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Development and Optimization of Orally Disintegrating Tablets (ODTs) Containing Standardized Curcumin Extract for Enhanced Bioavailability and Patient Compliance

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Abstract

This research centers on creating and perfecting orally disintegrating tablets with standardized curcumin extract to both increase its bioavailability and promote better patient adherence. Although curcumin has numerous therapeutic applications. It remains clinically ineffective due to its poor aqueous solubility and bioavailability constraints. The development of orally disintegrating tablets involved direct compression with various levels of superdisintegrants including sodium starch glycolate and cross povidone to address existing challenges. Research teams developed five distinct formulations known as F1–F5 and conducted evaluations on pre-compression parameters together with post-compression quality attributes as well as in vitro disintegration, drug release, and short-term stability. Batch F5 outperformed all other samples by achieving a disintegration time of 27 ± 1 seconds and releasing 94.1 ± 0.8% of the drug within 30 minutes. All powder blends exhibited optimal flow properties while each tablet successfully met the required pharmacopeial standards. Accelerated storage condition tests demonstrated the optimized batch-maintained stability. The results indicate standardized curcumin extract ODTs using crospovidone as superdisintegrants offer a beneficial delivery method that improves curcumin's therapeutic effects in patients facing swallowing challenges.

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INTRODUCTION

Curcumin from *Curcuma longa* rhizomes has attracted substantial research interest because of its variety of pharmacological effects which include anti-inflammatory, antioxidant, antimicrobial, and anticancer properties [1]. The clinical application of curcumin encounters significant barriers due to its limited aqueous solubility and low absorption in the gastrointestinal tract combined with fast systemic elimination which leads to poor bioavailability [2]. Researchers have investigated multiple formulation approaches including liposomes, nanoparticles, micelles, and phospholipid complexes to overcome these challenges [3]. Despite potential benefits these systems offer they present manufacturing

hurdles and financial burdens which restrict access for patients particularly in areas with fewer resources. Orally Disintegrating Tablets (ODTs) function as a novel drug delivery mechanism which disintegrates quickly inside the mouth without requiring water [4]. Orally Disintegrating Tablets (ODTs) provide an ideal solution for pediatric, geriatric, and dysphagic patients who struggle to swallow regular tablets or capsules. ODTs help patients stick to their medication schedules and they improve drug dissolution and absorption through pre-gastric absorption from the buccal cavity. The poor absorption of curcumin combined with the convenient patient-friendly design of ODTs makes the development of standardized curcumin extract within an ODT dosage form a strong candidate for further research [5]. This research focuses on creating and assessing ODTs that use standardized curcumin extract to enhance dissolution characteristics and potentially increase bioavailability while ensuring patients can easily take their medication and remain compliant [6].

MATERIALS AND METHODS

Materials

The active pharmaceutical ingredient consisted of standardized curcumin extract with at least 95% purity which came from a certified herbal supplier. The tablet formulation used microcrystalline cellulose (MCC) for dilution and binding purposes and sodium starch glycolate (SSG) along with crospovidone as superdisintegrants for faster tablet disintegration while mannitol added palatability and improved mouthfeel. Scientists included aspartame in the formula to conceal the bitter flavor of curcumin. During tablet compression magnesium stearate and talc functioned as lubricants and glidants to maintain smooth processing. The study utilized analytical grade chemicals and reagents which were employed directly without undergoing any purification process.

Preformulation Studies

Preformulation analysis examined both the physicochemical characteristics of curcumin extract and its compatibility with different excipients [7]. The organoleptic characteristics of color, taste, and odor were documented. Researchers measured the solubility of curcumin in water and ethanol and buffer solutions at pH values of 1.2 and 6.8 to examine its dissolution behavior within physiological environments [8]. The flow characteristics of the powder blend designated for tablet compression underwent evaluation. The evaluation of the blend's compressibility and direct compression suitability required the measurement of angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio [9].

