

Optimization of Basil (*Ocimum basilicum* L.) Extract Tablets Using Pregelatinized Starch and Explotab®

Hayatus Sa`adah^{1*}, Halimatus Sya`diah¹, Achmad Kadri Ansyori¹, Supomo Supomo¹

¹Department of Pharmacy,
Sekolah Tinggi Ilmu
Kesehatan Samarinda,
Samarinda, 75124, Indonesia

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Correspondence:

Hayatus Sa`adah
hayatus.akfarsam@gmail.com



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Abstract

Background: Basil (*Ocimum basilicum* L.) is recognized as a rich botanical source of secondary metabolites that exhibit notable antioxidant properties.

Objective: The present investigation sought to examine how variations in disintegrant type and proportion—specifically pregelatinized starch and Explotab—influenced the physical characteristics and antioxidant capacity of tablets prepared from basil leaf ethanol extract.

Methods: Three distinct formulations were developed based on differing pregelatinized starch-to-Explotab ratios: Formula I (0:1), Formula II (1:1), and Formula III (1:0). All prepared tablets underwent comprehensive physical evaluation and stability assessment, while antioxidant potential was quantified through the DPPH radical scavenging method. The formulation optimization process employed the Simplex Lattice Design (SLD) methodology executed via Design-Expert® version 13 software.

Results: Experimental findings demonstrated that the ratio variation between pregelatinized starch and Explotab exerted measurable effects on both granule and tablet physical attributes. Specifically, pregelatinized starch was found to predominantly elevate bulk density, weight uniformity, and disintegration time, whereas Explotab exhibited a stronger regulatory influence over moisture content, flow rate, Carr's index, and tablet friability. The optimal formulation was identified as containing 6.72% pregelatinized starch combined with 1.27% Explotab. Notably, all three formulations demonstrated very strong antioxidant activity, with IC₅₀ values spanning from 33.78 to 39.52 ppm. One-way ANOVA statistical evaluation revealed no significant interformulation differences ($p > 0.05$).

Conclusion: The collective data supports the conclusion that a strategic combination of pregelatinized starch and Explotab yields basil extract tablets with satisfactory physical quality alongside preserved antioxidant efficacy.

INTRODUCTION

Among the most pressing challenges in contemporary public health, degenerative diseases hold a prominent position as a leading cause of morbidity and mortality throughout Indonesia.¹ A fundamental mechanism underlying the emergence of these conditions involves the progressive inability of the body's endogenous antioxidant defenses to counteract mounting concentrations of reactive oxygen species.² Numerous chronic degenerative disorders—encompassing malignancies, cerebrovascular accident, hypertension, ischemic heart disease, and accelerated senescence—are directly attributable to the sustained destructive activity of free radicals.³ These reactive molecules represent exogenous compounds capable of penetrating biological systems and undermining immunological integrity.⁴ Their formation is linked to a complex array of endogenous metabolic cascades as well as external environmental exposures, including ionizing radiation, synthetic chemicals, atmospheric pollutants, biological toxins, consumption of highly processed foods, and dietary items subjected to excessive thermal processing.⁵ When free radical production surpasses physiological limits, deleterious pathological consequences inevitably ensue.⁶ Such harmful outcomes become manifest when the equilibrium between oxidative species and protective antioxidant mechanisms breaks down, with the resulting oxidative imbalance triggering lipid peroxidation within cellular membranes, precipitating structural cellular damage and, ultimately, programmed or necrotic cell death.⁷ To mitigate these detrimental processes, the organism must maintain an adequate supply of antioxidant molecules capable of quenching free radical activity.⁸

Antioxidant defense mechanisms are sustained through a dual system comprising endogenous biosynthetic pathways and exogenous dietary sources, most notably medicinal and edible plant species.⁹ Within the Indonesian

botanical pharmacopeia, basil (*Ocimum basilicum* L.) has garnered particular attention as a promising antioxidant-rich herb. The leaf tissue of this species is characterized by an exceptionally high content of phenolic compounds, which confer potent protective effects against oxidative insult and hold considerable promise for supporting human health.¹⁰ Furthermore, basil demonstrates a broad spectrum of pharmacological activities extending beyond antioxidant function, encompassing anti-inflammatory, antibacterial, antifungal, and hypoglycemic effects.¹¹ Empirical evidence indicates that administration of basil leaf extract at 200 mg/kg body weight sustained over an eight-week period produced meaningful enhancement of antioxidant enzyme activity¹². Additionally, prior research by Erviana et al. (2016) established that the radical scavenging capacity of basil leaf ethanol extract was characterized by an IC₅₀ value of 52.68 µg/mL, thereby classifying it within the strong antioxidant category¹³. Despite this accumulated evidence documenting the antioxidant potency of *Ocimum basilicum* leaf extract, the vast majority of existing investigations remain confined to crude extract evaluation, leaving a substantial research lacuna regarding the development of standardized, therapeutically applicable solid dosage forms.

Among the diverse pharmaceutical delivery platforms available, tablet formulations represent one of the most advantageous strategies for transforming plant-derived extracts into clinically viable products. Within the pharmaceutical sector, solid oral tablets are consistently preferred due to their inherent practical superiority in both storage and therapeutic administration, offering an ideal vehicle for oral drug delivery.¹⁴ These dosage forms additionally provide precise dose quantification and dimensional consistency, which are prerequisites for enhancing patient therapeutic adherence.^{15,16} Notwithstanding these structural advantages, the conversion of herbal extracts into tablet form frequently encounters technical challenges related to granule flowability, compressibility, and disintegration performance, underscoring the critical importance of selecting and optimizing appropriate disintegrant excipients.^{15,17}

The present formulation study was designed around a binary disintegrant system combining pregelatinized starch and Explotab. Although both disintegrant materials originate from natural sources, their direct contribution to antioxidant activity was considered negligible given their relatively low concentrations and the absence of meaningful antioxidant properties in preliminary investigations or existing literature.¹⁸ A recognized limitation of Explotab is its hygroscopic character, which may pose compatibility challenges when paired with moisture-sensitive active pharmaceutical ingredients.^{19,20} Conversely, pregelatinized starch presents a complementary advantage through its capacity to stabilize moisture-sensitive compounds.²¹ The rationale for combining these two excipients was, therefore, to exploit their complementary functional profiles and overcome the individual weaknesses of each component, thereby producing tablets with superior overall physical performance.

