

Research on the preparation and evaluation of the effects of excipients on the properties of tablets containing curcumin spray-dried powder

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ABSTRACT

Abstract—The foundational purpose of this pharmaceutical research was the systematic optimization of the critical excipient concentrations required for the preparation of compressed tablets containing curcumin powder, previously processed via spray-drying to enhance its dissolution characteristics. The optimization strategy employed was highly rigorous, leveraging a Central Composite Design (CCD) fully integrated with Response Surface Methodology (RSM). This design of experiments approach permitted the efficient mapping of the design space and the identification of significant factor interactions. All statistical computations and modeling were performed utilizing the specialized Design Expert 13 software suite, necessitating the execution of 19 distinct experimental batches. Three formulation components were selected as independent variables: the percentage mass fraction of the lubricant, magnesium stearate (%), the percentage mass fraction of the superdisintegrant, crospovidone (%), and the percentage mass fraction of the binder, PVP-K30 (%). The primary dependent variable rigorously investigated was the percentage of curcumin dissolved at the 45-minute time point, a standard metric correlating with in vivo release performance. Following the statistical modeling phase, the generated theoretical optimal parameters were subjected to meticulous experimental verification. The quality profile of the resulting optimized tablets was comprehensively evaluated against multiple metrics, including disintegration time, tablet mass uniformity, content uniformity, and the dissolution rate. The experimental outcomes confirmed that the optimal process parameters were defined by a magnesium stearate content of 1.083%, a crospovidone content of 3.106%, and a PVP-K30 content of 2.000%. The tablets fabricated using this precise optimized composition yielded dissolution results that were remarkably consistent with the software's predictions. Furthermore, they demonstrated substantially improved performance, achieving a 120% and 140% higher dissolution efficiency compared to the spray-dried powder and the raw curcumin starting material, respectively. Critically, the optimized tablets successfully adhered to all required stringent quality criteria for solid oral dosage forms as stipulated within the Vietnamese Pharmacopoeia V. In summation, this study successfully concluded the laboratory-scale optimization of a curcumin spray-dried powder tablet formulation, thereby establishing a validated, robust foundation for the crucial next step of scaling up toward industrial-level manufacturing.

Key words: curcumin, spray-drying, tablets, excipients, response surface method (RSM), central composite design (CCD)

INTRODUCTION

The term “curcumin” refers to a class of molecules called curcuminoids that are generated from turmeric (*Curcuma longa* L.). Of these, curcumin I makes up around 77%, curcumin II (demethoxycurcumin) approximately 17%, and curcumin III (bisdemethoxycurcumin) approximately 3%. Curcumin I is the primary biologically active component among them¹⁻³. Curcumin is a crystalline powder with an orange-yellow color that is soluble in methanol, ethanol, dimethyl sulfoxide, and acetone but insoluble in water at both acidic and neutral pH levels. Curcumin's max-

imum absorption (λ_{max}) in methanol is measured at 430 nm. Curcumin has a distribution coefficient of 3.2 and a water solubility of 0.6 $\mu\text{g/mL}$, respectively^{4,5}. Curcumin breaks down in less than 30 minutes and is less stable when exposed to light or alkaline conditions⁶.

The pharmacological properties of curcumin have been extensively researched. The findings demonstrate that curcumin possesses potent and varied biological properties, such as the ability to treat certain conditions like diabetes and cardiovascular disease and to have anti-inflammatory, anti-cancer, anticoagulant, antibacterial, antifungal, and antiviral proper-

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ties^{2,7-10}.

Despite its potential for wide application, curcumin exhibits low oral bioavailability. This limitation stems from its inefficient absorption through the gastrointestinal (GI) tract and rapid, extensive metabolism within the liver and intestines, which leads to unconjugated curcumin being detected in the blood only at submicromolar concentrations after ingestion.¹¹⁻¹³ Comparative pharmacokinetic analysis in rats demonstrated a significant disparity between administration routes. Following intravenous injection of 10 mg/kg of curcumin, the peak serum concentration reached 0.36 $\mu\text{g/mL}$ at the 45 minute mark. In stark contrast, an extremely high oral dosage of 500 mg/kg yielded only 0.06 $\mu\text{g/mL}$. Even increasing the oral dose to 1 g/kg resulted in a maximum serum level of a mere 0.5 $\mu\text{g/mL}$ after 45 minutes.^{11,14} In trials utilizing human subjects, serum analysis showed that curcumin remained undetectable after a single oral dose of either 0.5 g or 10 g. An exception was noted in one out of three subjects given the 10 g dose, who presented with transient serum concentrations ranging from 0.03 to 0.06 $\mu\text{g/mL}$ at the 1h, 2h, and 4h post-dosing intervals.

