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FORMULATION DEVELOPMENT OF FAST DISSOLVING TABLET BY USING CLOVE AND TURMERIC: THE BEST TOOTH ANALGESIC TABLET

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ABSTRACT:

The use of herbal drug has been gaining attention due to the implicit benefits and minimum side goods. The present work has been done to formulate a fast- dissolving tablet made from Turmeric and Clove is estimated for its effectiveness as a tooth analgesic. Turmeric has been shown to have anti-inflammatory effects, which makes it a promising seeker for pain relief. Clove, on the other hand, contains Eugenol, a natural anesthetic that can help numb tooth pain. Fast- dissolving tablets are getting popular due to their ease of administration and quick onset of action. They're particularly useful in the case of tooth pain, where immediate relief is demanded. The tablet is designed to disintegrate in the oral depression i.e., Buccal cavity, within seconds, leaving behind an easy- to- swallow residue. The use of herbal drug, particularly Turmeric and Clove, in the expression of the tablet makes it a safe and natural option for pain relief. The tablet's quick – dissolving nature makes it easy to administer and provides quick relief from tooth pain. The tablet's quality evaluation parameters also indicate that it's a well- made product that meets pharmaceutical norms. In conclusion, the fast- dissolving tablet made from Turmeric and Clove has shown promising results in its effectiveness as a tooth analgesic. The use of herbal drug, combined with the convenience of a fast- dissolving tablet, makes it a feasible option for pain relief. Further studies can be conducted to assess the tablet's efficacy in larger populations and compare it with other anesthetics available in the request.

Key words:- Fast dissolving tablet, Turmeric, Clove, Tooth analgesic, Anti-inflammatory properties, Super disintegrant.

INTRODUCTION

Super disintegrating tablets, also known as fast disintegrating or orally disintegrating tablets (ODTs), are a specialized form of tablet designed to rapidly disintegrate and dissolve in the mouth without the need for water.¹ These tablets are particularly useful for patients who have difficulty swallowing, such as paediatric, geriatric, or dysphagia patients, as well as those who prefer a convenient and discreet dosage form.²

The super disintegrating tablets are formulated using various techniques and excipients that promote rapid disintegration. Some common techniques include:

Direct Compression: This method involves compressing a mixture of API, super disintegrates, diluents, and other excipients directly into tablets. Super dis- integrands are

key ingredients that facilitate tablet disintegration by rapidly absorbing water, swelling,

and generating a porous structure. 3,4,5

Freeze-Drying: This technique involves freezing the tablet formulation and then

subjecting into a vacuum to remove the frozen water. The resulting porous structure

facilitates quick disintegration when placed in the mouth. ^{3,5}

Cotton Candy Process: In this method, a sugary syrup containing the drug and other

excipients is extruded through a spinning disk to form fibrous strands. These strands are

then milled into a powdered form, which can be directly compressed into tablets that readily disintegrate in the mouth. 3,5

1.2 ADVANTAGES OF SUPER DISINTEGRATING TABLET

1. Improved patient compliance,

- 2. Rapid onset of action,
- 3. Ease of administration. ^{6,7,8}

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They are commonly used for drugs that require immediate absorption or have a bitter taste, as the formulation allows for quick dissolution and absorption in the oral cavity. ⁹ Additionally, the convenience and palatability of FDTs can enhance medication adherence, particularly for individuals who have difficulty swallowing traditional tablets or capsules. ¹⁰

1.3 TOOTHACHE:

Toothaches, characterized by throbbing pain in the teeth or surrounding tissues, are a common dental ailment affecting individuals of all ages. The excruciating pain associated with toothaches can significantly impact an individual's quality of life, causing discomfort, difficulty in eating and speaking, and sleep disturbances. ^{11,12}

The primary cause of toothaches is often attributed to dental caries, pulp inflammation, or dental trauma. Prompt and effective pain relief is crucial for individuals suffering from toothaches, not only to alleviate their discomfort but also to address the underlying dental issues and prevent further complications.¹³ Natural products have gained considerable attention in recent years due to their potential therapeutic benefits and minimal adverse effects. Among these natural products, clove (Syzygium Aromaticum) and turmeric (Curcuma longa) have been recognized for their analgesic, anti-inflammatory, and antimicrobial properties.^{14,15}

Clove contains Eugenol, which possesses local anesthetic and analgesic properties, while turmeric contains curcumin, a compound known for its anti-inflammatory and antioxidant effects. The combination of these two natural ingredients holds promising potential for the development of an innovative tooth analgesic formulation. 16, 17, 18

1.4 BACKGROUND OF CLOVE AND TURMERIC:

Clove (Syzygium aromaticum) and turmeric (Curcuma longa) have long been utilized in traditional medicine systems for their therapeutic properties, including their beneficial effects on dental health.¹⁹