Standardization and Evaluation of Curcumin Extract

Researchers obtained standardized Curcumin extract from *Curcuma longa* rhizomes before performing physicochemical and phytochemical evaluations for formulation purposes. Scientists standardized the extract by measuring total curcuminoid contents at 425 nm using UV–Vis spectrophotometry as percentages of curcumin, desmethoxycurcumin, and bisdemethoxycurcumin. Researchers assessed the extract's visual appearance along with its solubility in various solvents while measuring its pH value and determining moisture content and total ash levels [10]. The phytochemical screening process verified the existence of curcuminoid while demonstrating that no interfering impurities were present. The extract maintained consistent quality throughout formulation by adhering to these parameters [11].

Formulation of Orally Disintegrating Tablets (ODTs)

The direct compression method was used to prepare orally disintegrating tablets. The formulation of several trial batches involved altering superdisintegrant concentrations while maintaining other excipients at fixed levels. The mortar was used to blend all ingredients from Table 1 except lubricants after precise weighing to achieve uniform mixing. The final blending step included magnesium stearate and talc as lubricants to enhance powder flow and prevent sticking. The final blend underwent compression in a rotary tablet compression machine with 8 mm round flat punches. After compression each tablet underwent evaluation for additional testing [12].

Table 1. Composition of orally disintegrating tablet batches of curcumin extract.

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)
Curcumin Extract	100	100	100	100	100
Microcrystalline Cellulose (MCC)	110	105	100	95	90
Sodium Starch Glycolate (SSG)	10	15	20	25	—
Crospovidone	—	—	—	—	25
Mannitol	50	50	50	50	50
Aspartame	5	5	5	5	5
Talc	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5
Total Weight	285	285	285	285	285

Evaluation of ODTs

A series of quality control tests were applied to the prepared ODTs to verify their suitability and compliance with pharmacopeial standards. The weight variation analysis involved individually weighing 20 tablets and comparing each of their weights to the sample average. The Monsanto hardness tester determined tablet hardness while the Roche friabilator evaluated friability by rotating tablets at 25 rpm for 4 minutes (100 revolutions) and recording the percentage weight loss [13]. The digital Vernier calliper provided measurements for both the thickness and the diameter of the tablets. The USP disintegration test apparatus used distilled water at 37 ± 2°C to measure how long it took for the tablets to fully disintegrate. The wetting time and water absorption ratio were determined by placing tablets on wet filter paper and measuring the time for water to reach their upper surface using the circular tissue paper method. The water absorption ratio measurement was derived from the difference in weight before and after the absorption process [14]. Researchers crushed ten tablets and measured curcumin concentrations spectrophotometrically at 425 nm using appropriate solvents including ethanol or phosphate buffer. The researchers conducted in-vitro dissolution testing with a USP Type II (paddle) dissolution apparatus using 900 mL of phosphate buffer (pH 6.8) at 50 rpm and a temperature of 37 ± 0.5°C. Researchers collected samples at set intervals for filtering and curcumin content analysis to create a release profile [15].

Short-Term Stability Studies

The optimized formulation underwent short-term stability testing as required by ICH guidelines. The tablets remained in airtight containers at 40°C ± 2°C and 75% ± 5% relative humidity throughout one month. The researchers removed samples from the experiment at 0-day mark followed by 15 days and again at 30 days to examine variations in their physical appearance along with disintegration time and drug content. The study aimed at evaluating the chemical and physical stability of tablets under fast-track conditions and verifying the strength of the chosen formulation [16].

RESULTS AND DISCUSSION

Evaluation of Curcumin Extract

The curcumin standardized extract displayed a bright yellow-orange powder form which emitted its distinctive fragrance. The extract dissolved easily in ethanol but only partially dissolved in water. The aqueous suspension had a measured pH value of 6.4 with a tolerance of 0.2. The extract had a moisture content of 4.2 ± 0.3% and total ash content of 6.8 ± 0.4% which are within herbal raw materials acceptable limits (Table 2). The UV–Vis analysis showed that curcuminoid content reached 95.2 ± 0.6% which demonstrates high purity. The phytochemical analysis confirmed the presence of curcuminoid while no non-curcuminoid compounds showed significant interference.