Curcumin's low bioavailability is commonly reported across multiple pharmacokinetic studies, with the primary underlying factors identified as poor solubility, expedited metabolism, and rapid clearance from the system¹⁵. Therefore, to improve the durability and solubility of curcumin, this study investigated the mixing of curcumin with excipients such as lubricant, disintegrant, and binder excipients in forming tablets to improve the solubility of curcumin. Central Composite Design (CCD) was implemented as the experimental strategy, which was subsequently analyzed using Response Surface Methodology (RSM)¹⁶ to optimize the objective function for curcumin tablets. The three parameters that are mentioned are the contents of the binder (PVP-K30), disintegrant (crospovidone), and lubricant (magnesium stearate).

MATERIALS AND METHODS

Preparation of curcumin suspension and curcumin powder by spray-drying method

Two separate solutions were meticulously prepared for the experiment. First, 30 mL of 96° ethanol (Nguyen Quan Ltd., Vietnam) was combined with 2 g of curcumin powder (95% pure, procured from Apollo Ingredients Ltd., India). Following this, the second mixture was constituted by dispersing 12 g of

gum Arabic (Willy Benecke GmbH, Hamburg, Germany) into approximately 100 mL of distilled water. The resulting solutions were then slowly introduced into water until the final reconstituted volume reached 1000 mL. Next, the mixture was pre-homogenized using a SY high-speed homogenizer for 40 minutes at a speed of 8400 rpm¹⁷. Subsequently, the resulting solution underwent homogenization utilizing a high-pressure homogenizer (GEA Lab Homogenizer TwinPANDA 400). This process was executed at a consistent pressure of 120 bar over a single pass.

After the suspension containing small-sized curcumin particles was formed, the system was subjected to spray drying to create powder for mixing with excipients to form tablets. Besides, the spray-dried powder was also easy to preserve and avoid changes in physicochemical properties over time. Curcumin was spray-dried with lactose as a carrier by using Lab Spray Dryer ASD-2000SG. The process was executed under constant operating conditions to ensure consistency. These fixed parameters were: intake air temperature 150 °C, drying air flow 300 m³/h, feed flow rate 0.9 L/h, compressed air pressure 2 bar, and the curcumin-to-carrier ratio 1:4.¹⁸

Content measurement of curcumin in spray-drying powder

Curcumin content in the prepared powder was determined using absorption spectroscopy via a Helios Epsilon instrument. The sample preparation process required that 0.05 g of powder be initially dissolved in 2 mL of water at 60 °C. This was followed by the addition of 6 mL of 96° ethanol and a 10-minute sonication period. Dilution to an appropriate ratio was performed if the sample concentration exceeded the measurable range.

Response surface methodology optimization of tablet forming process

To establish the connection between the studied parameters and the designated objective function, Response Surface Methodology (RSM) integrated with a Central Composite Design (CCD) was utilized following the data collection phase. The specific impact of each parameter was quantified through an examination of the regression equation's variable coefficients (Table 1). The mathematical representation using encoded variables is given as:

$$Y = B_0 + \sum B_i X_i + \sum B_{ii} X_i^2 + \sum B_{ij} X_i X_j$$

Within the regression equation, Y corresponds to the predicted outcome, and X_i are the encoded variables. The term B_0 is the intercept coefficient, while B_i , B_{ii} , and B_{ij} represent the linear, quadratic, and interaction coefficients, respectively. For this analysis, the model incorporated three independent variables¹⁹: Lubricant content: magnesium stearate (%), content of disintegrant: crospovidone (%), and content of binder: PVP-K30 (%), with the solubility of curcumin at 45 min serving as the output response.

Statistical treatment of the data was performed using Design Expert 13 software. Model validity was evaluated using the coefficient of determination R^2 , which measures how closely the model aligns with the experimental observations. Higher R^2 values, specifically those closer to 1, signify better predictive capability of the model¹⁷.

The tablets have a weight of 130 mg and contain 10 mg of curcumin along with excipients including lubricant, disintegrant, binder, and lactose as a filler excipient.

Determine disintegration

Disintegration is determined according to pharmaceutical testing regulations of the Ministry of Health²⁰. Add an appropriate volume of test medium (usually water) into the beaker. Operate the BJ-II disintegration tester at a test environment temperature of 37 ± 0.5 °C. After the specified time, or when the tablets have completely disintegrated, remove them from the liquid beaker.

If all six tablets disintegrate completely, the test sample meets the requirements for disintegration. If there are less than 2 tablets left that have not completely disintegrated, try again on another 12 tablets. The product meets the disintegration requirement when 16 out of 18 tested tablets reach the prescribed disintegration level.

