FORMULATION DEVELOPMENT AND OPTIMIZATION OF IMMEDIATE RELEASE TABLET FROM THE METHANOLIC EXTRACT OF *TINOSPORA CORDIFOLIA* AND COMPARATIVE EVALUATION WITH A MARKETED DRUG

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Abstract:

This study involved formulation development and evaluation of immediate-release tablets made from Tinospora cordifolia stem extract methanolic extract to determine its immunomodulatory properties. Soxhlet extraction produced a 19.41% yield of methanolic extract which demonstrates methanol extract bioactive compounds efficiently. Three super disintegrants including Croscarmellose Sodium (CCS) and Sodium Starch Glycolate (SSG) together with Crospovidone (CP) were utilized as excipients at concentrations of 2%, 4% and 6% in nine different formulations (F1–F9). The optimized formulation (F3) exhibited remarkable mechanical strengths through its measured hardness range between 6.8 kg/cm² to 7.4 kg/cm² along with a minimum friability of 1% to ensure tablet stability during storage and distribution. The disintegration time for F3 proved the fastest among all formulations because it required just 8.25 minutes. The drug release time reached its minimum point when measured at F3 (13 seconds). All prepared formulations exhibited drug content uniformity standards between 98.12% and 99.12% which indicates consistent delivery of medication. The stability assessment showed no detrimental changes in the physical characteristics during 60-day testing periods. The optimized Tinospora cordifolia IR tablet (F3) showed better dissolution performance along with faster disintegration times than the standard commercial product therefore establishing itself as an effective treatment option. The experimental data shows that Tinospora cordifolia extract holds promise for developing optimized immune-supporting drug formulations.

Keywords: Tinospora cordifolia, Immediate-release tablet, Methanolic extract, Super disintegrants

1. Introduction

Traditional healthcare approaches utilize medicinal plants as a valuable source of bioactive compounds that demonstrate therapeutic value. *Tinospora cordifolia* known as Guduchi and Amrita has emerged as a prominent medicinal plant because of its multiple therapeutic properties. *T. cordifolia* serves traditional Ayurvedic medicine because it demonstrates properties including immunomodulation and antioxidant defense as well as antimicrobial action and anti-inflammatory benefits[1]. Multiple therapeutic effects from *Tinospora cordifolia* are possible because it contains alkaloids and diterpenoids and glycosides and polysaccharides as bioactive constituents[2]. Rapid drug delivery occurs through pharmaceutical immediate-release tablets that speed up gastrointestinal absorption and disintegration operations in the gut. The development of these tablets requires super disintegrants through which rapid disintegration and speeder drug release become possible. Medical experts use Croscarmellose Sodium (CCS) alongside Sodium Starch Glycolate (SSG) and Crospovidone (CP) as super disintegrants because these agents demonstrate exceptional swelling power and wicking ability for better tablet breakdown which enhances bioavailability[3].

The scientific evidence indicates *Tinospora cordifolia* demonstrates considerable promise as an immune system modifier due to its

capacity to enhance phagocytic activity in addition to promoting neutrophil function along with the stimulation of cytokine production. The immunomodulatory properties of *Tinospora cordifolia* were observed in different laboratory tests and biological experiments indicates its potential for immune control therapy [4]. Multiple bioactive compounds joins forces to enhance therapeutic effectiveness when medicinal plant extracts are used in formulation development according to studies. Clinical development of *T. cordifolia* extract tablets as an immediate-release formulation would establish a convenient delivery system to optimize therapeutic benefits of immunomodulation alongside patient-friendly dosage accuracy protocols. These formulations prove advantageous for specific médical needs which demand immediate immune response and urgent therapeutic measures.

