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FORMULATION AND EVALUATION OF CURCUMIN CAPSULES FOR ENHANCED CHEMOPREVENTIVE ACTIVITY IN THE EFFECTIVE MANAGEMENT OF PANCREATIC CANCER

G. Ramya[1], S. Jayashree[2], R. Kasthuri[3], S. Dhilipkumar [4], Dr. P. Sriramcharan*

*Professor & HOD Department of Pharmaceutics ICMR-SRF (New Delhi), PSV College of Pharmaceutical Science and Research Krishnagiri, Tamilnadu, India, 635108.

[1,2,3,4] Bachelor of pharmacy, P. S. V College of Pharmaceutical Science and Research, Krishnagiri, Tamilnadu- 635108.

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***Corresponding Author**

Dr. P. Sriramcharan

Professor & HOD Department of Pharmaceutics ICMR-SRF (New Delhi), PSV College of Pharmaceutical Science and Research Krishnagiri, Tamilnadu, India, 635108.

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1. ABSTRACT

Pancreatic cancer is one of the deadliest cancer in the world, because of its aggressive nature, resistance to traditional treatments, and delayed diagnosis. The use of the chemo preventive agents like curcumin – that inhibits, delays, or reverse carcinogenesis and gained a significant attention as a potential strategy for preventing and controlling pancreatic cancer. Curcuma Longa is a bioactive poly phenolic molecule and having an antioxidant, anti-inflammatory, and antiproliferative properties but its low bioavailability and poor water solubility restrict its therapeutic efficacy. The goal of the current study is to improve the stability, consistency, and patient compliance of curcumin capsules as an oral chemopreventive dosage form. The manufactured curcumin capsules showed quick disintegration within the pharmacopoeial limitations and acceptable physicochemical qualities, according to the results. Drug release teste revealed a prolonged and effective release pattern, increasing curcumin's potential for bioavailability. The prepared curcumin capsules can serve a as stable and efficient oral chemopreventive dosage form for the treatment and prevention of pancreatic cancer.

KEYWORDS: UV spectrophotometry, curcumin, chemopreventive, pancreatic cancer, capsule formulation, and evaluation.

2. INTRODUCTION

Pancreatic cancer is one of the most aggressive cancer, characterized by fast progression, lack of early diagnosis, and a slow prognosis, with a five-year survival rate of less than 10%. Despite advances in chemotherapy and targeted therapies, conventional treatments are often limited by drug resistance, toxicity, and poor patient tolerance. Consequently, there is growing interest in the development of safe, natural, and effective chemopreventive agents. Curcumin, a polyphenolic compound derived from Curcuma longa (turmeric), has shown promising chemopreventive and therapeutic effects against several cancers, including pancreatic cancer. It exhibits multiple pharmacological activities such as antioxidant, anti-inflammatory, anti-proliferative, anti-metastatic, anti-angiogenic, and pro-apoptotic effects. Curcumin modulates key molecular pathways involved in cancer progression, including NF-κB, COX-2, STAT3, TNF-α, and apoptosis-related proteins, thereby inhibiting tumour growth, metastasis, angiogenesis, and enhancing cancer cell sensitivity to treatment. Its natural origin and favourable safety profile make it suitable for long-term chemoprevention. However, the clinical application of curcumin is limited by poor aqueous solubility, low oral absorption, rapid metabolism, and low bioavailability. To address these limitations, formulation development using capsule dosage forms with appropriate excipients is essential. The incorporation of solubility enhancers, along with suitable diluents, disintegrants, and glidants, can significantly improve curcumin’s dissolution and absorption. This study focuses on the formulation and evaluation of curcumin-loaded capsules designed to enhance solubility and dissolution, thereby improving its chemopreventive efficacy against pancreatic cancer. Standard quality control tests are employed to ensure the stability, safety, and effectiveness of the formulation.