Clove is a spice derived from the flower buds of the Syzygium aromaticum tree, native to Indonesia. It has been used for centuries in various cultures for its aromatic and medicinal properties. ²⁰ Clove contains a compound called Eugenol, which is responsible for its distinct aroma and possesses several pharmacological properties. ^{21,22}

In dental care, clove has been traditionally used for its analgesic, antibacterial, and anti-inflammatory effects. Eugenol, the active component of clove oil, exhibits local anesthetic properties by desensitizing the nerve endings in the affected area.²³ It can help alleviate toothache by reducing pain sensations. Additionally, Eugenol possesses antimicrobial properties, making it effective against oral bacteria, which contribute to dental infections and decay.^{7,23}

Turmeric is a yellow-coloured spice derived from the root of the Curcuma longa plant, primarily grown in Southeast Asia. It has been an integral part of traditional medicine, particularly in Ayurveda and traditional Chinese medicine, for thousands of years. Turmeric owes its medicinal properties to a compound called curcumin.^{24,25}

In the context of dental care, turmeric has been recognized for its anti-inflammatory,

antimicrobial, and antioxidant effects. Curcumin, the active constituent of turmeric, possesses potent antiinflammatory properties that can help reduce inflammation in the oral cavity, including gum inflammation (gingivitis) and dental pulp inflammation. ²⁶ Additionally, curcumin exhibits antimicrobial activity against oral pathogens, including bacteria responsible for dental caries and periodontal diseases. ²⁷

The combined use of clove and turmeric in dental care holds promise due to their complementary properties. Clove's analgesic and antimicrobial properties, coupled with turmeric's anti-inflammatory and antimicrobial effects, can potentially offer a comprehensive approach to managing toothaches and related dental conditions. ²⁸

1.5 MECHANISM OF ACTION OF CLOVE AND TURMERIC:

1. Clove (API): Works as an analgesic by blocking the prostaglandins that cause pain and inflammation. ¹⁸

2. Turmeric (API): Works as an Antimicrobial by disrupting the cell membranes of bacteria, preventing their growth and replication. ^{9,7}

1.6 DRUG PROFILE:-CLOVE:-Synonyms:- Laung Biological source : Dried part of Syzygium aromaticum Family: Myrtaceae Colour: Reddish Brown Length: about 13 to 19mm (0.5 to 0.75 inch) Active Constituent Used:- Eugenol

Uses:- are widely used as a spice and have a strong, aromatic flavour and fragrance. It contains different compounds. Roughly, 89% of the clove essential oil is Eugenol and 5% to 15% is Eugenol acetate and β -caryophyllene. Clove are strongly pungent owing to Eugenol. Clove oil derived from buds, is used in various natural remedies for toothaches, sore throats, and digestive issues. ^{29,30,31}

TURMERIC

Synonym: Haldi Biological source: Dried Rhizome part of Curcuma Longa Family: Zingiberaceae Colour: Bright Yellow- Orange Chemical constituent Used:- Curcumin (Polyphenol)

Uses:- Turmeric is widely used as spice in cooking, also adds a vibrant yellow colour and a warm, earthy flavour to dishes, curries, soups etc. Also used to support joint health and relieve joint pain. Turmeric is often consumed or taken as a dietary supplement to support overall health and wellbeing. ^{33,34,17}

CROSSPOVIDINE:

Synonym: PVP-C
Non- Proprietary Name:- BP/USP: Crospovidone
Family: - Spurges
Emperical Formula : 1-Ethenyl-2-pyrrolidinone homopolymer.
Description: Fine, white to creamy white coloured odourless, hygroscopic, amorphous powder.
Uses: - Used as a super disintegrating agent. It has a unique ability to swell and absorb water, which gives it unique functionality

LACTOSE:

Synonym: - Lactochem coarse crystals, Lactochem crystals **Non- Proprietary Name:** BP/USP: Lactose monohydrate

Emperical Formula: C12H22O11.H2O

Description: White to off-white crystalline particles or powder. Lactose is odourless and slightly sweet tasting **Uses:** - Widely used as filler or diluent in tablets and capsules. Usually, fine grades of lactose are used in the preparation of tablets by the wet-granulation method.

MAGNESIUM STEARATE:

Synonym: - Magnesium Salt

Non- Proprietary Name: - BP/USP: Magnesium Stearate

Emperical Formula: C36H70MgO4

Description: Very fine, light white, precipitated powder of low bulk density, faint odour, greasy to touch. **Uses:** - Used in cosmetic, foods and pharmaceutical formulation. Primarily used as lubricant in tablets and capsules.