2. Litraeture Review

Modi *et al.* (2020) explains the *T. cordifolia's* morphology, taxonomic classification and biological activities and the micropropagation methods. The study explores how *T. cordifolia* functions as a treatment for emerging illnesses like COVID-19 in addition to examining its medical potential. The review argues for scientific testing of traditional medical knowledge through thorough research. *Tinospora cordifolia* serves as a widely known médicinal plant that grows primarily across southern Asia where people know it as Guduchi or Gurjo. The Menispermaceae family shrub *Tinospora cordifolia* functions as a therapeutic agent in traditional medicine and grows in a climbing form. The traditional botanical uses of *T. cordifolia* extend back many years and doctors apply it frequently to treat patients with diabetes and jaundice and immune-related medical conditions. Medicinal properties in *T. cordifolia* result from its abundant composition of alkaloids together with sesquiterpenoids diterpenoids, phenolics, glycosides, steroids and polysaccharides. Phytoconstituents within *T. cordifolia* generate an extensive pharmaceutical profile because they lead to antidiabetic and immunomodulatory alongside antioxidant, anticancer and hepatoprotective and hypoglycemic properties. The therapeutic capabilities of *T. cordifolia* have made it a prominent focus of modern research for the development of solutions against diverse health problems.

Rahul *et al.* (2014) examined immediate-release drug delivery approaches because they enable quick drug absorption for acute and chronic illnesses. The widespread usage of tablets exists because they enable simple administration alongside outstanding manufacturing efficiency and self-use convenience. Drug disintegration and absorption from immediate-release formulations become more rapid through the use of superdisintegrants including sodium starch glycolate and polyvinylpyrrolidone. Drugs formulated with these techniques can be developed through wet granulation alongside direct compression methods. The immediate-release tablet product presents pharmaceutical companies with an opportunity to increase market exclusivity and patient adherence.

Jange *et al.*, (2023) demonstrates that tablet microstructure elements like pore geometry along with pore volume determine immediate-release drug release and disintegration times. The ability to precisely control dissolution onset and therapeutic performance should become possible with proper adjustment of microstructural properties. Complex processes prevent the achievement of desired microstructure because formulation components and manufacturing parameters interact against each other. Quality-by-Design (QbD) methodology enables systematic optimization of product performance by providing measurements of direct tablet microstructure for composition and process parameter adjustment. The article evaluates the crucial role which tablet microstructure along with liquid transport kinetics plays to optimize

the drug release and dissolution profiles. The article evaluates formulation and production parameters which define pore morphology and liquid absorption abilities and tablet breakdown features to support better immediate-release medication development.

Pande *et al.*, (2016) explains that tablets maintain their position as the preferred dosage form since they provide user-friendly administration along with excellent patient cooperation and economic benefits. The conventional tablet design fails to provide immediate therapeutic relief since it does not achieve rapid drug absorption. IR tablet formulations represent an effective approach to overcome this challenge. The designed formulation structure ensures quick drug disintegration after administration which leads to rapid dissolution and absorption. Manufacturers use several production methods to maximize immediate-release tablet function. The manufacturing techniques such as direct compression and wet granulation and tablet molding and mass extrusion techniques and super disintegrants function together to optimize immediate-release tablet performance. The different approaches help improve tablet disintegration properties thus enhancing both drug release speed and pharmacological availability. Modern pharmaceutical technology enabled the creation of new granulation methods while introducing electrostatic dry powder coating and hot-melt extrusion and injection molding and novel hole technology in fast-dissolving tablets. The modern approaches simultaneously enhance drug profiles and offer formulators enhanced flexibility during design processes.

3. Research Methodology

Preparation of Methanolic Stem Extract of *Tinospora cordifolia*

Fresh *Tinospora cordifolia* stems were collected from a local market, thoroughly washed with tap water to eliminate soil particles and debris, followed by rinsing with distilled water. The cleaned stems were shade-dried to preserve active constituents, then cut into small pieces and ground into a coarse powder using a mechanical grinder [9]. For extraction, 750 g of the powdered stem material was packed into a Soxhlet apparatus and subjected to continuous hot methanol extraction for 48 hours. The resulting extract was filtered using Whatman No. 1 filter paper, concentrated using a water bath, and yielded a dark reddish-brown residue. The final extract was weighed, and the percentage yield was calculated to assess extraction efficiency [10].