An essential component of this research was the assessment of antioxidant capacity in the formulated basil extract tablets through in vitro evaluation employing the DPPH assay. The DPPH (1,1-diphenyl-2-picrylhydrazyl) method operates by quantifying the degree to which a test compound inhibits a stable free radical species, providing a direct index of radical scavenging capability.²² The adoption of this methodology was justified by several well-recognized methodological advantages, including operational simplicity, high analytical sensitivity, compatibility with small sample volumes, and the exceptional stability of the DPPH radical relative to other commonly employed radical species, all of which contribute to its status as a highly reproducible and widely validated screening tool.^{23,24}

While previous research efforts have independently characterized either the antioxidant properties of basil extract or the physical tablet characteristics of herbal formulations, an integrated approach simultaneously addressing formulation optimization and biological activity evaluation remains insufficiently explored. Against this background, the present study was undertaken to formulate basil leaf (*Ocimum basilicum* L.) ethanol extract tablets with varying combinations of pregelatinized starch and Explotab as disintegrants, and to comprehensively evaluate both their physical quality parameters and antioxidant activity.

METHODS

Study Design and Variables

This study employed an experimental laboratory design using a Simplex Lattice Design (SLD) approach to optimize the proportion of disintegrants in tablet formulation. The study designated the concentrations of pregelatinized starch (factor A) and Explotab (factor B) as independent variables. Outcome measures encompassed granule-level parameters (loss on drying, flow rate, angle of repose, bulk density, and Carr's index), tablet-level characteristics (weight uniformity, hardness, friability, and disintegration time), and biological activity metrics (IC₅₀

values). Parameters held constant throughout the study included the basil extract quantity, manufacturing methodology, drying temperature, and compression settings.

Experimental Design and Optimization

Formulation optimization was conducted using the Simplex Lattice Design with two mixture components: pregelatinized starch (A) and Explotab (B). This design approach generated three distinct formulations representing the extremes and midpoint of the binary system: 0:1, 1:1, and 1:0 ratios. Response surface modeling was performed using Design-Expert® software version 13 (Stat-Ease Inc., USA), from which an optimal formulation was identified through evaluation of the composite desirability function.

Plant Material

Fresh basil leaves (*Ocimum basilicum* L.) were collected from Lempake, Samarinda, Indonesia, in June 2025. The plant material was authenticated at the Laboratory of Ecology and Conservation of Tropical Forest Biodiversity, Universitas Mulawarman, Samarinda. The leaves were harvested in the morning, washed, and air-dried in the shade at room temperature (25 ± 2 °C) until a constant weight was obtained, and then processed into dried simplicia prior to extraction.

Materials and Instruments

Ethanol 70% (technical grade, local supplier, Indonesia) was used as the extraction solvent. Pregelatinized starch (Colorcon, USA), Explotab® (JRS Pharma, Germany), Avicel PH 101 (FMC Biopolymer, USA; distributed by Brataco, Indonesia), PVP K30 (BASF, Germany; distributed by Brataco, Indonesia), magnesium stearate, talc, and Aerosil® (pharmaceutical grade, Brataco, Indonesia) were used as pharmaceutical excipients in tablet formulation. Ethanol 70% (analytical grade, Merck, Germany), DPPH (2,2-diphenyl-1-picrylhydrazyl, Sigma-Aldrich, USA) and ascorbic acid (analytical grade, Merck, Germany) were used to assess antioxidant activity.

The instruments used included a UV-Vis spectrophotometer (Shimadzu UV-1800, Japan), rotary evaporator (Heidolph Hei-VAP, Germany), drying oven (Memmert UN55, Germany), analytical balance (Ohaus Pioneer, USA), friability tester (Erweka TAR 120, Germany), hardness tester (Erweka TBH 125, Germany), disintegration tester (Erweka ZT 320, Germany), and tablet compression machine.

Preparation of extract

Basil leaf ethanol extract was produced through the maceration technique. A total of 1,335 g of dried simplicia was submerged in 7.35 L of 70% ethanol within a sealed glass vessel, subjected to mechanical stirring for 6 hours, then allowed to macerate undisturbed for 72 hours with periodic agitation before filtration. The resulting residue was subjected to a second maceration cycle using 6 L of fresh 70% ethanol under identical conditions. All collected filtrates were consolidated and concentrated using a rotary evaporator maintained at approximately 50°C, and the resulting liquid concentrate was further reduced on a water bath until a viscous semisolid extract was obtained.²⁵

Tablet Formulation

The ethanol extract of basil leaves was formulated into tablet dosage forms according to the compositional specifications presented in **Table 1**.

Table 1. Tablet Formulation of Basil Leaf (*Ocimum basilicum* L.) Ethanol Extract

| Ingredient | Formula for 250 tablets (each 100 mg) | | |
|----------------------------------|---------------------------------------|----------|----------|
| | I | II | III |
| Basil leaf extract (mg) | 25 | 25 | 25 |
| Pregelatinized starch (%) | 0 | 4 | 8 |
| Explotab (%) | 8 | 4 | 0 |
| PVP (%) | 5 | 5 | 5 |
| Avicel PH 101 (%) | Ad 100 | Ad 100 | Ad 100 |
| Magnesium stearate (%) | 3 | 3 | 3 |
| Talcum (%) | 5 | 5 | 5 |
| Aerosil (%) | 1 | 1 | 1 |

Note:

F I = Pregelatinized starch:Explotab (0:1)

F II = Pregelatinized starch:Explotab (1:1)

F III = Pregelatinized starch:Explotab (1:0)

Preparation of Tablet Dosage Form

All three tablet formulations were manufactured by wet granulation. Equipment and raw materials were prepared, with each component accurately weighed per batch calculation. Basil leaf extract was placed in a mortar, followed by thorough pre-blending of Avicel PH 101, pregelatinized starch, Explotab, and PVP to achieve compositional homogeneity. PVP was utilized as a dry binder activated through in situ hydration during granulation. Approximately 12 mL of warm purified water per batch was introduced incrementally as fine droplets under continuous mixing to ensure uniform binder activation and consistent granule formation. Liquid addition proceeded under controlled conditions until the mixture achieved a cohesive, workable wet mass. Adequacy of granulation endpoint was confirmed when the mass demonstrated sufficient plasticity for manual compression without fracture or excessive adhesion.