Determine mass uniformity

Accurately weigh any 20 tablets and determine the average weight of the tablets. Weigh each tablet individually and compare it with the average weight; calculate the percentage deviation from the average weight; and then calculate the range of the average value. There must be no more than two tablets whose mass differs by more than the limit of the average value, and no tablet must have a difference of more than twice the deviation in percentage terms²¹, according to Table 2.

Determine content uniformity

Content uniformity is evaluated according to the regulations given in Appendix 11.1, Vietnamese Pharmacopoeia V²¹.

For powdered preparations, the product is met if there is no more than one unit whose content is outside the limit from 85% to 115% and no unit is outside the limit from 75% to 125% compared to average content. If two or three units are outside the limits of 85% to 115% but within the limits of 75% to 125% of the average content, retest on another 20 units taken at random.

Solubility evaluation of tablets

Solubility assessment was conducted in accordance with the specifications outlined in the Vietnamese Pharmacopoeia V²¹. Curcumin content was precisely determined using High-Performance Liquid Chromatography (HPLC) on an Agilent 1260 system. Solubility itself was quantitatively evaluated as the ratio between the amount of curcumin that successfully passed through a $0.45 \mu\text{m}$ filter membrane²² and the total initial amount of curcumin used in the test.

RESULTS AND DISCUSSION

Content of curcumin in spray-dried powder

The spray-dried powder was tested for curcumin content using the UV-VIS method, which was 8.508%, smaller than the theoretical content of 9.091%. This may be due to curcumin being trapped in the drying chamber during the spray drying process with hot air and loss due to other storage devices.

Results of RSM optimization

The Central Composite Design (CCD) was constructed based on the previously established optimal parameter set. This design was subsequently employed to generate the specific parameters required for the subsequent experimental runs. The resulting matrix of generated parameters and their corresponding experimental outcomes are presented in Table 3. Table 4 displays the estimation results for the standard model after it has been fitted. To effectively visualize the interactive effects among the independent variables on the measured response, three-dimensional response surfaces were generated (Figure 1). In these plots, solubility is represented on the vertical axis, while two variables are shown on the horizontal axes. For each plotted cell, the third, unrepresented variable was held constant at its predetermined central level. The data reveal that lubricant and binder content exhibit analogous effects on solubility: an increase in

Table 1: The bound values for the RSM optimization’s examined parameters.

Value	Factors		
	Lubricant	Disintegrant	Binder
	Magnesium Stearate (X ₁) (%)	Crospovidone (X ₂) (%)	PVP-K30 (X ₃) (%)
Lower limit (-1)	0.20	0.50	2.00
Center point (0)	1.10	2.75	3.50
Upper limit (+1)	2.00	5.00	5.00
Encoding variables (X _i)	$X_1 = \frac{L-1.10}{0.90}$	$X_2 = \frac{D-2.75}{2.25}$	$X_3 = \frac{B-3.50}{1.50}$

Source: Authors’ own work

Table 2: Allowable limits for mass differences for tablets.

Average tablet weight	Percent difference
Up to 80 mg	± 10
Over 80 mg to 250 mg	± 7.5
Over 250 mg	± 5

Source: Authors’ own work

Table 3: Experimental parameters and responses for RSM optimization.

Experiment No.	Independent Variables			Response
	X ₁ (%)	X ₂ (%)	X ₃ (%)	Solubility Y (%)
1	0.20 (-1)	0.50 (-1)	2.00 (-1)	55.948
2	0.20 (-1)	5.00 (+1)	2.00 (-1)	55.916
3	0.20 (-1)	0.50 (-1)	5.00 (+1)	51.955
4	0.20 (-1)	5.00 (+1)	5.00 (+1)	54.236
5	0.20 (-1)	2.75 (0)	3.50 (0)	55.566
6	1.10 (0)	0.50 (-1)	3.50 (0)	56.152
7	1.10 (0)	5.00 (+1)	3.50 (0)	57.839
8	1.10 (0)	2.75 (0)	2.00 (-1)	61.134
9	1.10 (0)	2.75 (0)	5.00 (+1)	58.290
10	1.10 (0)	2.75 (0)	3.50 (0)	58.645
11	1.10 (0)	2.75 (0)	3.50 (0)	57.441
12	1.10 (0)	2.75 (0)	3.50 (0)	56.967
13	1.10 (0)	2.75 (0)	3.50 (0)	57.148
14	1.10 (0)	2.75 (0)	3.50 (0)	57.141
15	2.00 (+1)	0.50 (-1)	2.00 (-1)	54.602
16	2.00 (+1)	5.00 (+1)	2.00 (-1)	56.622
17	2.00 (+1)	0.50 (-1)	5.00 (+1)	48.819
18	2.00 (+1)	5.00 (+1)	5.00 (+1)	52.830
19	2.00 (+1)	2.75 (0)	3.50 (0)	53.759

Source: Authors’ own work

Table 4: Values for the standard regression model's coefficients.