2.1 DRUG PROFILE

CURCUMIN (API)

Curcumin, commonly known as Curcuma longa or diferuloylmethane, is an active component in spices. Unlike turmeric, curcumin is a polyphenol chemical. Curcumin, which makes up just 2–5% of the plant, is one of the substances found in turmeric species. Curcumin is a yellow pigment, which is extracted from turmeric. Biological activity: Turmeric has antioxidant, anti-inflammatory, antibacterial, anti-cancer, and neuroprotective properties. Research is being done on medications to treat diseases like Alzheimer's, diabetes, cancer, and arthritis. It

dissolves in chemical solvents and lipids but not in water. The limitations include poor water solubility, low bioavailability (poor absorption in the body), rapid metabolism, poor absorption, and systemic elimination. Curcumin is used in traditional medicine, particularly in Ayurvedic and Siddha medicine. Curcumin was discovered in 1815 by the scientists Vogel and Peltier. Milkomeda and Lampe.

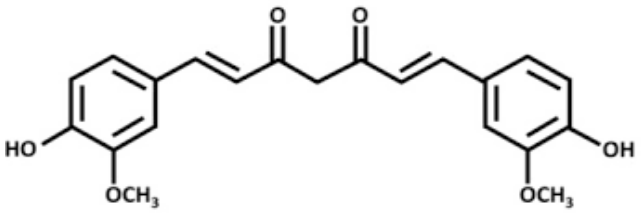


Figure No. 1: Structure of Curcumin.

Molecular weight – 368.39 g/mol Melting point – 183^{o}C

Chemical formula – $C_{21}H_{22}O_6$

Solubility – Insoluble in water, slightly soluble in hot water, oftenly they dissolve less than 0.01mg/l of water.

2.2 CHEMOPREVENTIVE ACTION OF CURCUMIN IN PANCREATIC CANCER:

Curcumin exhibits strong chemopreventive activity against pancreatic cancer by multi-targeted mechanism and its low toxicity make curcumin a promising natural agent for chemoprevention, though).

1. KRAS-Driven Signalling Suppression

Over 90% of pancreatic tumours have mutations in the KRAS oncogene. Curcumin blocks downstream KRAS-mediated pathways, including the MAPK/ERK pathway. The PI3K/Akt/mTOR pathway as a result, the growth and survival of pancreatic cancer cells are decreased.

2. NF-κB Activation Inhibition In pancreatic cancer.

NF-κB is constitutively activated and plays a role in angiogenesis, chemoresistance, inflammation, and tumour development. Curcumin inhibits IκB kinase (IKK) to reduce NF-κB activation. As a result, NF-κB-regulated genes such as COX-2, Bcl-2, cyclin D1, VEGF, and MMPs are downregulated.

3. Antioxidant and Anti-Inflammatory Properties

One of the main risk factors for pancreatic cancer is persistent inflammation. Curcumin reduces pro-inflammatory cytokines (TNF-α, IL-6, and IL-1β) and inhibits COX-2 and iNOS to provide its anti-inflammatory actions. These steps lessen DNA damage and stop the development of tumours.

4. Apoptosis Induction

In pancreatic cancer cells, curcumin specifically causes apoptosis by:

Caspases 3, 8, and 9 are activated and Bax is rising while Bcl-2 and Bcl-xL are falling that disturbing the potential of the mitochondrial membrane. This condition encourages planned cell death.

5. Arrest of the Cell Cycle

By causing cell cycle arrest at the G2/M or G0/G1 phase, curcumin prevents cell division by downregulating cyclin D1 and CDK4 and upregulating p21 and p27.

6. Prevention of Metastasis and Angiogenesis

Curcumin stops tumours from growing and spreading by, Vascular endothelial growth factor (VEGF) suppression Matrix metalloproteinase (MMP-2 and MMP-9) inhibition decreasing the EMT (epithelial-mesenchymal transition).