Evaluation of Pre-Compression Parameters

The powder blends from all formulations F1 through F5 underwent flow property assessment before they were compressed. The angle of repose between 26.7° and 29.3° demonstrated excellent flow characteristics (Table 3). The measured bulk and tapped densities fell within acceptable boundaries and

the compressibility index along with Hausner's ratio supported the analysis of sufficient flowability for direct compression applications.

Table 2. Standardization parameters of standardized curcumin extract.

Parameter	Result
Appearance	Bright yellow-orange powder
Solubility	Ethanol-Freely soluble; Water-Sparingly soluble
pH (1% solution)	6.4 ± 0.2
Moisture Content (%)	4.2 ± 0.3
Total Ash (%)	6.8 ± 0.4
Curcuminoid Content (%)	95.2 ± 0.6
Phytochemical Screening	Positive for curcuminoids

Table 3. Pre-compression parameters of powder blends.

Batch	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Carr's Index (%)	Hausner's Ratio
F1	29.3 ± 0.6	0.44 ± 0.01	0.53 ± 0.01	16.9 ± 0.8	1.20 ± 0.01
F2	28.6 ± 0.5	0.45 ± 0.01	0.54 ± 0.01	16.6 ± 0.7	1.20 ± 0.02
F3	27.4 ± 0.4	0.46 ± 0.01	0.55 ± 0.01	16.4 ± 0.5	1.19 ± 0.01
F4	26.9 ± 0.5	0.47 ± 0.01	0.55 ± 0.01	14.5 ± 0.4	1.17 ± 0.01
F5	26.7 ± 0.4	0.48 ± 0.01	0.56 ± 0.01	14.0 ± 0.3	1.16 ± 0.01

Evaluation of Post-Compression Parameters

The study assessed tablet batches F1 through F5 by measuring post-compression characteristics including hardness, friability, disintegration time, wetting time, and drug content. The study found consistent results across all trials showing that tablet performance improved with variations in disintegrant levels because disintegration time and drug release saw positive changes. Increasing the superdisintegrants concentration resulted in faster tablet disintegration and enhanced drug release rates. From Table 4, we observe that F5 achieved better disintegration characteristics and improved bioavailability due to its use of crospovidone as the disintegrates.

Table 4. Evaluation parameters of formulated curcumin ODTs.

Batch	Weight Variation (mg)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (sec)	Wetting Time (sec)	Water Absorption Ratio (%)	Drug Content (%)	Cumulative Drug Release (%) at 30 min
F1	285.1 ± 2.3	4.3 ± 0.2	0.79	52 ± 2	58 ± 2	62.4 ± 1.8	96.3 ± 0.5	72.5 ± 1.2
F2	284.7 ± 1.9	4.2 ± 0.3	0.76	41 ± 1	47 ± 1	71.2 ± 2.1	97.0 ± 0.4	81.6 ± 1.4
F3	285.3 ± 2.1	4.1 ± 0.2	0.74	33 ± 2	38 ± 2	78.5 ± 1.6	97.8 ± 0.6	88.9 ± 1.0
F4	284.9 ± 2.2	4.1 ± 0.2	0.73	29 ± 1	33 ± 1	83.3 ± 1.4	98.2 ± 0.5	92.4 ± 0.9
F5	285.0 ± 2.0	4.0 ± 0.3	0.75	27 ± 1	31 ± 1	85.1 ± 1.5	98.6 ± 0.4	94.1 ± 0.8

In Vitro Drug Release Studies

The dissolution characteristics of each batch were evaluated during a 30-minute test period using phosphate buffer at pH 6.8. Improved disintegration behaviour emerged as a key factor leading to better drug release outcomes, results are shown in Table 5 and Figure 1.

Table 5. *In Vitro* drug release profile of curcumin ODTs.