Preformulation Studies

Preformulation studies were conducted to evaluate the flow properties and compressibility of the powder blend using established methods.

Angle of Repose [11]

The angle of repose was determined using the funnel method, where the sample was poured through a funnel 2 cm above a solid base until a conical pile formed. The radius was measured, and the angle was calculated using the formula:

$$\mathbf{Tan\ \theta\ = \frac{h}{r}}$$

Bulk Density [12]

For bulk density assessment, 25 g of sieved powder (40-mesh) was gently poured into a 100 ml graduated cylinder, and the bulk volume was recorded. The bulk density was calculated as:

$$\boldsymbol{Bulk\ Density = M/Vb}$$

Tapped Density [13]

Tapped density was determined by tapping a measured powder sample in a graduated cylinder until the volume stabilized. The tapped density was calculated as:

$$\text{Tapped Density (pt)} = \frac{\text{Weight of the powder blend}}{\textit{Minimum volume occupied by the cylinder}}$$

Carr's Index [14]

Carr's Index was calculated to assess compressibility using the formula:

$$\text{Carr' index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

Hausner's Ratio [15]:

Hausner's ratio, indicating powder flow efficiency, was calculated as:

:

$$\text{Hausner's ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Formulation of Immediate Release Tablet from Methanolic Stem Extract of *Tinospora cordifolia*

Immediate release tablets of *Tinospora cordifolia* were formulated in nine batches (F1 to F9) using varying concentrations (2%, 4%, and 6%) of super disintegrants such as croscarmellose sodium and sodium starch glycolate. Each tablet had a uniform weight of 500 mg. The direct compression method was employed following standard protocols. All ingredients were milled separately using a #60-mesh sieve, followed by drying at 40–45°C to minimize moisture content. The drug and excipients (excluding magnesium stearate and talc) were blended manually for 20 minutes using the geometric addition method. Magnesium stearate and talc were sieved (#80-mesh) before being added to the primary blend. The final mixture was compressed into tablets using a Karnavati 10-station rotary punching machine with a 2 mm round concave punch at a force of 58.5 KN[16].

Table 1: Composition of Immediate Release tablet from *Tinospora cordifolia*

Ingredients (Mg)	Formulation Batches								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Tinospora cordifolia Extract	300	300	300	300	300	300	300	300	300
Crosspovidone	-	-	-	-	-	-	2%	4%	6%
Croscarmellose Sodium	2%	4%	6%	-	-	-	-	-	-
Sodium Starch Glycolate	-	-	-	2%	4%	6%	-	-	-
Microcrystalline Cellulose	150	150	150	150	150	150	150	150	150
Magnesium Stearate	10	10	10	10	10	10	10	10	10
Talc	10	10	10	10	10	10	10	10	10
Mannitol	30	30	30	30	30	30	30	30	30

Optimization Studies

i. Effect of different excipients on Dissolution Studies

A USP Type II (paddle) dissolution apparatus served for performing dissolution studies. The study utilized 900 mL of phosphate buffer solution (pH 2) at 37 ± 0.5°C under 50 rpm stirring. The method involved the periodic removal of 5-milliliter filtrate sections while maintaining the sink condition using fresh medium. The UV-Visible spectrophotometer measured the drug concentration at 247 nm during analysis. The data from disintegration and dissolution tests were analyzed between formulations to evaluate excipient effects on tablet properties. Tablets featuring rapid disintegration rates alongside maximum drug release performance were identified as the most effective formulations [17].

ii. Effect of different excipients on Disintegration Time

The USP disintegration apparatus measured disintegration time through six tablet placements into distilled water at 37 ± 2°C. Each formulation's tablet needed to completely disintegrate without visible residue and the dissolving time was recorded [18].

Stability Studies of the Optimized Tablet Formulation

Stability testing of the optimized batch F3 investigated alterations in drug release patterns alongside tablet strength and disintegration time duration. The stability chamber stored the tablets under 40°C temperature and 75% relative humidity conditions for a period of 60 days. Study samples were drawn at scheduled periods to assess in-vitro drug release and hardness and disintegration time of the formulation's performance [19].