Independent Variable	Coefficient	Standard Error	Prob > t
Intercept	57.8900	0.2760	< 0.0001
Lubricant – Magnesium Stearate content	-0.6988	0.2384	0.0167
Disintegrant – Crospovidone content	0.9967	0.2384	0.0024
Binder - Polyvinyl pyrrolidone content	-1.8100	0.2384	< 0.0001
Lubricant content × Disintegrant content	0.4726	0.2666	0.1100
Lubricant content × Binder content	-0.4879	0.2666	0.1005
Disintegrant content × Binder content	0.5381	0.2666	0.0743
(Lubricant content) ²	-3.7600	0.4561	< 0.0001
(Disintegrant content) ²	-1.4300	0.4561	0.0122
(Binder content) ²	1.2900	0.4561	0.0197

the concentration of either component generally results in enhanced solubility. Conversely, increasing the disintegrant content led to a reduction in solubility. It is important to note, however, that this trend is only maintained up to a specific threshold; beyond this point, a reverse relationship is observed. Furthermore, the analysis indicates that the cross-interaction between the pairs of variables does not exert a statistically significant influence on the solubility outcome. Figure 2 simulates data points formed by actual and predicted responses. The data distribution is close to the 45° line, indicating that the experimental results are consistent with the predicted results. In addition, the calculated regression coefficient is $R^2 = 0.9623$, showing a good fit between the experimental data and the established model.

The influence of individual factors on the solubility of tablets is shown in Figure 3. Within each factor, one variable was allowed to vary, and the two missing variables were kept at their central points. Clearly, solubility responds most rapidly to changes in binder content, as shown by the slope of the curves.

The objective function is defined by the following equation after compacting the model by eliminating variables with p-values greater than 0.05:

$$Y = -0.699X_1 + 0.997X_2 - 1.809X_3 - 3.759 X_1^2 - 1.426X_2^2 + 1.291X_3^2 + 57.892$$

Inferring from the final model, solubility is greatly affected by all three types of excipients in tablets, including lubricant content (X_1), disintegrant content (X_2), and binder content (X_3).

Evaluate the effectiveness of the optimization process

The conditions for the parameters to meet the tablet solubility target are presented in Table 5.

To check the compatibility of the model and experimental results, tablets were created with the selected optimal conditions, and the experiment was repeated three times. The results of testing the repeatability of the optimization model are presented in Table 6.

The solubility result of the tablet after three repetitions of the experiment was 58.323%. The difference between the average solubility of the three experiments and the optimal solubility is 4.436% < 5%, which shows that the model has high compatibility and reliability.

$$\Delta\% = \frac{|Y_e - Y_s|}{Y_s} = \frac{|58.323 - 61.030|}{61.030} = 4.436\%$$

Evaluate optimal product properties

Curcumin tablets with optimized parameters were tested for disintegration, mass uniformity, content uniformity, and solubility according to the standards of Vietnamese Pharmacopoeia V²¹.

In terms of appearance, the tablets produced have a uniform orange-yellow color; the tablet surface is smooth, without surface pitting; and it is not broken or crumbly during the tableting process.

For the drug in a tablet to dissolve and be absorbed, the tablet must first disintegrate. Disintegration time and degree of disintegration significantly affect the rate of dissolution and absorption of the drug. Therefore, disintegration testing is a mandatory criterion