The wet granule mass was forced through a 16-mesh screen and subjected to oven drying at 50°C for 5 hours. Drying was maintained until the loss on drying reached the target range of 2–5% to preclude over-wetting while ensuring batch-to-batch reproducibility. The dried granules were subsequently sized through a 20-mesh screen and blended with external phase excipients (magnesium stearate, talc, and Aerosil) until uniform distribution was achieved. The final lubricated granule blend was then compressed into tablet form.

Evaluation of Basil Leaf Extract Granules

Granule physical characterization encompassed measurement of moisture content, flow time, angle of repose, tapped density, and bulk density. Subsequently, compressed tablets were subjected to evaluation of weight uniformity, dimensional uniformity, hardness, friability, and disintegration time

Loss on Drying (LOD)

An accurately weighed 5-g granule sample was transferred to a drying oven operating at 105°C. Following drying, the sample was cooled to ambient temperature within a desiccator prior to reweighing. This cycle of drying, cooling, and weighing was repeated at 30-minute intervals until a constant mass was obtained, defined operationally as successive weight readings differing by no more than 0.5%.^{26 27} The pharmacopeial acceptance criterion for LOD is 2–5%.²⁵

Flow Rate

Granule flowability was evaluated using the fixed funnel method. Due to the limited batch size, 25 g of granules were accurately weighed and allowed to flow freely through a stainless-steel funnel with a specified orifice diameter. The time required for the entire sample to pass was recorded using a stopwatch. The transit time for complete sample discharge was recorded using a precision stopwatch. Acceptance criterion was set at a flow rate exceeding 10 g/s.²⁸ Flow rate was expressed in grams per second according to Equation (1).

$$\text{Flow rate } \left(\frac{\text{g}}{\text{s}}\right) = \frac{\text{mass (g)}}{\text{time (s)}} \dots\dots\dots (1)$$

Angle of Repose

Twenty-five grams of granules were allowed to flow freely through a funnel onto a horizontal surface.²⁰ The angle formed between the powder heap and the horizontal plane was then measured. The resulting powder cone geometry was measured to determine the angle subtended between the heap slope and the horizontal baseline. Satisfactory flow characteristics are indicated by an angle of repose within the range of 25°–45°.²⁰ The angle of repose was calculated using the following Equation (2).

$$\tan \alpha = \frac{h}{r} \dots\dots\dots (2)$$

Note:

- θ = angle of repose
- h = height of the powder cone (cm)
- r = radius of the cone base (cm)

Bulk Density and Compressibility Index

Bulk density determination was performed following the pharmacopeial tapped density methodology described in USP <616>. A 50-g granule portion was carefully loaded into a 100-mL graduated cylinder without compaction, and the initial unsettled volume (V₀) was recorded. The cylinder was subsequently mounted on a mechanical tapped density apparatus and tapped repetitively at a standardized drop height until no further volume change was observed (V_t), with constant volume defined as successive readings differing by no more than 2%. The bulk density was calculated using the following Equation (3).

$$\rho_b = \frac{m}{V_0} \dots\dots\dots (3)$$

Tapped density values from the same measurement were used to derive the Carr's compressibility index via Equation (4). Granule compressibility is considered acceptable when this index falls below 20%.²⁰

$$CI = \frac{\rho_t - \rho_b}{\rho_t} \times 100 \dots\dots\dots (4)$$

Note:

- ρ_b = bulk density (g/mL)
- ρ_t = tapped density (g/mL)
- m = mass of granules (g)
- V_0 = initial bulk volume (mL)
- V_t = tapped volume after tapping (mL)
- CI = Carr's compressibility index (%)

Evaluation of Basil Leaf Extract Tablets

Weight Uniformity

Twenty tablets were weighed individually to calculate the mean weight. For tablets with a target weight of 100 mg, the acceptance criteria follow the Indonesian Pharmacopeia, which stipulates that no more than two tablets may deviate by more than 10% from the mean, and no single tablet may deviate by more than 20%.²⁹ Weight consistency was additionally characterized through the coefficient of variation (CV); values below 5% indicate satisfactory weight uniformity.³⁰

Size Uniformity

Diameter and thickness of twenty tablets were measured using a vernier caliper. Tablets comply with size uniformity requirements when the diameter does not exceed three times nor fall below 4/3 times the tablet thickness.³⁰

Hardness

Diameter and thickness of twenty tablets were measured using a vernier caliper. Tablets comply with size uniformity requirements when the diameter does not exceed three times nor fall below 4/3 times the tablet thickness.²⁰

Friability

Twenty pre-weighed, dedusted tablets (W_0) were subjected to 100 rotations (4 minutes at 25 rpm) in a Roche friability tester. Following testing, tablets were dedusted and reweighed (W_1). The pharmacopeial friability threshold requires weight loss not exceeding 1%.³¹ Friability was quantified using Equation (5).

$$\text{Friability (\%)} = \frac{W_0 - W_1}{W_0} \times 100 \dots\dots\dots (5)$$

Note:

- W_0 = initial weight of tablets before the test (g)
- W_1 = final weight of tablets after the test (g)

Disintegration Time

Individual tablets were placed in each tube of the disintegration apparatus, discs were inserted, and the apparatus was activated using water maintained at 37°C as the immersion medium. Upon test completion, the basket assembly was raised and the condition of each tablet examined. All tested units must have completely disintegrated within the allotted time. Should one or two tablets fail this criterion, the test is repeated with 12 supplementary tablets, requiring that at least 16 of 18 total tablets disintegrate fully. The accepted disintegration limit for uncoated tablets is less than 15 minutes.³¹

Antioxidant Activity Assay (DPPH Method)

A stock 2,2-diphenyl-1-picrylhydrazyl (DPPH) solution of 40 ppm was prepared by dissolving 4 mg of DPPH in 100 mL of 70% ethanol and maintained in an amber container protected from light. The wavelength of maximum absorption (λ_{max}) was established by spectrophotometric scanning of the DPPH solution across a 450–600 nm range.