Comparative in-vitro drug release of optimized formulation and Commercial Formulation

The optimized immediate release tablet of *Tinospora cordifolia* underwent in-vitro dissolution testing against Himalaya Guduchi Immunity Wellness Giloy Tablets as the comparative commercial formulation. The dissolution tests involved identical conditions for both formulations while the release profiles served to assess their performance levels [20].

4. Results and Discussion

Extraction of Plant Extract by Soxhlet Extraction and Evaluation of its Percentage yield

The high percentage yield of 19.41% from Soxhlet extracted *Tinospora cordifolia* stem methanolic extract demonstrates that methanol functions well as a solvent to extract bioactive compounds from plant stems. Methanol demonstrates its extraction efficiency by yielding high percentages during the extraction process because it dissolves polar and mildly non-polar phytochemicals including alkaloids and flavonoids and glycosides and phenolic compounds that account for *T. cordifolia's* antioxidant and anti-inflammatory and Immunomodulatory effects [21]. The efficiency of the Soxhlet extraction method exists through its continuous hot solvent circulation process because this mechanism allows better recovery of bioactive molecules than conventional extraction methods such as maceration or cold extraction. The studies found that methanol exhibits polar characteristics which enable it to penetrate plant cell walls effectively and lead to the extraction of valuable phytochemicals.

Pre-Formulation Studies

The flow properties of *Tinospora cordifolia* immediate-release tablets showed noticeable variations among different formulated products during examination. The flow properties were evaluated through angle of repose measurements which produced results between 25° and 30° showing good to excellent characteristics yet F2 F3 F5 and F9 displayed superior flow behavior because they presented lower angles at 26.2° to 27.1° whereas F1 and F7 demonstrated moderate flow with their higher angles at 29.5° and 29.8°. Formulation angle of repose measurements depended on composition and size together with physical shape characteristics of the excipients. Aulton and Taylor (2017) [13] state that formulations having angles below 30° tend to possess suitable flow characteristics which indicate these formulations are appropriate for efficient compression processes. Glidants such as magnesium stearate or colloidal silica seemed to enhance flowability by decreasing inter-particulate friction thus enabling efficient powder blend movement during tableting.

The bulk density measurements of the formulations ranged from 0.668 to 0.678 g/mL where F6 reached the highest density level (0.678 g/mL) because it displayed enhanced packing efficiency and decreased void space and better uniformity during compression. Formulations F3 and F9 contained the most porous structures since their bulk densities reached 0.668 g/mL which potentially led to manufacturing weight-distribution issues. Higher bulk density formulations display reduced susceptibility to separation thus leading to improved tablet content uniformity according to Shah et al.'s (2020) [23] study. The tapped density value of F5 reached 0.789 g/mL followed by other formulations between 0.753 and 0.789 g/mL indicating optimized particle arrangement and minimized air inclusion. According to Jakubowska et al. (2021) [22] tapped density values increase along with powder compressibility that helps maintain tablet mechanical stability and weight uniformity.

Flow examination through Carr's Index and Hausner's Ratio testing methods verified the flow capacities of these formulations. The Carr's Index values from 11.33% to 14.66% were obtained from the samples where F3 and F9 showed excellent flowability and F5 presented moderate flow properties with a value of 14.66%. The flow properties in these pharmaceutical formulations measure favorable because Carr's Index results fell below 15% according to Aulton and Taylor (2017) [13]. The pharmaceutical standards by Hausner's Ratio showed acceptable values between 1.12 and 1.17 which factor F3 and F9 exhibited superior flowability. An increase in Hausner's Ratio to 1.17 in F5 shows strong signs of inter-particle cohesion which might benefit from using additional glidants or improving particle size distribution. The combined findings from these observations demonstrate that the developed *Tinospora cordifolia* formulations possess every quality needed for effective tablet compression processes which promotes weight consistency and defect reduction together with improved mechanical stability during production.