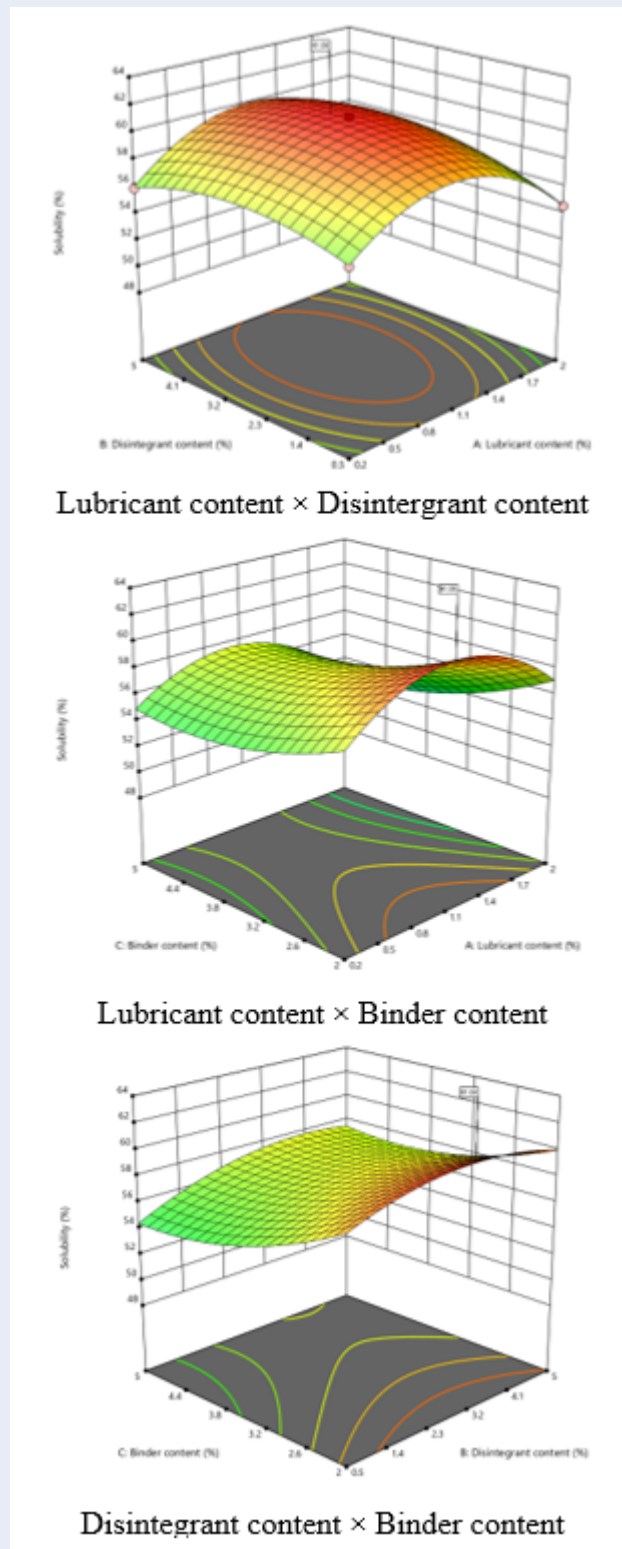


Figure 1: Interaction effects of factor pairs on response surface. [Source: Authors' ownwork]