A 1,000 ppm ascorbic acid stock solution was prepared by dissolving 10 mg of vitamin C in 10 mL of 70% ethanol, subsequently diluted to a 100 ppm working solution, from which a dilution series of 2, 4, 6, 8, and 10 ppm was constructed.

For tablet sample preparation, twenty tablets were pulverized and 100 mg of the resulting powder was dissolved in 70% ethanol and volumetrically adjusted to 100 mL to yield a 1,000 ppm stock solution. The suspension was clarified by centrifugation, and the collected supernatant was diluted to test concentrations of 10, 20, 30, 40, and 50 ppm.

For sample preparation, twenty basil leaf extract tablets were powdered, and 100 mg of powder was dissolved in 70% ethanol and diluted to 100 mL to obtain a 1,000 ppm stock solution. The solution was centrifuged, and the supernatant was used to prepare sample concentrations of 10, 20, 30, 40, and 50 ppm.

For radical scavenging measurement, 1 mL of each test or reference solution was combined with 2 mL of DPPH solution (40 ppm) and incubated under light exclusion at 25 ± 2°C for 30 minutes, after which absorbance was recorded at λ_{max} using a UV-Vis spectrophotometer. All measurements were performed in triplicate.³² A reagent blank of 3 mL of 70% ethanol was used for instrumental zeroing, while the negative control comprised 1 mL of 70% ethanol mixed with 2 mL of DPPH solution, representing 100% radical activity. The percentage of radical scavenging activity was calculated using the following equation (6).

$$\% \text{ Inhibition} = \frac{A_{\text{control}} - A_{\text{sample}}}{A_{\text{control}}} \times 100 \dots\dots\dots (6)$$

The IC₅₀ values were derived from the linear regression relationship between inhibition percentage and sample concentration (y = bx + a) at y = 50. The DPPH assay was conducted in accordance with established validated methodologies.³³

Data Analysis

All quantitative experimental data were subjected to statistical evaluation. Formulation optimization utilized the Simplex Lattice Design with pregelatinized starch (A) and Explotab (B) as mixture factors. Antioxidant activity results were analyzed through one-way analysis of variance (ANOVA) to assess interformulation differences. Statistical significance was evaluated at p > 0.05, at which threshold the null hypothesis of no significant interformulation difference was considered tenable.

RESULTS AND DISCUSSION

Granule Evaluation

Granule preparation was accomplished via wet granulation, and the resulting material underwent comprehensive physical characterization including moisture content, angle of repose, flow time, and bulk and tapped density measurements. Mean ± SD values for all granule parameters are summarized in **Table 2**.

Table 2. Evaluation of Granule Physical Properties

| Parameter | Formula | | |
|---------------------|---------------|---------------|---------------|
| | I | II | III |
| Loss on Drying (%) | 4.80 ± 0.01 | 3.60 ± 0.03 | 3.80 ± 0.01 |
| Angle of Repose (°) | 28.64 ± 3.69 | 32.53 ± 2.29 | 28.46 ± 3.12 |
| Flow Time (s) | 2.17 ± 0.07 | 1.86 ± 0.07 | 1.53 ± 0.06 |
| Flow Rate (g/s) | 11.51 ± 0.43 | 13.48 ± 0.47 | 16.36 ± 0.04 |
| Bulk Density (g/mL) | 0.520 ± 0.015 | 0.510 ± 0.011 | 0.530 ± 0.010 |
| Carr's Index (%) | 8.04 ± 2.36 | 10.55 ± 2.25 | 6.53 ± 4.23 |

Note:

F I = Pregelatinized starch:Explotab (0:1)

F II = Pregelatinized starch:Explotab (1:1)

F III = Pregelatinized starch:Explotab (1:0)

Evaluation Results of Basil Leaf Extract Granules

The data obtained from the evaluation of the granule responses were processed using the Simplex Lattice Design (SLD) approach to generate predictive mathematical models. These equations delineate the specific contributions and functional roles of pregelatinized starch (A) and Explotab (B) for each investigated response (**Table 3** and **Figure 1**).

Table 3. Simplex Lattice Design (SLD) Model Equations

| Responses | Equation |
|----------------|-----------------------|
| Loss on Drying | Y = 3.566A + 4.566B |
| Flow Time | Y = 1.533A + 2.173B |
| Flow Rate | Y = 16.36A + 11.51B |
| Bulk Density | Y = 0.5250A + 0.5150B |
| Carr's Index | Y = 6.53A + 8.04B |

Note: A = pregelatinized starch; B = Explotab

Moisture content, as determined by loss on drying (LOD), remained within the acceptable pharmaceutical range of 2–5% across all formulations, satisfying established quality requirements.³⁴ Maintaining this defined moisture window is essential for ensuring adequate compressibility during the tableting operation. Excessive residual moisture renders granules adhesive and prone to sticking to compression surfaces, creating mechanical failures such as capping or lamination. Conversely, over-dried granules lack sufficient inter-particle cohesion, producing tablets of unacceptably low mechanical strength.³⁵ The LOD parameter therefore functions as a critical determinant of tablet mechanical performance, directly conditioning hardness, friability, and disintegration characteristics.³⁴

LOD values across all formulations fell consistently within the accepted 2–5% range,³⁴ confirming the suitability of the drying protocol. The SLD equation ($Y = 3.566A + 4.566B$) revealed that Explotab (B) exerted a greater influence on moisture retention than pregelatinized starch (A). This higher coefficient for Explotab reflects its characteristically hygroscopic nature and its propensity to engage water molecules through hydrophilic functional groups, establishing hydrogen bonding networks and liquid bridge structures.³⁶ Elevated moisture levels enhance interparticle cohesion and stabilize the powder bed structure. While moderate moisture availability can enhance granule plasticity, higher moisture levels may paradoxically increase inter-particle cohesion and negatively affect powder flow behavior.³⁷