7. STAT3 Signalling Modulation

In pancreatic cancer, STAT3 is continuously active and encourages immune evasion, invasion, and survival. Curcumin reduces the expression of surviving, cyclin D1, and VEGF via blocking STAT3 phosphorylation.

Despite its strong chemopreventive properties, curcumin has low water solubility, fast metabolism, and low oral bioavailability. To increase curcumin's therapeutic potential in the prevention of pancreatic cancer, new formulations like curcumin capsules, nanoparticles, liposomes, and phospholipid complexes are being developed.

3. METHODOLOGY

This work is an **experimental laboratory-based study** aimed at the formulation of curcumin capsules using suitable excipients to obtain capsules with acceptable pharmaceutical characteristics.

3.1 EXCIPIENTS USED

1. STARCH (diluent)

Starch is a naturally occurring polysaccharide derived from plants like potatoes and maize that is made up of amylose and amylopectin. Starch is a fine, odorless, white to off-white powder that swells and gelatinizes in hot water but is insoluble in cold water. Starch is frequently utilized as a diluent, binder, and disintegrant in medicinal formulations.

Starch was added to the current formulation to facilitate curcumin capsule dissolution and enhance medication release.

2. SODIUM LAURYL SULPHATE (Solubility enhancer)

SLS is a anionic surfactant .The molecular weight of this substance is 288.38 g/mol, and its chemical formula is $C_{22}H_2$•SO_4Na. It is easily soluble in water and appears as a white or pale yellow crystalline powder with a distinct smell.

Sodium lauryl sulphate is frequently employed as a wetting and solubilizing ingredient in pharmaceutical formulations to improve the dissolving and bioavailability of medications that are poorly soluble in water. SLS was added to the current formulation to increase curcumin's wettability and rate of dissolution.

3. TALC (Glidant)

Talc is a naturally occurring hydrated magnesium silicate that has the chemical formula $Mg_3Si_4O_{20}(OH)_2$. It is an odorless, white-to-greyish-white powder that is insoluble in both organic solvents and water.Talc is frequently used as a lubricant and glidant in pharmaceutical formulations to enhance powder flow characteristics and stop formulation components from sticking to processing machinery.

Talc was added to the current formulation to improve the curcumin capsules' uniform filling and flowability.

4. MAGNESIUM STEARATE (Lubricant)

Magnesium stearate has a molecular weight of 591.27 g/mol and the chemical formula C_3·H·$70MgO_4$, it is the magnesium salt of stearic acid. Magnesium stearate is a white, thin, odorless powder that dissolves somewhat in alcohol but is insoluble in water.

Magnesium stearate is frequently used as a lubricant in pharmaceutical formulations to improve

flow characteristics and guarantee smooth capsule filling by lowering friction between powder particles and processing machinery.

Magnesium stearate was added to the current formulation to help with consistent capsule filling and avoid sticking.

5. HARD GELATIN CAPSULES

Hard gelatin capsules are made with gelatin, filtered water, and permitted coloring additives. The body and cap of hard gelatin capsules are prefabricated components that fit together to encapsulate the medicine and excipient mixture.

As needed for formulation, the capsules were of the appropriate size (e.g., size "00") is used. The simplicity of administration, precise dose, quick breakdown, and patient acceptability of hard gelatin capsules make them popular for oral medication delivery.

The curcumin combination in the current formulation was encapsulated in hard gelatin capsules, guaranteeing consistent medication content and easy oral administration.

3.2 METHOD OF PREPARATION

Curcumin capsules are prepared by the manual capsule filling method using hard Gelatin capsules, which is a simple and commonly used technique for laboratory-scale capsule formulation.

Table No. 1: Ingredients used in formulation.

S.NO	INGREDIENTS	QUANTITY (PER 1 CAPSULE)
1.	Curcumin	250mg
2.	Starch	237.5mg
3.	Sodium lauryl sulphate	2.5mg
4.	Magnesium stearate	5mg
5.	Talc	5mg

3.2.1 PROCEDURE

1. WEIGHING OF INGREDIENTS:

All the ingredients needed for the formulation are weighed in a digital analytical balance in accurate and precise manner.