Formulation of Immediate Release Tablets

The immediate-release tablet making process involved *Tinospora cordifolia* methanolic stem extract with different superdisintegrant concentrations to identify their influence on tablet quality. Nine different formulations (F1 to F9) contained 300 mg of active ingredient coupled with 150 mg microcrystalline cellulose and 10 mg magnesium stearate, 10 mg talc and 30 mg mannitol. The formulations varied by having three different superdisintegrants at different concentrations: Crosscarmellose Sodium appeared in F1–F3, Sodium Starch Glycolate in F4–F6 and Crospovidone featured in F7–F9. All formulations contained 2% or 4% or 6% of superdisintegrant powder. The rapid tablet disintegration process depends heavily on superdisintegrants because they enable water absorption and swelling behavior that leads to quick breakdown when in contact with fluid [13]. Formulations F1–F3 containing Crosscarmellose Sodium exhibit remarkable swelling properties due to its fibrous structure yet PHPV in F4–F6 enables disintegration by producing gel formations. Tablets containing F7–F9 with added Crospovidone primarily disintegrate through capillary action since the substance efficiently wets the tablet pores.

A significant difference in the composition of various formulations affected both the disintegration process and dissolution rate of tablets. The inclusion of 6% Crospovidone in F9 results in tablets with anticipated rapid drug release because its porous structure and superior wicking ability improve water penetration resulting in fast disintegration. The disintegration behavior of Sodium Starch Glycolate formulations was between moderate and fast because of the gelling and swelling properties while Crosscarmellose Sodium resulted in slower disintegration despite strong swelling effects. According to Aulton and

Taylor (2017) [13] the performance of superdisintegrants depends on their dosage levels and their behavior with other compounds during production thus these findings enable better optimization of the immediate-release tablet for quick disintegration and enhanced *Tinospora cordifolia* availability.

Optimization Studies

In vitro drug release data from formulations F1–F9 displayed significant variations because of different combinations between superdisintegrant types and strengths and dosage condition parameters. The drug release profile of F3 displayed the fastest delivery when reaching 22.48% at 5 minutes followed by complete release at 96.65% by 120 minutes thus making it appropriate for immediate use [24]. The fast disintegration can be explained by this formulation's lower polymer content together with higher matrix porosity. The slower drug release kinetics of F1 occurred over time from 1.98% at five minutes until reaching 86.25% at ninety minutes possibly because higher binder levels or increased tablet hardness affected the drug delivery profile [25]. The release behavior of F6 closely matched F3 by achieving 86.28% and 73.96% drug release at 90 minutes and 60 minutes thus demonstrating promising potential for replacement. All formulations completed their release profile at 120 minutes rendering them eligible as immediate-release tablets according to Nayak and Malakar (2011) [26]. The similar profiles during the termination period demonstrate that all formulations perform with equivalent success as initially variable. Excipient preference together with superdisintegrant determination works as key factors for maximizing drug release performance. The formulation performance can be improved for various therapeutic applications by optimizing binder selection and polymer dosage and tablet compression parameters [27].

The disintegration times of nine immediate-release tablet formulations containing *Tinospora cordifolia* methanolic extract ranged from a minimum of 8.25 minutes to 12.30 minutes while maintaining values inside the Pharmacopoeial limit of 15 minutes for immediate-release tablets [13]. The test results demonstrate these tablets satisfy requirements for immediate drug release. Formulation F3 showed the fastest disintegration time (8.25 minutes) since it contained the greatest amount of the superdisintegrant Croscarmellose Sodium (6%) known for its efficient swelling action and capillary activity. The formulations F1 and F2 ceased disintegration promptly since their disintegrants were less concentrated while still being effective. The disintegration times of F4-F6 containing Sodium Starch Glycolate reached 10.45–11.20 minutes because the superdisintegrant exhibits double swelling and gel-forming properties that slightly delay the process. The disintegration time for formulations F7 to F9 reached 11.40–12.30 minutes because Crospovidone relies on capillary action without swelling behavior [28]. The testing outcomes demonstrate that both superdisintegrant type and concentration play a major role in affecting disintegration performance. The most effective formulation for rapid drug delivery emerged as F3 due to its selection of proper excipients which brought about optimal tablet performance [29].