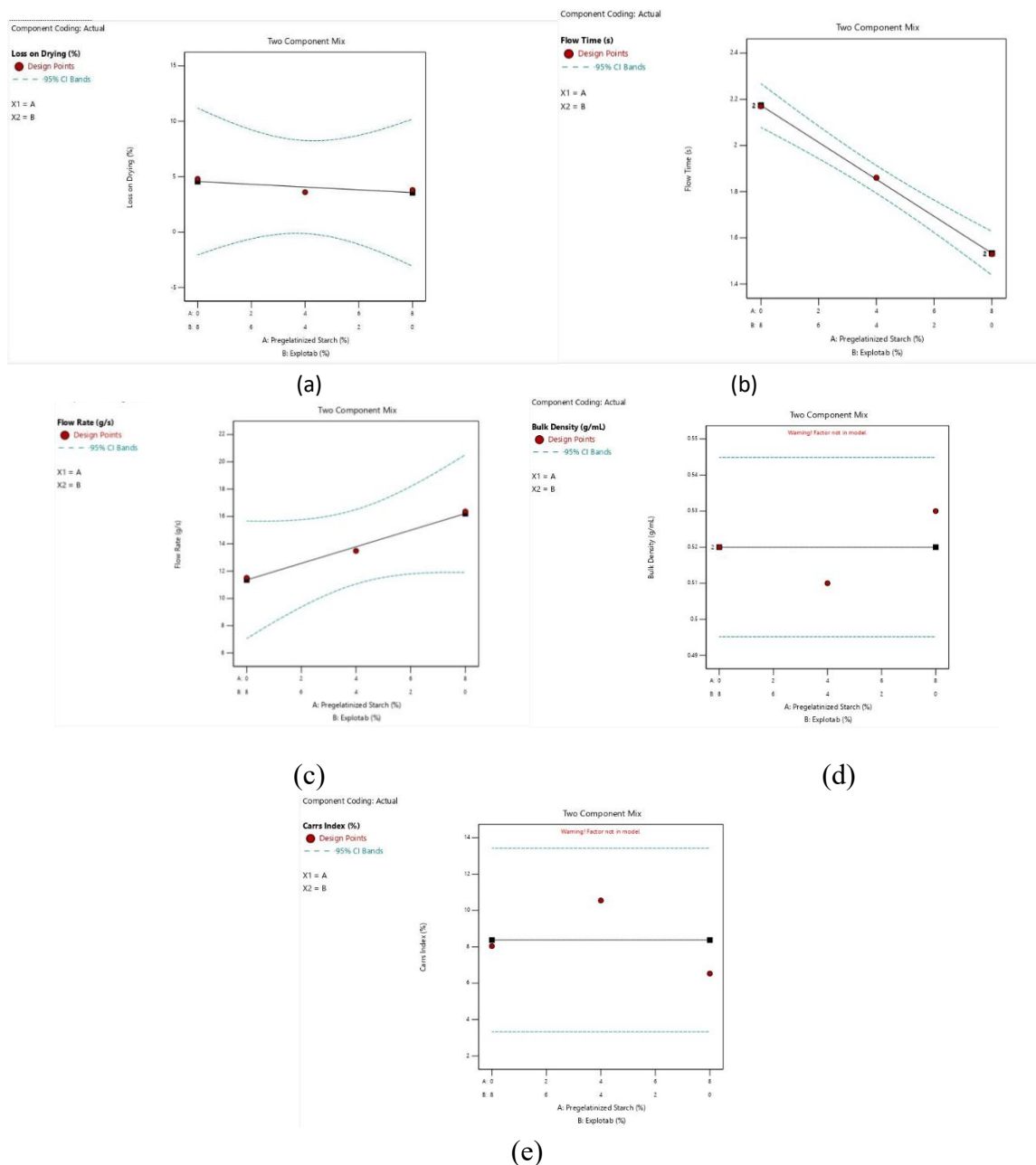


Figure 1. Graph of pregelatinized starch and Explotab. (a) Loss on Drying; (b) Flow time; (c) Flow rate; (d) Bulk density; (e) Carr's Index.

Granule flowability was comprehensively characterized through the combined assessment of angle of repose, flow time, and flow rate. All formulations yielded acceptable angles of repose (25–45°), reflecting generally satisfactory flow characteristics.³⁸ However, Formula II recorded the highest angle of repose, consistent with its elevated Explotab (B) proportion and the associated moisture-induced cohesive tendency. The SLD model for flow time ($Y = 1.533A + 2.173B$) corroborated that Explotab imposed a stronger positive influence on flow time, reflecting slower granule bed discharge attributable to heightened inter-particle adhesion.³⁹ Since flow time and flow rate are inversely related, the flow rate model ($Y = 16.36A + 11.51B$) requires contextual interpretation. The larger coefficient for pregelatinized starch (A) indicates that its incorporation more substantially enhances flow rate by improving particle mobility and reducing resistance between granules. The smaller Explotab coefficient reflects its tendency to suppress flow rate through moisture-mediated cohesion, a phenomenon widely recognized as governing powder flow behavior through liquid bridge formation and modification of inter-particle surface interactions.³⁷ The predominant mechanistic contribution of Explotab thus remains cohesion enhancement rather than flow improvement.⁴⁰

The superior flow properties observed in Formula III (Table 2), evidenced by its lowest flow time and highest flow rate, are attributed to the flow-facilitating characteristics of pregelatinized starch. Its comparatively lower hygroscopicity and favorable particle geometry reduces inter-particle friction and facilitate particle rearrangement during discharge. This interpretation is substantiated by Carr's index data, where the higher Explotab coefficient (6.53A vs. 8.04B) indicates greater volume reduction upon tapping—behavior consistent with cohesion-dominated packing mechanisms—although the experimental value for Formula II suggests a possible nonlinear interaction between the two components.^{40 41} The marginally elevated bulk density contribution of pregelatinized starch reflects improved initial packing efficiency prior to mechanical consolidation.⁴¹

All formulations yielded Carr's index values below 20%, confirming satisfactory compressibility.⁴² Formula III exhibited the lowest index, reflecting superior packing efficiency and minimal volume loss upon tapping. Low Carr's index values correspond to reduced inter-particle friction and facilitated particle rearrangement under mechanical stress, both of which are advantageous during tableting.⁴³ This superior compressibility profile of Formula III is mechanistically consistent with the deformation characteristics of pregelatinized starch.

