

OPTIMIZATION OF IMMEDIATE-RELEASE IBUPROFEN TABLETS USING A 3² FACTORIAL DESIGN: INFLUENCE OF POVIDONE K-30 AND SODIUM STARCH GLYCOLATE

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ABSTRACT

Background: The development of immediate-release tablets requires an appropriate balance between mechanical strength, disintegration, and drug dissolution. Binder and superdisintegrant concentrations are important formulation variables that may influence these quality attributes. **Objective:** The present study aimed to investigate the combined effects of Povidone K-30 and sodium starch glycolate (SSG) on the pharmaceutical properties of immediate-release ibuprofen tablets using a 3² factorial design. **Materials and Methods:** Nine formulations (F1–F9) containing 200 mg of ibuprofen per tablet were investigated by varying Povidone K-30 and SSG concentrations at three levels. Povidone K-30 was evaluated at 2%, 4%, and 6%, while SSG was evaluated at the same concentration levels. The prepared formulations were assessed for average tablet weight, thickness, hardness, friability, disintegration time, drug content, and in vitro drug release. The reported experimental findings were interpreted in relation to the individual and combined effects of the selected excipients. **Results:** Average tablet weights ranged from 399 to 402 mg, hardness ranged from 62 to 86 N, and friability ranged from 0.42% to 0.81%. Drug content varied between 98.25% and 100.50%. Disintegration time ranged from 115 to 280 seconds. Formulations F3 and F6 demonstrated approximately 99% drug release at 30 minutes. F3 exhibited a disintegration time of 115 seconds, whereas F6 showed 125 seconds, a hardness of 72 N, friability of 0.53%, and drug content of 100.10%. The reported results indicated that increasing SSG concentration generally improved disintegration and drug-release performance, while increasing binder concentration improved mechanical strength. **Conclusion:** The findings demonstrate the usefulness of factorial formulation development for examining excipient-related changes in immediate-release ibuprofen tablets. F6 represents a promising formulation when mechanical strength and dissolution are considered together; however, definitive selection requires verified statistical analysis and predefined multiresponse optimization criteria.

KEYWORDS: Ibuprofen, immediate-release tablets, Povidone K-30, sodium starch glycolate, factorial design, tablet optimization, dissolution.

1. INTRODUCTION

Oral tablets are among the most widely used pharmaceutical dosage forms because of their convenience, accurate dosing, stability, portability, and suitability for large-scale manufacturing. The quality and performance of a tablet depend on the physicochemical properties of the active pharmaceutical ingredient (API), excipient selection, manufacturing conditions, and interactions between formulation components.^[1,2]

Immediate-release tablets are designed to release their active ingredients without an intentional mechanism for delaying or extending drug release. Following administration, the tablet should disintegrate in the

surrounding fluid, exposing drug particles to the dissolution medium. The subsequent dissolution process is important because dissolved drug becomes available for absorption. Disintegration and dissolution are related but distinct processes; therefore, both should be evaluated during formulation development.^[3,4]

Ibuprofen is a non-steroidal anti-inflammatory drug widely used for its analgesic, antipyretic, and anti-inflammatory properties. Its therapeutic effects are primarily associated with the inhibition of cyclooxygenase-mediated prostaglandin synthesis. Although ibuprofen is an established pharmaceutical ingredient, its formulation requires appropriate

consideration of its limited aqueous solubility under certain conditions and the influence of formulation composition on dissolution performance.^[5]

Pharmaceutical excipients contribute to the manufacturability and performance of tablets. Binders improve the cohesion of powder particles and contribute to tablet mechanical strength, whereas superdisintegrants facilitate tablet breakup following contact with an appropriate liquid medium. Their combined concentrations may influence hardness, friability, disintegration time, and drug dissolution.^[1,6]

Povidone K-30 is commonly used as a pharmaceutical binder, while sodium starch glycolate promotes tablet disintegration primarily through liquid uptake and swelling. An appropriate balance between these excipients is necessary because excessive binding may increase resistance to tablet breakup, whereas insufficient binding may result in inadequate mechanical integrity. The effects depend on the formulation composition, excipient concentrations, and manufacturing conditions.^[6,7]

Design of Experiments (DoE) provides a systematic approach for investigating formulation variables and their effects on product quality. A 3^2 factorial design evaluates two independent factors at three levels each, resulting in nine combinations when a complete factorial arrangement is used. This design permits systematic examination of factor effects and can support the

evaluation of interactions and curvature when the experimental structure and statistical model permit.^[8,9]

Accordingly, the present study investigated the influence of Povidone K-30 and sodium starch glycolate concentrations on the quality attributes of immediate-release ibuprofen tablets. The objective was to identify a formulation providing a suitable balance between mechanical strength, disintegration, drug content, and in vitro drug release.