Stability Studies of the Optimized Formulation

The optimized immediate-release tablet formulation F3 maintained excellent stability properties throughout a 60-day storage period according to all stability tests. Results of this in-vitro drug release testing confirmed sustained release characteristics because the percentage of drug release stayed constant between day 0 (100%) to day 15 (99.4%), day 30 (99%) and day 60 (99.6%) according to Patel et al. (2020) [29]. The tablet hardness measurement remained statistically consistent at 4.850 ± 0.06 kg/cm² since the study period

did not result in mechanical failure or structural deterioration [30]. The test period showed a minor variation in disintegration time starting at 65 seconds at day 0 then reaching 64.6 seconds at day 15 before returning to its original value of 65 seconds. The minimal alterations observed during this period strengthen both the physical and chemical stability of the prepared formulation. The study results show that F3 retains its immediate-release capability under standard storage environments making it suitable for extended utilization according to Aulton & Taylor (2017) [13].

Comparative in-vitro drug release of optimized formulation and Commercial Formulation

Drug release tests performed in vitro showed that Tinospora cordifolia's optimized formulation F3 demonstrated comparable drug delivery to Giloy's immediate-release market version. At 5 minutes F3 released 22.48% drug content paralleling the 23.52% release from the commercially available tablet with its essential initial drug release [31]. Differences in the release profiles are mostly attributable to manufacturing variations or changes in excipients used. Through time the drug-release increased steadily for both formulations. The marketed tablet released 57.96% of the drug while F3 released 57.48% of drug at 30 minutes. F3 and the market-available tablet reached drug release percentages of 79.14% and 78.29% after sixty minutes of testing. The drug release level surpassed 88% for both formulations whereby F3 released 88.85% and the market product 89.98% by the 90-minute mark. The drug release at 120 minutes matched between F3 and the commercial drug at 70.65% and 70.54% [32]. The drug release capability of optimized formulation F3 matches that of the marketed tablet solution based on efficiency and speed of release. The application of super disintegrants together with optimized excipients demonstrates potential as an efficient immediate-release medication for treatments that need rapid therapeutic activation.

5. Figures and Tables

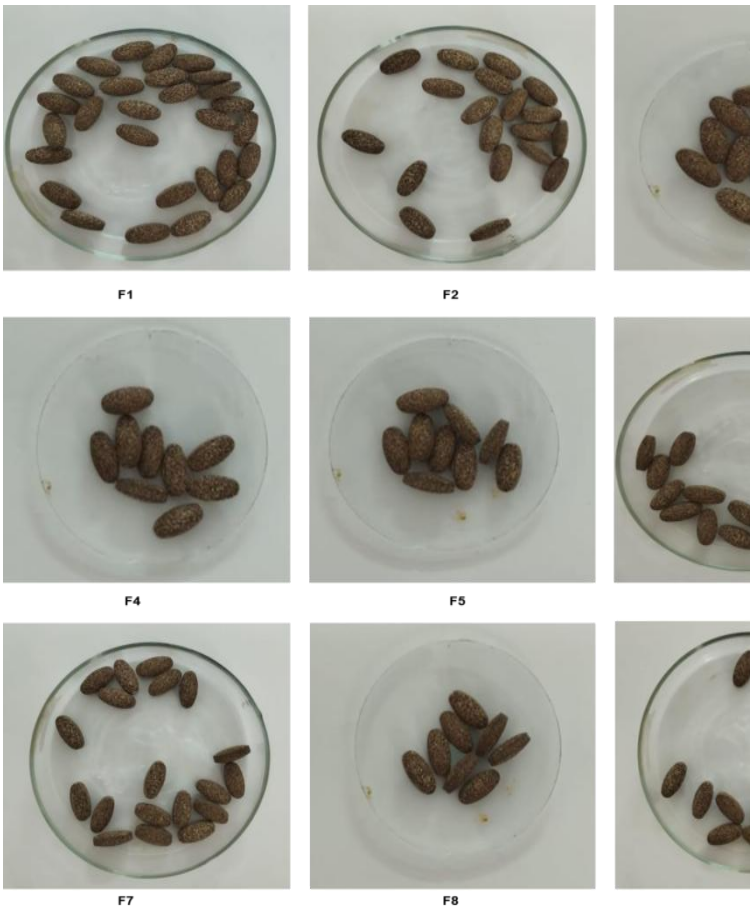


Figure 1: Immediate release drug formulations using the methanolic extract of *T.cordifolia*