Beyond its flowability contributions, pregelatinized starch exerts a highly significant role during tablet compression. The enhanced compactibility of pregelatinized starch is fundamentally attributable to disruption of its native crystalline architecture and reduction of crystallinity occurring as a consequence of the pregelatinization process.^{44 45} These structural shifts are essential for facilitating plastic deformation when compression force is exerted. As particles undergo plastic deformation, they experience permanent morphological changes that broaden the interparticle contact zones, which in turn promotes the development of solid bridges throughout the tablet matrix. This mechanism is vital for improving bonding density and elevating the mechanical durability of the dosage form. Research indicates that compared to native starches, pregelatinized variants display a much higher degree of plastic deformation, thus serving as a primary driver for their enhanced compacting capabilities.^{44 45}

Excipients exhibiting limited plastic deformation capacity or excessive cohesive characters generally fail to establish robust inter-particle bonds under compression, constraining overall compaction performance. The optimized particle geometry and plastic flow properties of pregelatinized starch thus provide functional complementarity to the cohesion-modulating effects of Explotab. These synergistic interactions between the two components collectively define the compaction behavior characterizing each experimental formulation.^{45 46}

The SLD analysis collectively indicates that granule performance is governed by an equilibrium between moisture-mediated cohesion contributed primarily by Explotab, and morphology- and deformation-mediated compressibility conferred by pregelatinized starch. These complementary mechanistic contributions account for the observed variability in granule rheology, packing behavior, and anticipated compaction performance across the formulation series.⁴⁵

Tablet Evaluation

Physical characterization of the compressed tablets encompassed evaluation of weight uniformity, dimensional uniformity, hardness, friability, and disintegration time. Summarized results are presented in **Table 4**. Subsequently, the quantitative data derived from the tablet responses—specifically weight uniformity, friability, and disintegration time—were also modeled using the SLD framework. This yielded specific regression equations that represent the definitive impact of pregelatinized starch (A) and Explotab (B) on each evaluated tablet response (**Table 5** and **Figure 2**).

Table 4. Physical Properties of Basil Leaf Extract Tablets

| Parameter | Formula | | |
|--------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | I | II | III |
| Average Weight (mg) | 106.80 ± 2.24 | 106.20 ± 2.31 | 108.15 ± 2.30 |
| Coefficient of Variation (%) | 2.095 | 2.172 | 2.126 |
| Size Uniformity (mm) | D = 0.58 ± 0.00 T = 0.22 ± 0.00 | D = 0.58 ± 0.00 T = 0.22 ± 0.00 | D = 0.58 ± 0.00 T = 0.22 ± 0.00 |
| Hardness (kg/cm ²) | 1.90 ± 0.29 | 1.64 ± 0.37 | 2.11 ± 0.28 |
| Friability (%) | 0.92 ± 0.03 | 0.46 ± 0.21 | 0.45 ± 0.09 |
| Disintegration Time (seconds) | 12.24 ± 1.03 | 09.00 ± 1.26 | 13.28 ± 0.90 |

Note: F I = Pregelatinized starch:Explotab (0:1); F II = Pregelatinized starch:Explotab (1:1); F III = Pregelatinized starch:Explotab (1:0).

Weight uniformity assessment (**Table 4**) confirmed that all formulations satisfied the acceptance criteria. Per pharmacopeial specifications, no more than two tablets may deviate from the mean weight by more than 10%, and no individual tablet may deviate by more than 20%.²⁹ Calculations confirmed that none of the tablets from Formulas I, II, or III exceeded these permissible deviations. CV values of 2.095, 2.172, and 2.126 for the respective formulations all remained below the 5% threshold, demonstrating satisfactory weight consistency.⁴⁷

Table 5. Simplex Lattice Design (SLD) Model Equations for Tablet Responses

| Responses | Equation |
|---------------------|-------------------------------|
| Weight uniformity | $Y = 2.146 (A) + 2.115 (B)$ |
| Friability | $Y = 0.375 (A) + 0.845 (B)$ |
| Disintegration time | $Y = 12.026 (A) + 10.986 (B)$ |