SACCHARIN SODIUM:

Synonym: Sodium Saccharinate
Non- Proprietary Name: BP/USP: saccharin sodium
Emperical Formula: C7H4N.NaO3S
Description: White odourless or faintly aromatic efflorescent, crystalline powder very soluble in water
Uses: - Used as Calorie free sweetener in beverages and pharmaceuticals.

TALC:

Synonym: - Altac, Hydrous magnesium calcium silicate.
Non- Proprietary Name: - BP: Purified talc USP: Talc
Emperical Formula: - Mg6(SiO5)4(OH)4
Description:- Very fine, white to greyish white, odourless, crystalline powder.
Uses: - Widely used in oral solid dosage formulations as a lubricant and diluent.

MANNITOL:

Synonyms: - D-mannitol, mannitol, osmitrol
Non – Proprietary Name: - BP/USP: Mannitol
Emperical Formula: - C6H14O6
Description: - Odourless white crystalline powder or free-flowing granules.
Use: - Used as a sweetening agent, diluent, excipient for chewable tablet, vehicle (bulking agent).

2. MATERIALS AND METHODS Formula for 1000mg 2.1 LIST OF INGREDIENTS USED

Table No.1 ingredients				
S.No.	S.No. Ingredient			
1.	Clove (API)	800 mg		
2.	Turmeric (API)	30 mg		
3.	Saccharin Sodium	1 mg		
4.	Lactose (Diluent)	130 mg		
5.	Crospovidone (Super Disintegrant)	5 mg		
6.	Magnesium Stearate (Lubricant)	2 mg		
7.	Talc (Glident)	2 mg		
8.	Mannitol (Filler/Binder)	Q.S		

2.2 List of Equipment's Used:-

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	Table No.2 equipments			
ment		Model		

S.No	Equipment	Model
1.	Electronic Balance	FGH-600
2.	Hot Air Oven	Kemi
3.	Manual Tablet Machine	Acme Tech
4.	Monsanto Hardness Tester	Acme Tech

3.1 Methodology

1. Preparation of Herbal Powder:-

1. Processing of Material:

i. Dried clove buds and the rhizome of Turmeric were finely grinded in a mixer grinder.

ii. The clove powder was then kept in Hot air oven for 20 minutes at below 35°C until the moisture got removed. iii. Now the prepared clove powder was passed from the sieve no. 22 to remove all the particulates present in the powder.⁴³

2. Preparation of Mixture of Powder Blend: 53

i. Following the geometric mixing Clove powder, Turmeric powder, Lactose, sodium Saccharin, Crospovidone were mixed for 20 minutes.

ii. Now the Magnesium stearate and Talc were mixed to the powder blend with the help of glass rod.

iii. After the proper mixing of powder, the granules were further sent for compression to form a tablet.

3. Procedure for compression of tablet: ⁵⁴

The so formed powder granules were now compressed into 250 mg tablet using manual compressing machine by Direction compression method and tablets were then kept in an air tight container.

Butterfly pea flower powder: These flowers were purchased from the local market of Saharanpur U.P from a general store named Govind Avtar. The plant is authenticated



Figure.1 Direct Compression of Tablet



Figure.2 FDT of Clove and Turmeric

3.2 PROCEDURE OF EVALUATION OF POWDER BLEND

3.2.1 Pre-Formulation Studies:

1. ANGLE OF REPOSE 55

a. Firstly, we took a clean burette stand.

b. Then we attached a funnel between the holder of burette stand and kept a butter paper at the surface of the burette stand.

c. Then the orifice of the funnel was blocked by thumb for a while and powder was poured onto the horizontal surface and the angle of the resulting pyramid was measured.

d. Then it was calculated through the formula.

2. BULK DENSITY 56

a. Weighed accurately 10 gm of powder blend, and transferred into 100 ml graduated cylinder.

b. Then marked the level of powder without compacting and read the unsettled volume containing voids and powder.

c. Then it was calculated through the formula.

3. TAPPED DENSITY 53

a). Weighed accurately 10 gm of powder mixture and transferred it in 100 ml of measuring cylinder.

b). Then manually tapped the cylinder containing the sample 500 times and the current volume after tapping was measured.

4. CARR'S COMPRESSIBILITY INDEX 57

It was determined by the following formula:

Carr's index = Tapped density- Bulk density * 100 / Tapped density

5. HAUSNER'S RATIO 58,59

It is done to indicate the flow ability of granular powders in a wide variety

Hauser's ratio = Tapped density/ Bulk density

3.2.2 Post- Formulation studies of Tablets:

1. PHYSICAL APPEARANCE

The general appearance of tablet studies were visually in shape, colour, texture and sensory studies used in colour. It can be seen through two aspects viz. Patient compliance and is it legible and good. ⁵³

2. THICKNESS

The thickness was calculated by Vernier callipers. tablet was put in between two jaws vertically and measured thickness and 5 tablets were used for this. ⁵³

3. WEIGHT VARIATION

It was done by weighing 20 tablets individually, calculating the average weight and comparing individual tablet weight to the average. It is helpful in determining the drug content uniformity. ⁵³

4. HARDNESS

It is the tablet crushing strength. The tablet hardness was determined by Monsanto hardness tester. The tablet was placed lengthwise between upper and lower plunger and force applied by turning a threaded bold until the tablet fractures and measured hardness of tablet in kg/cm2.⁵³

4. RESULT AND DISCUSSION:

The technique direct compression method was used for conventional from nutraceutical tablet which minimize processing steps and eliminated wetting and drying process. The physicochemical property showed satisfactory results.