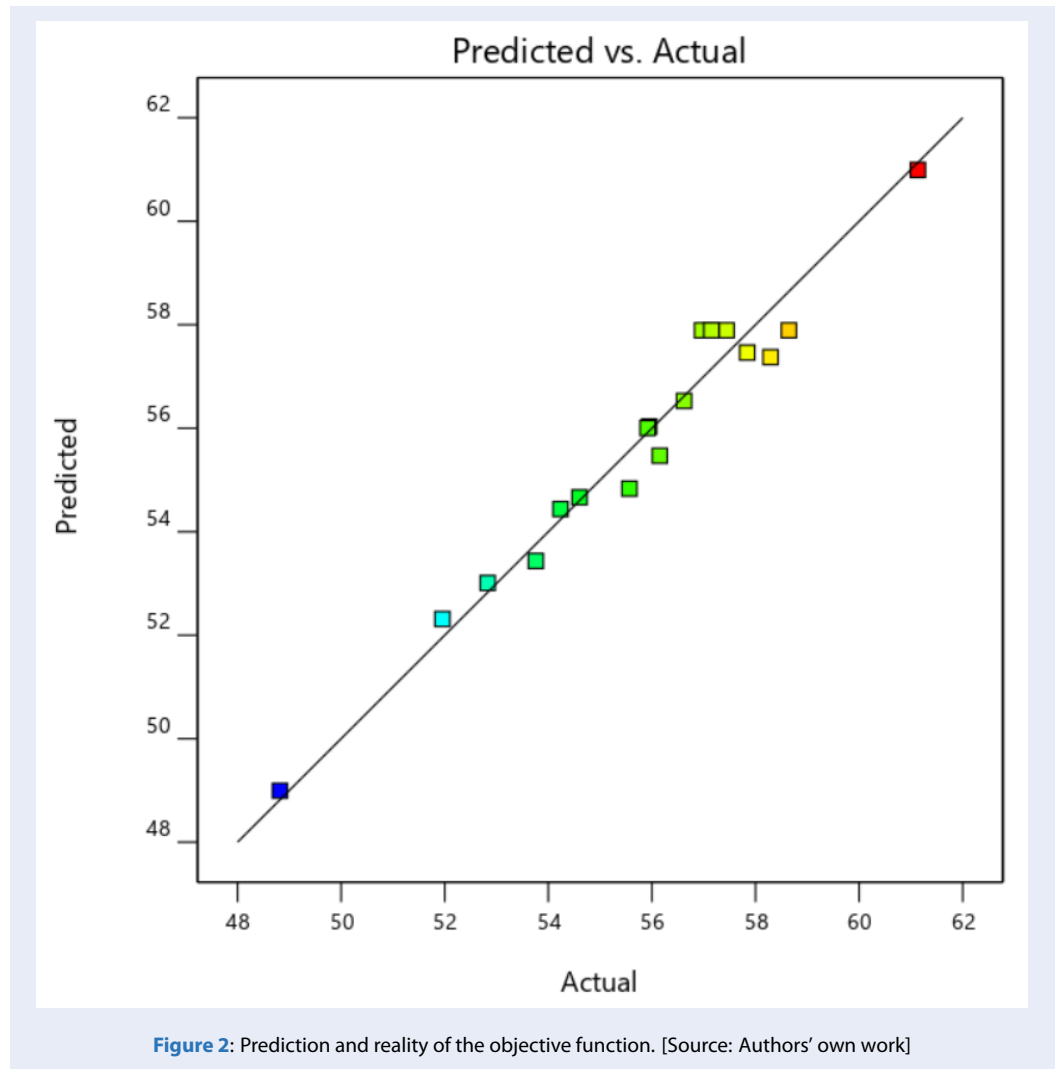


Table 5: Results of the optimization process

Parameters	Critical value
Lubricant content (%)	1.083
Disintegrant content (%)	3.106
Binder content (%)	2.000
Solubility (%)	61.030

[Source: Authors' own work]

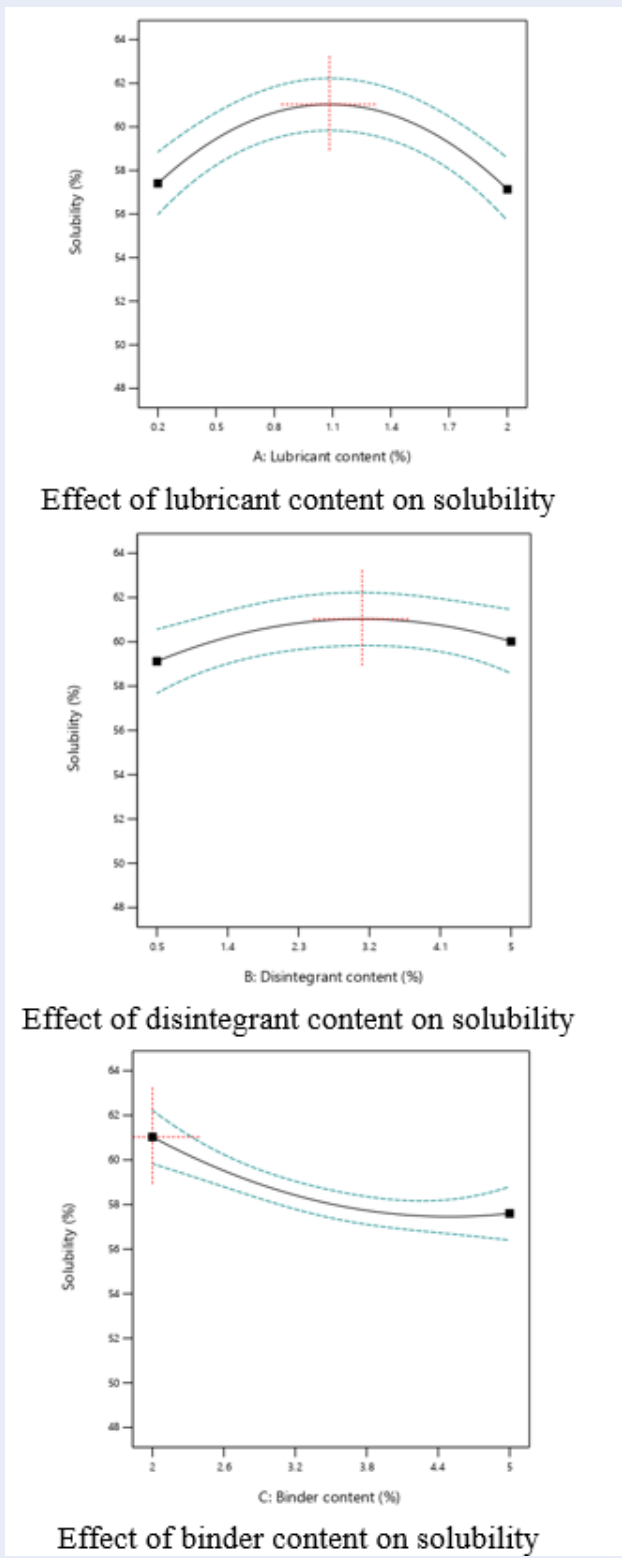


Figure 3: Trend changes in solubility with varying survey factors. [Source: Authors' own work]