Note = A = pregelatinized starch; B = Explotab

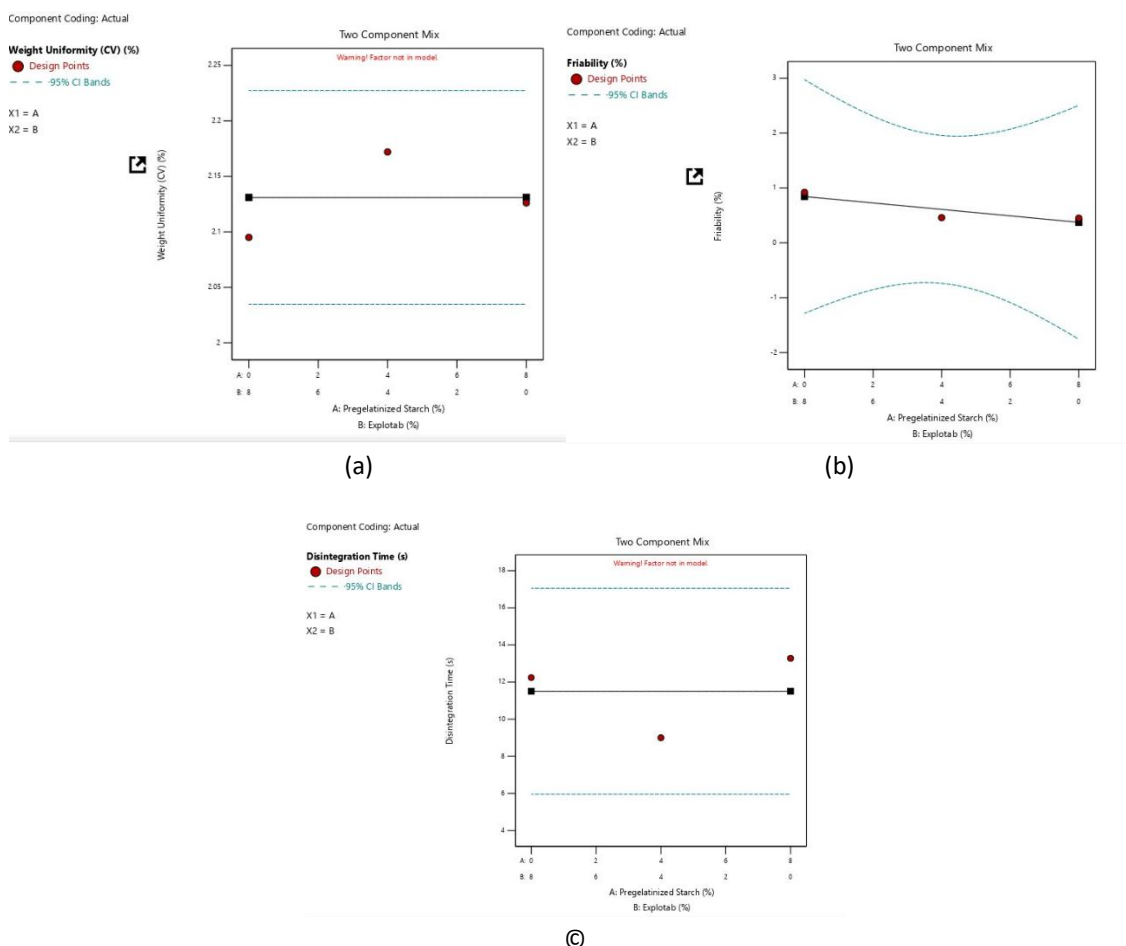


Figure 2. Graph of pregelatinized starch and Explotab. (a) Weight uniformity (CV); (b) Friability; (c) Disintegration time.

The SLD equation for weight uniformity CV ($Y = 2.146A + 2.115B$) reveals that both components contribute comparably to weight variability, with a marginally higher coefficient for pregelatinized starch. The negligible inter-component coefficient difference implies that altering the disintegrant ratio exerts minimal influence on overall tablet

weight consistency. Weight variation in these systems is predominantly conditioned by granule flowability and die-filling precision during compression rather than disintegrant identity. Irregular granule flow predisposes to uneven volumetric die filling, which is the primary driver of interformulation weight disparities.

Hardness evaluation (**Table 4**) revealed that all formulations fell below the accepted standard range of 4–10 kg/cm², with measured values between 1.64 and 2.11 kgf/cm². Despite this finding, the low friability values (all <1%) merit mechanistic explanation. Tablet hardness reflects resistance to diametral fracture, which depends on bonding area extent and bond strength developed during compression. Materials exhibiting substantial plastic deformation generate broader inter-particle contact zones, thereby increasing tensile strength.^{48 49}

In contrast, friability quantifies resilience against cumulative low-intensity mechanical abrasion, which depends on surface cohesion and architectural robustness of the tablet structure rather than resistance to singular fracture events. The relatively low tablet mass of approximately 100 mg likely attenuated kinetic impact energy during standardized friability testing, reducing weight loss despite limited crushing strength.⁵⁰ Residual moisture-related cohesion within the granule matrix may additionally reduce surface attrition.⁵¹ The SLD model ($Y = 0.375A + 0.845B$) indicates that Explotab contributes more substantially to friability due to limited plastic flow and increased elastic recovery, while pregelatinized starch generates broader bonding surfaces that improve abrasion resistance despite lower crushing strength.^{50 52}

All formulations met pharmacopeial disintegration requirements, completing the process within 15 minutes (**Table 4**). Disintegration time reflects the duration required for tablet fragmentation into particles amenable to dissolution, a process governed primarily by disintegrant type and concentration, with secondary contributions from other excipients.⁵³ Formula II demonstrated the most rapid disintegration, attributable to the synergistic co-disintegrant activity of pregelatinized starch and Explotab. Pregelatinized starch promotes structural fragmentation through a swelling mechanism, expanding upon hydration to generate internal pressure within the tablet core.⁵⁴ Simultaneously, Explotab (sodium starch glycolate) functions as a superdisintegrant with exceptional capacity for rapid water uptake, driving swift matrix rupture through combined wicking and swelling effects.⁵⁰ This dual-action mechanism optimizes aqueous penetration and starch granule expansion, yielding an accelerated disintegration profile.

Such accelerated fragmentation is critical, as it typically enhances dissolution rates and may lead to a faster onset of therapeutic action.⁴⁷ In contrast, Formula III exhibited the longest disintegration time, consistent with its comparatively higher crushing strength. Elevated tablet hardness is generally associated with reduced porosity, which impedes fluid ingress and consequently slows the disintegration sequence.⁵⁰ The SLD model ($Y = 12.026A + 10.986B$) indicates that pregelatinized starch exerts a stronger prolonging effect on disintegration time relative to Explotab, confirming that higher pregelatinized starch concentrations tend to retard tablet disintegration within the studied formulation range.

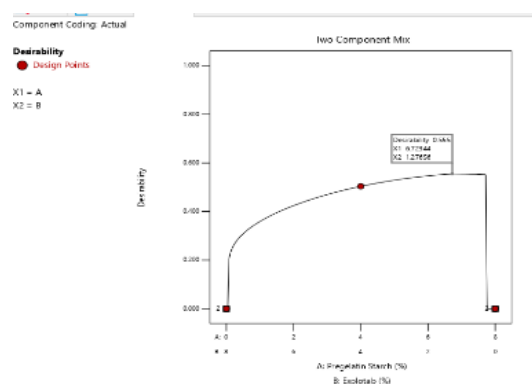


Figure 3. Predicted result of the optimum formula.

The optimal formulation within the Simplex Lattice Design framework was identified as consisting of 6.72% pregelatinized starch and 1.27% Explotab (**Figure 3**), corresponding to Formula III, which yielded a composite desirability value of 0.555. An optimized formulation is technically defined by its ability to maintain all response variables within predetermined acceptable limits. The desirability index quantifies proximity to optimization targets, with higher values indicating more favorable overall formulation performance.⁵⁵

Antioxidant Activity Test

Radical scavenging capacity of the formulated basil leaf extract tablets was evaluated in vitro using the DPPH assay, with ascorbic acid serving as the positive control reference. The mechanistic basis of the DPPH method relies on the transfer of hydrogen atoms from antioxidant molecules to the DPPH radical, converting it to a stable non-radical product. This chemical transformation manifests as a visible chromatic change from intense violet to pale yellow, quantifiable as decreased absorbance at the peak wavelength.⁵⁶ The DPPH methodology was selected for its procedural simplicity, high analytical sensitivity, low sample volume requirements, and the exceptional stability of the DPPH radical compared to other reactive species, collectively ensuring experimental reliability and reproducibility.⁵⁶

Determination of the maximum wavelength was performed by measuring the absorbance of a 40 ppm DPPH solution using UV–Vis spectrophotometry in the range of 450–600 nm.⁵⁶ The measurement produced a maximum wavelength of 522 nm with an absorbance of 0.7530. This wavelength served as the fixed measurement parameter for all subsequent antioxidant analyses.