2. PRE-FORMULATION OF MATERIALS

Pass all the ingredients separately through sieve no.60 in order to achieve good flow characteristics and content consistency, to ensure uniform particle size and eliminate agglomerates.

3. PREPARATION OF POWDER BLEND

In a dry, clean mortar, the weighed amount of curcumin was first combined with sodium lauryl sulphate. The purpose of this process was to improve the weakly water-soluble curcumin's wettability and dissolving properties.

Figure No. 2: Preparation of curcumin powder blend.

Starch was then added as a disintegrant and diluent to boost the formulation's volume. To ensure that the medicine was evenly distributed throughout the powder blend, the geometric dilution approach was used for mixing. Until a homogenous mixture was achieved, the blending process was repeated.

4. LUBRICATION

Talc and magnesium stearate were added to the powder mixture once it had been well mixed. To enhance flow characteristics, lower friction, and stop the powder from sticking during capsule filling, these excipients were gently combined for few seconds. To avoid negative effects on medication release, over-mixing was avoided.

5. CAPSULE FILLING

Finally, the prepared powder was filled into the suitable sized Hard Gelatin capsules (size ‘00’) using a manual capsule filling machine.

Initially the body and cap of the capsule are separated and the required amount of powder was filled in body.

After that, the caps were put back on and tightly fastened.

Figure No. 3: Manual capsule filling machine.

6. CLEANING AND STORAGE

The filled capsules are cleaned to remove the adhering powder and inspected visually for any flaws like incorrect locking or leakage.

Then the capsules are stored in a tightly sealed airtight container at room temperature for further evaluation studies.

3.3 EVALUATION STUDIES OF CAPSULES

The prepared curcumin hard Gelatin capsules were evaluated for various physical and pharmaceutical parameters to ensure quality, uniformity, and performance.

1 GENERAL APPEARANCE

The curcumin capsules re visually inspected for colour, shape, surface texture, cracks, locking and leakage defects. Capsules are should be in uniform appearance and free from flaws.

Proper locking of the capsule shells was investigated in all capsules, indicating satisfactory physical appearance.

Figure No. 4: Prepared Curcumin capsules.

2 WEIGHT VARIATION TEST

This test was performed to ensure the uniformity of capsule filling and consistency in the amount of drug present in each capsule.

Procedure

Twenty hard Gelatin capsules were selected at random and weighed individually with a digital analytical balance. Each capsule was carefully opened, and its contents were totally extracted and empty pill shell was weighed separately.

The weight of the capsule contents was determined by subtracting the weight of the empty shell from the total weight of the filled capsule. Calculate the average weight of capsule contents and compared it to the individual capsule weights.

Calculation

Weight of capsule content = weight of filled capsule – weight of empty shell

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{Average}}{\text{Average weight}} \times 100$$

Acceptance Criteria

According to pharmacopoeial standards, the percentage deviation of individual capsule weights should fall within the specified limits. The prepared capsules complied with the pharmacopoeial requirements for weight variation.

3 IN-VITRO DISSOLUTION STUDY

The in-vitro dissolution of curcumin capsule is performed to evaluate the rate and extent of release of curcumin from hard Gelatin capsules into the dissolution medium. Dissolution is the

important parameter that provide the in-vitro performance of oral dosage forms in body environment.

Apparatus and medium conditions

- Dissolution apparatus: USP Type II (paddle)
- Dissolution medium: 900ml 6.8pH phosphate buffer
- Temperature: 37 ± 0.5°C
- Paddle speed: 75 - 100 rpm
- Labelled claim: 250 mg of curcumin per capsule

Procedure

Preparation of 6.8 pH phosphate buffer: Dissolve 8.64g of Sodium dihydrogen phosphate (NaH_2PO_4) and 3.98g of Disodium hydrogen phosphate (Na_2HPO_4) into a 1L beaker with 800ml distilled water. Stir thoroughly until dissolved.