2. MATERIALS AND METHODS

2.1 Materials

Ibuprofen was used as the active pharmaceutical ingredient. Povidone K-30 served as the binder, and sodium starch glycolate was used as the superdisintegrant. Microcrystalline cellulose PH102 and lactose monohydrate were included as diluents. Talc and magnesium stearate were identified as additional formulation excipients in the thesis. Analytical-grade reagents and distilled water were used where applicable.

2.2 Experimental design

A 3^2 factorial design was employed to investigate the effects of two independent formulation variables: Povidone K-30 concentration (Factor A) and sodium starch glycolate concentration (Factor B). Each factor was investigated at three levels: 2%, 4%, and 6%. The nine combinations were designated F1–F9, as presented in Table 1.

Table 1: Factorial design of the ibuprofen tablet formulations.

Formulation	Povidone K-30 (%)	Sodium starch glycolate (%)
F1	2	2
F2	2	4
F3	2	6
F4	4	2
F5	4	4
F6	4	6
F7	6	2
F8	6	4
F9	6	6

Each formulation was designed to contain 200 mg of ibuprofen, with a reported target tablet weight of approximately 400 mg. The precise final composition should be confirmed against the actual manufacturing records before publication.

2.3 Preformulation studies

Ibuprofen was examined for physical appearance, solubility, melting-point range, and powder-flow characteristics. Bulk density and tapped density were used to calculate Carr's index and Hausner ratio. The angle of repose was also determined to assess powder flow. Drug–excipient mixtures were examined for visible changes in appearance and texture; such observations

were considered preliminary compatibility assessments rather than definitive evidence of chemical compatibility.

2.4 Preparation of tablets

The formulation approach involved weighing the API and selected excipients, blending the powders, incorporating the lubricant and other appropriate excipients, and compressing the blend into tablets using a tablet compression machine. The manufacturing process was intended to remain consistent across the nine formulations so that differences in tablet performance could be evaluated in relation to the selected formulation variables.

The final manuscript should specify the actual compression method, batch size, mixing times,

compression conditions, and quantities of all excipients from the laboratory records.

2.5 Evaluation of tablet properties

The prepared formulations were evaluated for average tablet weight, thickness, crushing strength, friability, disintegration time, drug content, and in vitro drug release.

Tablet weight was determined by weighing individual tablets and calculating the average mass. Thickness was measured using an appropriate measuring instrument, while crushing strength was recorded in newtons. Friability was evaluated by determining tablet weight loss after mechanical rotation in a friabilator.

Disintegration time was measured using a disintegration apparatus under the specified test conditions. Drug content was determined using a UV-visible spectrophotometric procedure, and dissolution testing was performed using a suitable dissolution apparatus and analytical method. The complete analytical procedures, dissolution medium, operating conditions, calibration data, and applicable acceptance criteria should be reported from the verified experimental protocol.

2.6 Statistical analysis

The study used a factorial-design approach to investigate the effects of binder and superdisintegrant concentrations on tablet hardness, friability, disintegration time, and drug release. Regression analysis and analysis of variance (ANOVA) were identified as the intended statistical methods.

A statistically justified model should be fitted using the original experimental observations, with suitable assessment of model adequacy, residuals, and factor effects. The reported statistical results require

verification against the original data and complete statistical output before they are interpreted as confirmatory evidence.

3. RESULTS AND DISCUSSION

3.1 Preformulation and powder-flow characteristics

Ibuprofen was reported as a white crystalline powder, practically insoluble in water and freely soluble in ethanol and methanol. The reported melting-point range was 75–78°C. Bulk density was 0.42 ± 0.01 g/mL, and tapped density was 0.51 ± 0.01 g/mL. Carr's index, Hausner ratio, and angle of repose were reported as 17.65%, 1.21, and $29.4 \pm 0.5^\circ$, respectively.

The formulation blends showed Carr's index values between 14.04% and 16.98%, Hausner ratios between 1.16 and 1.20, and angles of repose between 27.9° and 30.5° . These reported values suggest generally acceptable flow characteristics for powder processing. Nevertheless, powder flow should be interpreted alongside the actual manufacturing method and die-filling consistency.

3.2 Physical properties of tablets

The average tablet weight ranged from 399 to 402 mg, indicating limited variation in the reported batch averages. Tablet thickness increased from 4.11 mm for F1 to 4.25 mm for F9.

Hardness values ranged from 62 N to 86 N, whereas friability ranged from 0.42% to 0.81% (Table 2). The reported pattern showed higher hardness and lower friability toward the formulations containing greater binder concentrations. This trend is consistent with the role of binders in promoting interparticle cohesion and improving the mechanical integrity of compressed tablets.^[1,6]

Table 2. Physical properties of ibuprofen tablets

Formulation	Average weight (mg)	Thickness (mm)	Hardness (N)	Friability (%)
F1	401	4.11	62	0.81
F2	400	4.13	64	0.76
F3	402	4.14	63	0.70
F4	401	4.15	71	0.63
F5	400	4.16	74	0.57
F6	399	4.17	72	0.53
F7	402	4.21	82	0.49
F8	401	4.23	84	0.45
F9	400	4.25	86	0.42

Source: Values reported in the supplied thesis.