Ascorbic acid served as the benchmark positive control, selected for its well-documented role as a potent natural antioxidant often used as a standard in radical scavenging evaluations.⁵⁷ From a 1,000 ppm stock solution, a series of dilutions were prepared to reach concentrations of 2, 4, 6, 8, and 10 ppm. These solutions were reacted with DPPH and subjected to a 30-minute incubation period in the absence of light; The characteristic color transition from purple to yellow confirmed progression of the antioxidant reaction.⁵⁸ This observed reduction in absorbance values directly quantifies the radical-neutralizing capacity of the test material.⁵⁹

For the sample analysis, a stock solution of basil leaf ethanol extract tablets (1,000 ppm) was prepared and centrifuged at 4,000 rpm for 10 minutes to obtain a clear supernatant. This resulting solution was subsequently diluted to establish a concentration gradient of 10, 20, 30, 40, and 50 ppm.³²

Absorbance values were measured using UV–Vis spectrophotometry, and each formula was tested in triplicate to ensure reliable data (43). All measurements were conducted in triplicate, and IC₅₀ values were derived from linear regression analysis.⁶⁰

The results indicated that basil leaf ethanol extract tablets exhibited very strong antioxidant activity in the formulation containing 100 mg of basil leaf extract. The antioxidant activity test results are presented in **Table 6**.

Table 6. Antioxidant Activity (IC₅₀) of Basil Leaf Extract Tablets Compared with Vitamin C

| Sample | Linear Regression Equation | IC ₅₀ (ppm) ± SD |
|---------------|----------------------------|-----------------------------|
| Ascorbic acid | $y = 5.4349x - 3.4536$ | 11.61 ± 6.11 |
| Formula I | $y = 1.2310x + 1.7867$ | 39.52 ± 4.79 |
| Formula II | $y = 1.5226x - 0.4308$ | 33.78 ± 5.76 |
| Formula III | $y = 1.2347x + 3.1354$ | 37.97 ± 2.48 |

The positive control, ascorbic acid, yielded an IC₅₀ of 11.61 ppm, reflecting its well-established potent radical scavenging capability and validating its selection as a reference compound for antioxidant benchmarking.⁶¹ A concentration-dependent decrease in absorbance was observed across all test samples, reflecting proportionally increasing DPPH radical inhibition attributable to greater availability of antioxidant molecules at elevated concentrations. This chemical reduction mediated by hydrogen atom or electron donation is visually manifested as the purple-to-yellow chromatic transition, with the resulting absorbance decline serving as a direct quantitative indicator of radical scavenging activity.

All three tablet formulations exhibited very strong antioxidant activity, with IC₅₀ values of 39.52 ppm (Formula I), 33.78 ppm (Formula II), and 37.97 ppm (Formula III). Although all formulations classified as strong antioxidants (IC₅₀ < 50 ppm), their activity remained below that of pure ascorbic acid, which is expected given that the latter is a chemically pure compound,⁶² whereas tablet formulations contain pharmaceutical excipients that may dilute or partially attenuate the apparent antioxidant activity of the extract.

The comparable antioxidant performance across formulations reflects the standardized basil extract content of 25 mg per tablet in all preparations. The antioxidant activity of *Ocimum basilicum* is primarily attributable to the presence of phenolic compounds, flavonoids, tannins, and essential oil constituents, which function as effective hydrogen- or electron-donating free radical scavengers. Flavonoid compounds such as apigenin are recognized as particularly significant contributors to basil's antioxidant profile.⁶³ One-way ANOVA analysis yielded a P-value of 0.3458 (> 0.05), confirming the absence of statistically significant differences in antioxidant activity among the three formulations.

Limitation

The present study is subject to certain methodological constraints. The application of a linear SLD model may not fully represent non-linear component interactions, as suggested by the deviation observed in the Carr's index value for Formula II. Additionally, characterization was restricted to fundamental granule and tablet parameters without advanced physicochemical characterization.

Despite these constraints, the study generates meaningful insights into the respective roles of pregelatinized starch and Explotab in determining granule flowability and compressibility profiles. These findings may serve as a practical reference for future optimization of binary excipient systems in herbal tablet development.

CONCLUSION

This investigation was conducted to evaluate the influence of pregelatinized starch and Explotab proportions on the physical quality of basil leaf (*Ocimum basilicum* L.) ethanol extract tablets and to identify the optimum formulation through the Simplex Lattice Design approach. Tablets were manufactured using wet granulation technique and subjected to comprehensive granules and tablet evaluation. The findings established that pregelatinized starch predominantly enhanced bulk density, weight uniformity, flow rate, and disintegration time, while Explotab exerted greater influence over moisture content, flow time, Carr's index, and friability. The optimal formulation predicted by Design-Expert® 13 comprised 6.72% pregelatinized starch and 1.27% Explotab. All formulations demonstrated very strong antioxidant activity with IC₅₀ values ranging from 33.78 to 39.52 ppm, collectively confirming that the tablets possess both satisfactory physical quality attributes and notable antioxidant potential.

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GENERATIVE AI DISCLOSURE STATEMENT

Generative artificial intelligence tools, including ChatGPT and Grammarly, were employed for linguistic refinement and grammatical improvement during manuscript preparation. All content was critically reviewed and edited by the authors, who retain full responsibility for the accuracy and scientific integrity of the final manuscript.

AUTHOR CONTRIBUTION STATEMENT

Hayatus Sa'adah: Conceptualization, Methodology, Investigation, Formal Analysis, Writing—Original Draft Preparation; **Halimatus Sya'diyah:** Data Curation, Visualization; **Achmad Kadri Ansyori:** Validation, Resources; **Supomo Supomo:** Supervision, Writing—Reviewing and Editing.

CONFLICT OF INTEREST DECLARATION

The authors declare that no financial or personal relationships exist that could have influenced the work described in this manuscript.

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