4.1 PRE-FORMULATION EVALUATION OF POWDER:

The powder blend was evaluated for various parameters such as angle of repose, bulk density, tapped density, Carr's index and their results are shown below. After evaluation of pre-formulation parameters, it showed that there is limited presence of moisture in powder and showed uniformity of powder blend. After study of flow rate it conclude that powder blend exist optimum proportion that leads to maximum flow rate. So the result showed that the powder have good flowing property.

4.2 POST-COMPRESSION EVALUATION:

1. PHYSICAL APPEARANCE:

The general appearance of tablet containing clove and turmeric was found to be round in shape, yellowish brown in colour, smooth texture, and having characteristic odour.

2. THICKNESS

The thickness of tablet containing clove and turmeric of F3 batch was found to be 1.8 ± 0.1 cm.

S.No.	Tablet weight	S.No.	Tablet weight	S.	No.	Tablet weight
1.	242mg	8.	243mg	15	5.	241mg
2.	249mg	9.	258mg	16	5 .	262mg
3.	241mg	10.	249mg	17	7.	251mg
4.	244mg	11.	252mg	18	3.	249mg
5.	255mg	12.	257mg	19).	253mg
6.	252mg	13.	242mg	20).	247mg
7.	242mg	14.	238mg			

(Table.No.3: WEIGHT VARIATION OF 20 TABLETS)

3. WEIGHT VARIATION

The average weight variation test as the average percentage weight variation was within the IP limits of $\pm 7.5\%$. The weight of 20 tablets was measured and it was it was found to be 0.225 \pm 0.021 to 0.255 \pm 0.034 for all formulations respectively.

5. HARDNESS

The hardness of the tablet was done through Monsanto hardness tester of batch F3 was found to be 3.12 ± 0.21 kg/cm2 to 3.28 ± 0.11 kg/cm2

6. DISINTEGRATING TIME

On the basis of disintegration, the formulation F3 was best compared to all other

formulations. The prepared tablet formulation F3 has disintegrated within 162 ± 2.50 sec.

(Table.No.4: RESULT OF PRE-FORMULATION STUDIES)

Parameters	Batch F1	Batch F2	Batch F3
Angle of Repose	19.29 ± 0.11	17.74 ± 0.12	18.77 ± 0.17
Bulk Density	0.1282 ± 0.21	0.1315 ± 0.21	0.1298 ± 0.32
Tap Density	0.1449 ± 0.17	0.1492 ± 0.08	0.1496 ± 0.02
Carr's Index	14.23 ± 0.12 1	10.30 ± 0.14	14.30 ± 0.16
Hausner's Ratio	1.16	1.07	1.16

Angle of repose - Excellent flow (<20) Carr's index - Good flow (11-15) Hausner's Ratio - Good flow (1.12-1.18)

Table.No.5: RESULT OF POST COMPRESSION EVALUATION:

Batch	Thickness (mm2)	Hardness	%Wt. variation(g)	Disintegration time(sec)
F1	1.21 ± 0.1	3.12 ± 0.21	0.225 ± 0.021	171 ± 1.47
F2	1.27 ± 0.21	3.01 ± 0.21	0.245 ± 0.012	168 ± 2.18
F3	1.18 ± 0.21	3.38 ± 0.11	0.255 ± 0.034	162 ± 2.50

5. CONCLUSION

The effectiveness of tablets in providing dental care will examine the active properties of clove and turmeric and their benefits in dental care. This study can explore he different formulations and ingredients of clove and turmeric to determine the best combination for dental treatment. This combination of several different herbs believed to have complimentary or synergistic effects. Fast disintegrating drug delivery is widely accepting new technology for rapid dissolving or disintegrating the drug molecule/extract within few minutes. Generally super disintegrant are added to a drug formulation to facilitate the break up or disintegrant. Based on results of this study it can be concluded that this tooth analgesic tablet of clove and turmeric containing crosspovidone have relatively faster dissolution rate and release of active medicaments which is used in dental problem and inflammation and other various treatment.

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COMPETING INTERESTS

It is made known that the collaborating authors have no contrasting interest.

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