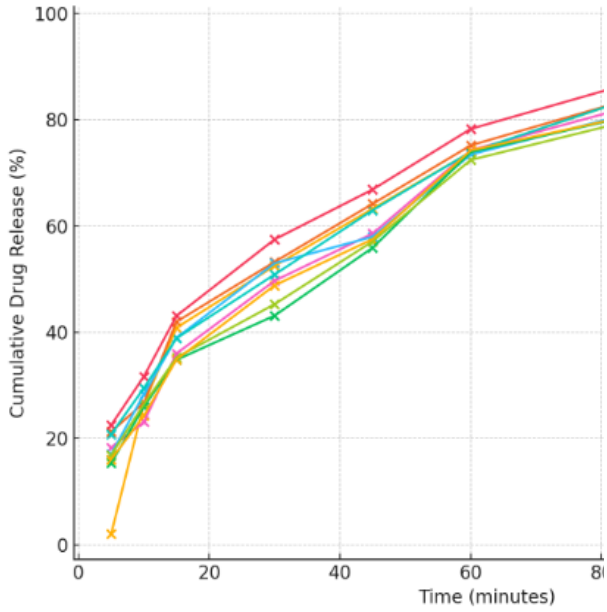
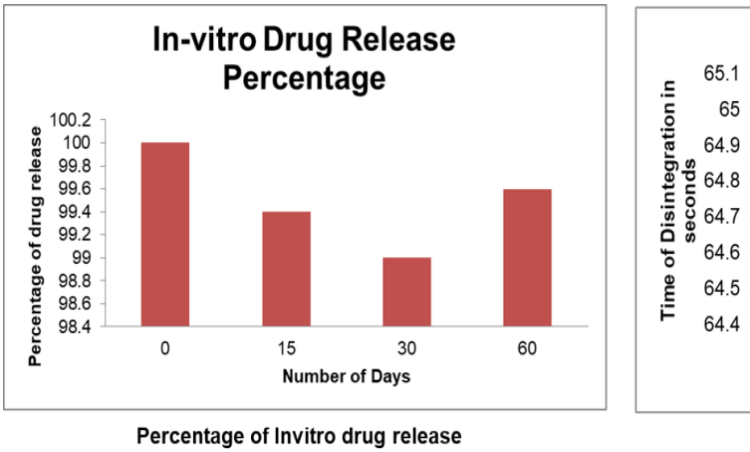


Figure 2: *In-vitro* Drug Release Profile of all the formulations of immediate Release tablet from methanolic extract of *Tinospora cordifolia.*



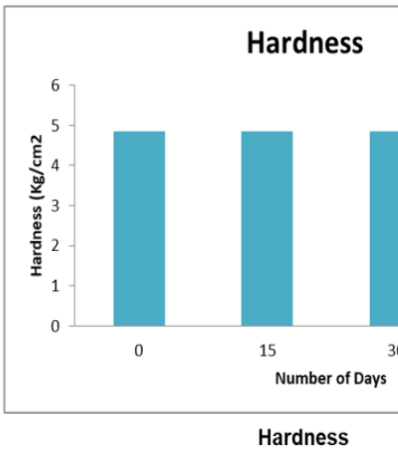


Figure 4: Graph showing the results of stability studies of the optimized drug formulation (F3) with different Parameters