Table 6: Checking the repeatability of the optimization model

No.	Lubricant content (X ₁) (%)	Disintegrant content (X ₂) (%)	Binder content (X ₃) (%)	Solubility (%)
1	1.080	3.110	2.001	58.215
2	1.085	3.106	2.001	58.364
3	1.085	3.105	2.001	58.389
	Average			58.323

[Source: Authors' own work]

for testing tablet quality. After the product was evaluated, the results showed that the average disintegration of the six tested tablets was 12 minutes and 57 seconds, meeting the disintegration time requirement for uncoated tablets that must disintegrate in 15 minutes.

Regarding the mass uniformity criterion, for tablets with an average weight of 80 mg to 250 mg, the allowable percentage difference is $\pm 7.5\%$ when tested with any 20 tablets. Tablets with optimal parameters had an average mass uniformity of 0.556%, and none of the 20 tested tablets had a difference exceeding the allowable level compared to the average value.

For uniform content, the test sample met the requirements because there was a difference in content compared to the average value of 4.200%, with no tablets having content outside the limit of 85–115% (i.e., the difference exceeded $\pm 15\%$) compared to the average content.

The solubility of the tablets was investigated at different times and compared with two controls: raw curcumin and curcumin powder after spray drying. The survey results are shown in Figure 4. The results showed that, during the first 15 minutes, in both environments, the solubility of the tablets was lower than that of the controls; this may be due to the influence of binder excipients in the tablet composition, which causes tablets to disintegrate more slowly, leading to low solubility. However, after the disintegration stage, the drug release ability of the tablets is much higher than that of raw curcumin and spray-dried powder. When stabilized, the solubility of the tablets is approximately 40% in both environments, higher than that of spray-dried powder, which is 35%, and about 1.3 times higher than the solubility of raw curcumin, which is 30%.

CONCLUSIONS

From a suspension with curcumin concentration of 2 g/L through the spray-drying process to create curcumin powder for mixing with excipients to form tablets. This mixing is to investigate the influence of

excipients such as lubricant, disintegrant, and binder excipients on the solubility of tablets. After the excipient ingredient optimization process, in the 130 mg tablet containing 10 mg curcumin, the tablet product has the percentage content of PVP-K30 (binder excipient), crospovidone (disintegrant excipient), and magnesium stearate (lubricant excipient) of 2.000%, 3.106%, and 1.083%, respectively, giving an optimal solubility of 61.030% in distilled water. Besides, the results also show the influence of individual factors on tablet solubility. Among them, solubility responds fastest to changes in binder excipient content. In addition, the tablets were also evaluated for their properties based on the standards stated in Vietnamese Pharmacopoeia V (21), and the results were as follows: Disintegration: 12 minutes and 53 seconds; mass uniformity: 0.556%; content uniformity: 4.200%. The above parameters all meet the standards for tablets. Finally, the solubility at pH 4.5 and 6.8 after 60 minutes was 38.786% and 41.341%, respectively, demonstrating that the solubility of the tablets was higher than that of spray-dried powder and raw curcumin.

