Tester; and (c) Disintegration Time.

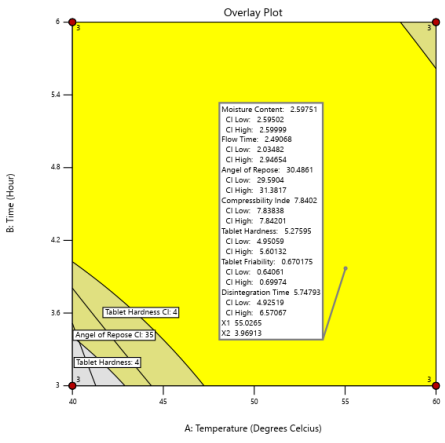

Figure 5. Superimposed Contour Plot.

temperature is the primary factor influencing tablet disintegration time.

Figure 4(a) shows the interaction between temperature and drying time, depicted by black and red lines that are not parallel. Increasing in temperature from 40°C to 60°C reduces tablet friability, indicating improved flow properties. Figure 4(b) shows that the interaction between temperature and drying time is represented by black and red lines that are not parallel and intersect at high temperatures. At low temperatures (40°C), tablet hardness significantly increases with longer drying times. Conversely, tablet hardness decreases at high temperatures (60°C) when the drying time is extended to 6 hours, indicating an over-drying effect that makes granules brittle and increases the risk of cracking and chipping. The interaction between temperature and time is statistically significant. Figure 4(c) shows the interaction between temperature and drying time with black and red lines that are not parallel. The interaction is minimal, as the lines do not intersect or touch, indicating that both factors work independently, with temperature being the dominant factor. Lower temperatures accelerate tablet disintegration, while higher temperatures result in longer disintegration times. Figure 5 shows the superimposed contour plot with the optimal drying temperature marked by the yellow area indicating an optimal response for the physical properties of granules and tablets.

CONCLUSIONS

Optimization of drying temperature and time in the production of paracetamol tablets using wet granulation with Polyvinylpyrrolidone K-25 shows a significant effect on the physical properties of granules and tablets. There are optimal responses for the physical properties of granules and tablets that meet quality standards. The optimal formulation was achieved at 55°C for 4 hours. Formula A (40°C, 6 hours) and Formula B (60°C, 3 hours) demonstrated the best results in producing tablets with desirable physical properties.

CONFLICT OF INTEREST

The authors declared no conflict of interest.

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