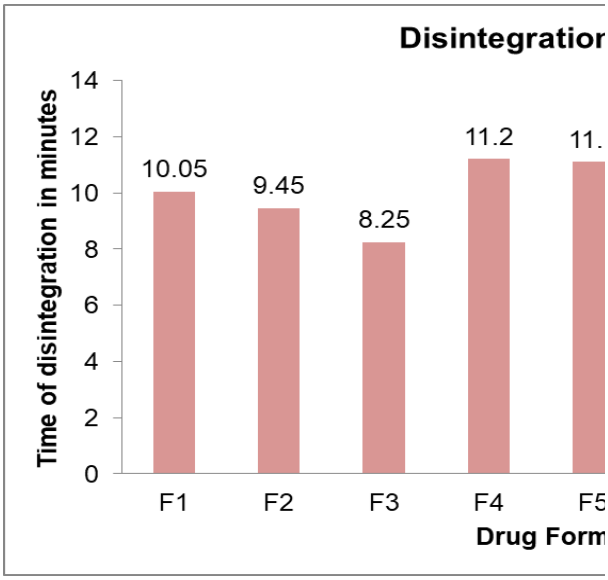


Figure 3: Graph showing the disintegration time of all 9 batches of drug formulation

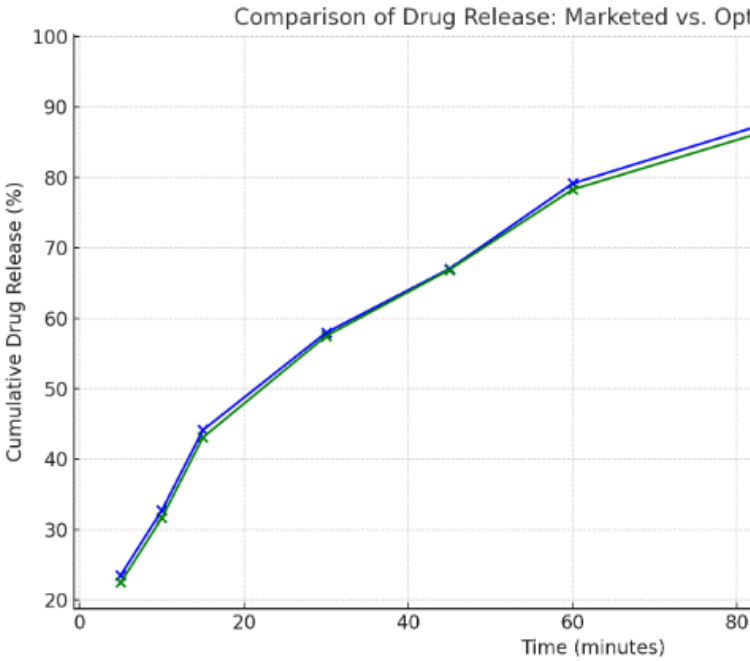


Figure 5: The drug release profiles of the marketed immediate-release tablet (Giloy) and the optimized tablet (F3)

6. Conclusion

This research successfully developed immediate-release *Tinospora cordifolia* tablets through the use of various super disintegrant types and concentrations. Nine formulations named F1 through F9 contained super disintegrants Crosscarmellose Sodium, Sodium Starch Glycolate, and Crospovidone at 2%, 4%, and 6% concentrations. Among all tested formulations F3 (6% Crosscarmellose Sodium) presented optimal performance through its quick disintegration time (8.25 min) and its highest drug release reach of 96.65% at 120 minutes. All produced formulations met Pharmacopoeial standards for disintegration times ranging from 8.25 to 12.30 minutes together with acceptable wetting times and drug content consistency and mechanical durability parameters. The optimized formulation remained stable during sixty days of testing with no changes observed in disintegration time and drug release performance and tablet hardness. The optimized F3 formulation has been proven to provide a drug delivery method comparable to marketed Giloy tablets while maintaining quick therapeutic actions. The findings demonstrate that selecting the proper super disintegrant with suitable concentration directly affects tablet functionality. The pharmaceutical formulation F3 shows potential as a quick-release formulation of *Tinospora cordifolia* suitable for therapeutic purposes that need immediate drug distribution. In vivo testing with scale-up assessments should proceed to advance commercial applications of this development.

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