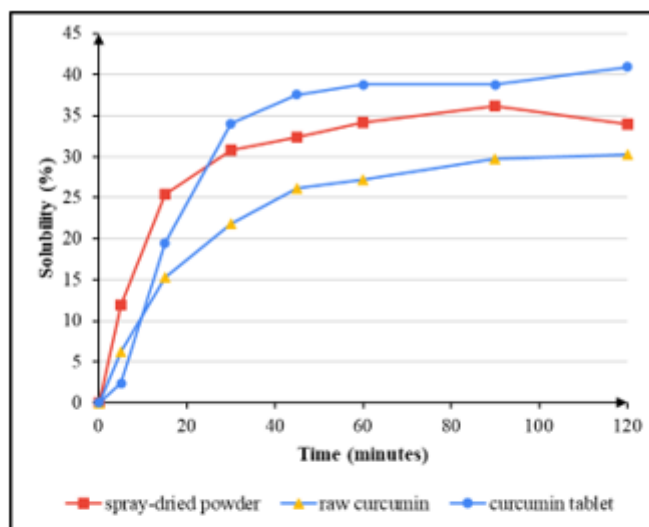
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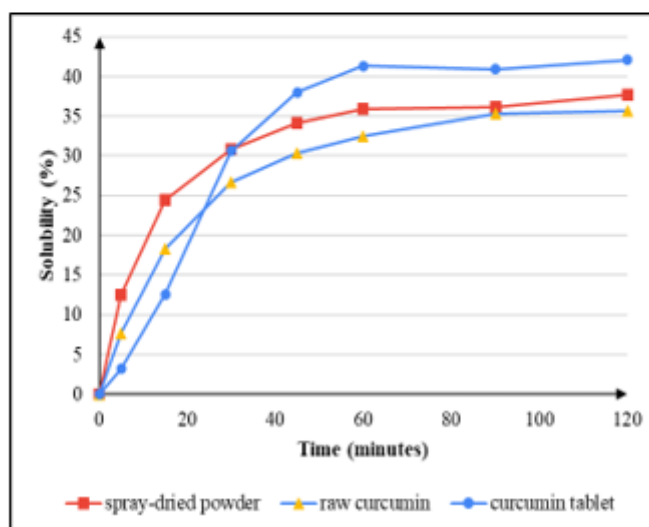
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pH 4.5



pH 6.8

Figure 4: Comparison of tablet solubility with control at pH 4.5 and 6.8. [Source: Authors' own work]

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Nghiên cứu bào chế và đánh giá ảnh hưởng của các tá dược đến tính chất của viên nén chứa bột sấy phun curcumin

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Bản quyền

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TÓM TẮT

Mục đích cơ bản của nghiên cứu về lĩnh vực dược phẩm này là tối ưu hóa một cách hệ thống các nồng độ các tá dược chủ yếu cần thiết cho việc điều chế viên nén chứa bột curcumin, nguyên liệu đã được xử lý bằng phương pháp sấy phun nhằm cải thiện đáng kể khả năng hòa tan. Nghiên cứu sử dụng phương pháp đáp ứng bề mặt (RSM) kết hợp với mô hình lặp tâm (CCD) để tiến hành khảo sát. Cách thiết kế thí nghiệm này cho phép thiết lập hiệu quả các yếu tố ảnh hưởng và xác định các yếu tố tương tác có ý nghĩa. Tất cả các tính toán và mô hình thống kê được thực hiện bằng cách sử dụng bộ phần mềm chuyên dụng Design Expert 13, yêu cầu thực hiện 19 lô thí nghiệm riêng biệt. Ba thành phần công thức được chọn làm biến độc lập, bao gồm: phần trăm khối lượng tá dược trơn, magnesi stearate (%), phần trăm khối lượng tá dược rã, crospovidone (%), và phần trăm khối lượng tá dược dính, PVP-K30 (%). Biến phụ thuộc được khảo sát là độ hòa tan của curcumin ở thời điểm 45 phút, một chỉ số tiêu chuẩn tương quan với hiệu suất giải phóng *in vivo* (trong cơ thể). Sau giai đoạn mô hình hóa thống kê, các thông số tối ưu lý thuyết được tạo ra đã được đưa vào xác minh bằng thực nghiệm. Chất lượng của các viên nén tối ưu được đánh giá toàn diện dựa trên nhiều chỉ số, bao gồm thời gian rã, độ đồng đều khối lượng viên, độ đồng đều hàm lượng và tốc độ hòa tan. Kết quả thực nghiệm xác nhận rằng các thông số quy trình tối ưu được xác định là: hàm lượng magnesi stearat là 1.083%, hàm lượng crospovidone là 3.106%, và hàm lượng PVP-K30 là 2.000%. Các viên nén được chế tạo bằng công thức tối ưu có kết quả hòa tan rất phù hợp với các dự đoán của phần mềm. Hơn nữa, chúng đạt được hiệu suất hòa tan cao hơn 120% và 140% so với bột sấy phun và nguyên liệu curcumin thô tương ứng ban đầu. Đặc biệt, các viên nén tối ưu đã thành công trong việc đáp ứng được tất cả các tiêu chí chất lượng nghiêm ngặt đối với dạng bào chế rắn đường uống, như được quy định trong Dược điển Việt Nam V. Tóm lại, nghiên cứu này đã thành công trong quá trình tối ưu hóa công thức viên nén bột curcumin sấy phun ở quy mô phòng thí nghiệm, qua đó thiết lập một nền tảng cho bước tiếp theo quan trọng là mở rộng quy mô hướng tới sản xuất cấp độ công nghiệp.

Từ khoá: curcumin, sấy phun, viên nén, tá dược, đáp ứng bề mặt (RSM), mô hình lặp tâm (CCD)

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