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)
5	25.4	32.8	40.2	45.5	49.3
10	38.6	47.3	56.4	63.8	68.5
15	52.7	61.9	70.1	78.6	82.4
20	63.1	72.5	81.3	86.5	89.8
30	72.5	81.6	88.9	92.4	94.1

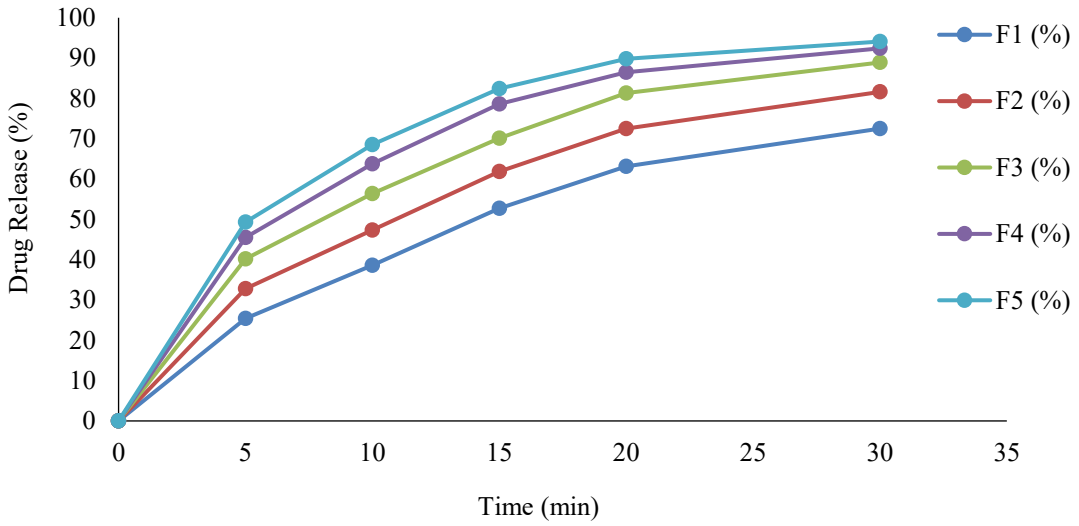

Figure 1. *In Vitro* drug release profile of ODTs.

Short-Term Stability Studies

Researchers kept the optimized formulation F5 under accelerated conditions for one month to evaluate its stability performance. The formulation exhibited physical and chemical stability throughout the storage period because no significant changes appeared in its physical properties or drug content while only its disintegration time remained constant (Table 6).

Table 6. Stability data of optimized batch F5.

Parameter	0 Days	15 Days	30 Days
Appearance	Yellow, smooth	No change	No change
Disintegration Time (sec)	27 ± 1	28 ± 2	28 ± 2
Drug Content (%)	98.6 ± 0.4	98.2 ± 0.5	97.9 ± 0.6

CONCLUSIONS

This study achieved the creation and assessment of orally disintegrating tablets (ODTs) with standardized curcumin extract to boost bioavailability and patient compliance. The formulation used direct compression techniques which incorporated superdisintegrants like sodium starch glycolate and crospovidone. The batch formulation F5 with crospovidone demonstrated superior performance with the best disintegration time at 27 ± 1 seconds and highest water absorption ratio of 85.1 ± 1.5%, along with a maximum drug release rate of 94.1 ± 0.8% in 30 minutes. The satisfactory pharmacopeial ranges for pre-compression and post-compression parameters demonstrated that all powder blends showed excellent flowability and compressibility along with uniformity and robustness in the resulting tablets. The optimized formulation demonstrated significantly improved curcumin release characteristics during in vitro dissolution testing despite curcumin's inherent challenges with solubility and bioavailability. The optimized batch F5 maintained both physical stability and chemical integrity for one month when tested under accelerated conditions for short-term stability. The research indicates that curcumin ODTs represent a new patient-friendly delivery system which could address conventional curcumin formulation limitations for those patients who struggle with solid dosage forms. Subsequent research should implement in vivo assessments to determine both the pharmacokinetic benefits and clinical effectiveness of this formulation in practical applications.

Conflict of Interest

No.

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