Then add 0.1g SLS slowly while stirring. Continue stirring until completely dissolved. Check pH using calibrated pH meter

- ✓ Add small amount of 0.1 M NaOH if pH is less than 6.8.
- ✓ If pH is more than 6.8 add 0.1 M HCl.

At last, the final volume makes up to 1000ml with distilled water.

Operating procedure

One curcumin capsule was placed in the dissolution vessel containing the dissolution medium maintained at 37 ± 0.5°C. The paddle was rotated at a specified speed.

At predetermined time intervals (5, 10, 15, 30, 45, and 60 minutes), 5 mL of sample was withdrawn and replaced with an equal volume of fresh dissolution medium maintained at the same temperature.

The withdrawn samples were filtered and suitably diluted. The absorbance was measured using a UV–Visible spectrophotometer at the predetermined mix at 425nm. The amount of drug released was calculated using a calibration curve.

Figure No. 5: Dissolution Chamber (USP Apparatus).

Acceptance criteria

The dissolution profile showed a gradual and consistent release of curcumin from the hard Gelatin capsules. More than 85% drug release was observed within 60 minutes, indicating satisfactory dissolution characteristics.

4 DISINTEGRATION TIME

The disintegration test measures how long it takes hard Gelatin capsules to disintegrate into tiny pieces under particular circumstances. Effective dissolving and medication absorption depend on proper disintegration.

Apparatus and Conditions

Apparatus: USP Disintegration test Apparatus Medium: Distilled water

Temperature:37 ±2^{o} C Number of capsules:6

Procedure

Disintegration Time Test Procedure (Hard Gelatin Capsules) Setting Up the Equipment The disintegration test equipment has been thoroughly cleaned and put together. A temperature of 37 ± 2°C is maintained and regulated in the water bath. The pharmacopoeia specifies that the disintegrating medium should be either pure water or 0.1 N hydrochloric acid (simulated gastric fluid). Placement of Capsules Each of the six glass tubes in the basket-rack arrangement contains six hard Gelatin capsules. Each capsule is covered with a plastic disc if necessary to stop it from floating. Basket Assembly Immersion Making sure the capsules are fully

submerged, the basket-rack assembly is carefully lowered into the beaker with the disintegration media. operating of Equipment. The basket goes up and down at a pace of 29–32 cycles per minute when the equipment is in operation. Under constant motion, the capsules are permitted to break apart. Observation of Disintegration Every capsule's total disintegration time is tracked and noted. When there is no solid substance left on the sieve, complete disintegration is considered to have occurred. The contents passed through the mesh. Time Recording A stopwatch is used to record the disintegration time for each capsule sep.

Figure No. 6: Disintegration Test Apparatus.

Acceptance criteria

According to pharmacopoeial standards for hard Gelatin capsules, the test is deemed satisfactory if all six capsules dissolve in 30 minutes.

4. RESULTS AND DISCUSSION

4.1 GENERAL APPEARANCE

Table No. 2: Results of general appearance test.

S. NO.	Parameter evaluated	Observation	Result
1.	Colour	Uniform yellow filled capsules	Within acceptable limits
2.	Shape	Cylindrical, Standard capsule shape	Within acceptable limits
3.	Size	Uniform size	Within acceptable limits
4.	Surface texture	Smooth, free from roughness	Within acceptable limits
5.	Cracks	No cracks observed	Within acceptable limits
6.	Leakage	No powder observed	Within acceptable limits
7.	Locking of cap and body	Properly locked	Within acceptable limits

RESULT

The prepared curcumin hard Gelatin capsules passed the requirements of visual examination and had an acceptable overall look.

4.2 WEIGHT VARIATION

Table No. 3: Result of Weight variation test.