The physical results suggest that binder concentration contributed to the mechanical properties of the tablets. However, the observed pattern should not be interpreted as proof of a statistically significant binder effect without verification of the underlying observations and statistical analysis.

3.3 Disintegration time

Disintegration time ranged from 115 to 280 seconds. F3 exhibited the shortest disintegration time (115 seconds), followed by F6 (125 seconds). F7 showed the longest disintegration time (280 seconds).

The results generally indicated that increasing sodium starch glycolate concentration was associated with shorter disintegration times. This observation is consistent with the water-uptake and swelling mechanisms associated with sodium starch glycolate. In contrast, greater binder concentration was generally associated with longer disintegration, potentially reflecting the increased resistance of the compact structure to breakup.^[6,7]

These observations emphasize that excipient concentrations should be evaluated together rather than independently. A formulation with rapid disintegration must also retain sufficient mechanical strength to withstand routine handling.

3.4 Drug-content analysis

Drug content ranged from 98.25% to 100.50% of the theoretical ibuprofen content (Table 3). F6 exhibited a reported drug content of 100.10%, while F9 showed the highest value of 100.50%.

Table 3. Drug content of the nine formulations

Formulation	Measured drug content (mg/tablet)	Drug content (%)
F1	196.5	98.25
F2	198.4	99.20
F3	199.1	99.55
F4	197.8	98.90
F5	199.3	99.65
F6	200.2	100.10
F7	198.7	99.35
F8	199.8	99.90
F9	201.0	100.50

The results indicate that the reported samples contained drug quantities close to the theoretical 200 mg dose. However, drug content from a tested sample should be distinguished from compendial uniformity of dosage units, which requires the applicable individual-unit testing procedure.

3.5 In vitro drug-release study

The dissolution results demonstrated differences in the release profiles among the nine formulations. At 30 minutes, F3 and F6 each achieved approximately 99% drug release, whereas F1 and F4 showed 83% and 80% release, respectively.

Table 4: Reported cumulative drug release (%).

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	21	28	34	20	27	33	18	24	31
10	39	51	61	38	49	60	35	47	58
15	56	69	81	53	67	79	49	63	76
20	69	82	92	66	80	91	62	77	89
30	83	94	99	80	92	99	77	89	97
45	92	99	100	90	98	100	87	96	99

Source: Values reported in the supplied thesis.

The relatively rapid release observed for F3 and F6 is consistent with the generally shorter disintegration times of formulations containing higher SSG concentrations. Faster tablet breakup may expose a greater surface area of drug particles to the dissolution medium, thereby facilitating dissolution. Nevertheless, dissolution performance is also influenced by drug solubility, particle characteristics, tablet porosity, and test conditions.^[3,4]

The results suggest that SSG concentration is an important variable in this formulation system. However,

the dissolution profiles alone do not establish bioavailability or in vivo therapeutic performance.

3.6 Formulation optimization

F6 was identified in the thesis as the optimized formulation. Its reported characteristics included hardness of 72 N, friability of 0.53%, disintegration time of 125 seconds, drug content of 100.10%, and approximately 99% drug release at 30 minutes.

F3, however, demonstrated a shorter disintegration time of 115 seconds and approximately 99% drug release at the same time point, with hardness of 63 N and friability

of 0.70%. Consequently, the preferred formulation depends on the relative importance assigned to mechanical integrity, rapid disintegration, friability, and dissolution.

F6 can reasonably be described as a promising candidate because it combined relatively high mechanical strength with rapid drug release. Nevertheless, the claim that it is the definitive optimum should be supported by predefined response targets, verified factorial-model results, and confirmation experiments. A complete statistical analysis is particularly important because a 3^2 factorial design is intended to provide more information than a comparison of individual formulation means alone.^[8,9]

4. CONCLUSION

The present study investigated immediate-release ibuprofen tablets using a 3^2 factorial design to examine the combined effects of Povidone K-30 and sodium starch glycolate concentrations. The reported results showed average tablet weights of 399–402 mg, hardness values of 62–86 N, friability values of 0.42–0.81%, and drug content ranging from 98.25% to 100.50%. Disintegration time ranged from 115 to 280 seconds.

Increasing sodium starch glycolate concentration was generally associated with shorter disintegration times and improved drug-release performance, whereas higher binder concentrations were associated with greater tablet hardness and lower friability. Formulations F3 and F6 achieved approximately 99% drug release within 30 minutes. F6 exhibited a potentially useful balance of mechanical strength, friability, disintegration, and drug content, although F3 showed slightly faster disintegration.

Overall, the findings support the use of systematic experimental design in immediate-release tablet development. Before final publication, the formulation composition, statistical analysis, dissolution method, and selection criteria for the optimized batch should be verified against the original experimental records. Further confirmatory testing is necessary before making definitive optimization or broader performance claims.

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