Capsule no	Weight of filled capsules(mg)	Weight of empty shell(mg)	Weight of capsules content(mg)
1	617	**120**	**497**
2	620	**120**	**500**
3	621	**120**	**501**
4	620	**120**	**500**
5	**619**	**120**	**499**
6	**620**	**120**	**500**
7	**618**	**120**	**498**
8	**622**	**120**	**502**
9	**620**	**120**	**500**
10	**615**	**120**	**495**

Average weight of capsules content = 499mg

1. Weight of capsules content

For capsule no.1: = 617-120

= 497mg

2. Percentage deviation For capsule No.1:

$$= \frac{497-499}{499} \times 100$$

= - 0.40%

RESULT

Each capsule displayed a percentage deviation that fell within the pharmacopoeial limitations, demonstrating consistent filling. As a result, the weight variation test was passed by the manufactured curcumin capsules.

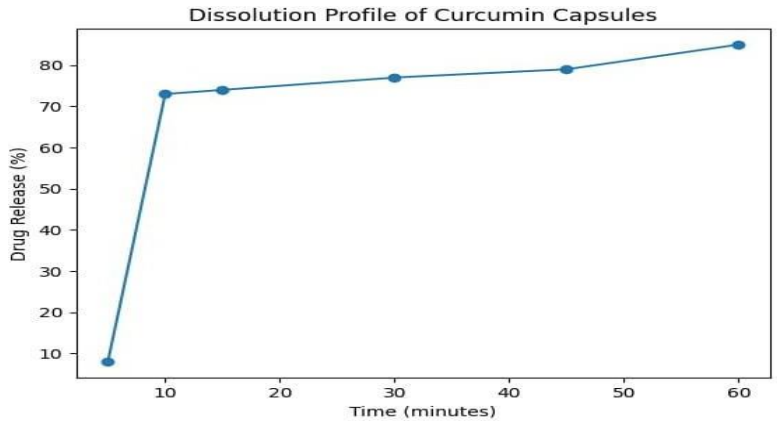
4.3 DISSOLUTION STUDY

The dissolution profile of prepared capsule was,

Table No. 4: Results of Dissolution study test.

S.NO	TIME(MINS)	DRUG RELEASE (%)
1.	5mins	8.27
2.	10mins	73.33
3.	15mins	74.00
4.	30mins	77.07
5.	45mins	78.80
6.	60mins	85.87

The following graph represents the dissolution profile of curcumin capsules.



RESULT

The dissolution study showed a gradual and continuous release of curcumin from the hard Gelatin capsules. More than 85% drug release was achieved within 60 minutes, indicating satisfactory in-vitro performance.

4.4 DISINTEGRATION TIME

Table No. 5: Result of disintegration time.

CAPSULE NO	TIME (min: sec)
1	6.45
2	7.10
3	6.30
4	7.25
5	6.55
6	7.05

Average Disintegration time = 6.98 mins (≈7)

RESULT

According to Indian Pharmacopoeia, hard Gelatin capsules should disintegrate within 30 minutes. The disintegration time of the formulated curcumin hard Gelatin capsules was found to be ≈ 7 minutes, which complies with pharmacopoeial standards and supports good in-vitro

performance of the dosage form.

5. CONCLUSION

- ✓ The project was successfully carried out to formulate and evaluate curcumin capsules using suitable pharmaceutical excipients. The selected excipients such as starch, magnesium stearate, talc and sodium lauryl sulphate played an important role in improving the flow properties, uniformity, and overall performance of the formulation.
- ✓ The prepared capsules showed acceptable physical characteristics, including uniform weight, satisfactory disintegration time, and appropriate dissolution behaviour. The dissolution study indicated effective release, confirming the suitability of the formulation and excipients used. The results obtained were found to be within acceptable pharmacopoeial limits.

Thus, the study concludes that curcumin capsules can be successfully formulated, and the prepared formulation demonstrated satisfactory quality, stability and performance. This formulation approach may be useful for improving patient compliance and ensuring effective delivery of curcumin.

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