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FORMULATION & EVALUATION OF IMMUNO - ENHANCHIG HERBAL CHEWABLE TABLETS

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ABSTRACT

The goal of the current study was to use herbal ingredients to make chewable, Immuno herbal pills. The four most revered herbs in Indian traditional medicine are Curcuma longa (turmeric), Foeniculum vulgare (fennel), and Zingiber officinale(Ginger), Cuminum (Cumin). These four herbs were used in the current study's oral chewable tablets, which were made using the wet granulation process and direct compression. Both procedures started with a prepared powder of ginger, fennel seed, and turmeric, and cumin which was then combined with preservatives and other ingredients. To assess the quality and purity of the conformation, pre-formulation studies, post-formulation standardization, and physicochemical analysis of the individual medications were conducted. All of the parameters examined for the constituents in the pre- formulation study were found to be within the typical range. Therefore it is, concluded that the developed chewable tablets may be better alternative to the conventional uses of the herbs.

KEYWORDS: Quick dissolve, Swallow Free Tablet, Fast acting Tablet, Palatable Medication, Gum Core.

INTRODUCTION

Chewable polyherbal tablets are a type of medicine you chew before swallowing. They are made by combining different herbal or plant extracts. The benefit of these tablets is that they bring together the healing effects of several herbs in one dose. When used together, the herbs may work better than when used alone. These tablets can be made for different purposes, like helping with digestion, boosting the immune system, reducing stress, or treating specific health problems.[1]

Chewable tablets are made to be broken and chewed between the teeth before swallowing. They are often given to children who have trouble swallowing and to adults who don't like swallowing pills. These tablets break down easily in the mouth, either with or without chewing. They usually have a smooth texture, taste good, and don't leave a bad or bitter taste behind. Chewable tablets are made to be chewed in the mouth, where they break down and release their ingredients quickly. This means they work faster than regular tablets, which need time to dissolve in the stomach first. Chewable tablets are often used when the medicine needs to work in the mouth or nearby areas, rather than being absorbed into the whole body. They taste good and can be taken with little or no water. Mannitol is commonly used in chewable tablets because it doesn't absorb moisture from the air, which makes it good for protecting medicines that are sensitive to moisture.[2]

Ideal characteristics of chewable tablets

1. It should be Simple to bite.[4]
2. It should be elegant product having its own identity while being free of defects such as chips, cracks, discoloration and contamination.[5]
3. It should be in appropriate size and shape.[4]
4. It should able to break down promptly to encourage dissolution.[4]
5. It Should have the physical stability to maintain its physical attributes over time.[5]
6. It should be palatable.[4]
7. It should have strength to withstand the rigors of shocks encountered in its production, packaging, shipping and dispensing.[5]

Advantages[2]

1. Better bioavailability through by passing disintegration (that increase dissolution).
2. Improved patient acceptance (especially pediatric) through pleasant taste.
3. Patient convenience; need no water for swallowing.
4. Possible to use as a substitute for liquid dosage forms where rapid onset of action is needed.
5. Absorption of drug is faster.
6. Effectiveness of therapeutic agent is improved by the reduction in size that occurs during mastication of tablet before swallowing.

Disadvantages[6]

1. Difficult to swallow in case of children and unconscious patients.
2. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
3. Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.
4. Irritant effects on the GI mucosa by some solids (e.g., aspirin).
5. Possibility of bioavailability problems resulting from slow disintegration and dissolution.

OBJECTIVES

1. To ensure that the active compounds from the herbal products are delivered efficiently through a convenient, chewable form.

2. To improve patient compliance especially for children, elderly, and those with difficulty swallowing conventional tablets.
3. To enhance taste and palatability using sweeteners, flavors and pleasant mouth feel.
4. To provide rapid onset of action (buccal absorption) potentially speeding up the therapeutic effect .
5. To offer dosage accuracy.
6. To create a convenient, portable dosage form offering consistent and accurate immuno support without the need for water.
7. To support body's natural defense mechanisms by providing daily supplementation with scientifically validated herbal ingredients.
8. To deliver effective concentrations of immuno modulatory phytochemicals.
9. To develop a stable chewable tablet formulation containing standardized herbal extracts known for their immune boosting properties.

Formulation Method: Wet Granulation

To prepare chewable tablets on a small scale using the wet granulation method, each ingredient was weighed, pulverized, and passed through a fine sieve (sieve no. 80). All the ingredients were mixed well, except for magnesium stearate and talc. These two were crushed separately using a mortar and pestle and also passed through sieve no. 80. Next, starch/ acacia/ HPMC (q.s) were slowly added while mixing continued.

The mixture was then passed several times through a coarser sieve (sieve no. 24) to make granules. These granules were dried in a hot air oven at 100°C.

After drying, the granules were passed again through sieve no. 24 to make them uniform size. Then, magnesium stearate and talc were added and mixed with the granules.

Finally, the granules were compressed into 500 mg tablets using a single rotary tablet machine. The machine was set to ensure the correct tablet weight before compression.[12]

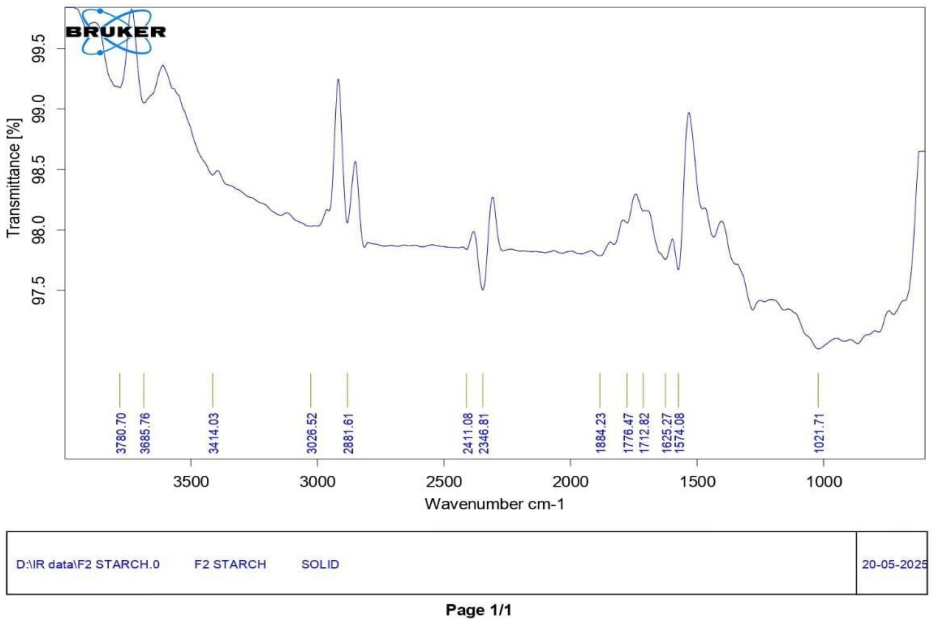
Ingredients and It's Function

Ingredients	Role
Turmeric	Antibacterial
Fennel	Carminative
Ginger	Antinflammatory
Cumin	Boost Immunity and Metabolism
Stevia	Sweetner
Mannitol	Filler
MCC	Disintegrant
Citric Acid	Acidify
Starch Paste/ Acacia Paste/HPMC	Binder
Black Salt	Muscle Relaxant
Methyl Paraben	Preservative
Mg. Sterate	Lubricant
Talc	Glidant
Black Salt	Muscle Relaxant

Formulation Table of Tablet

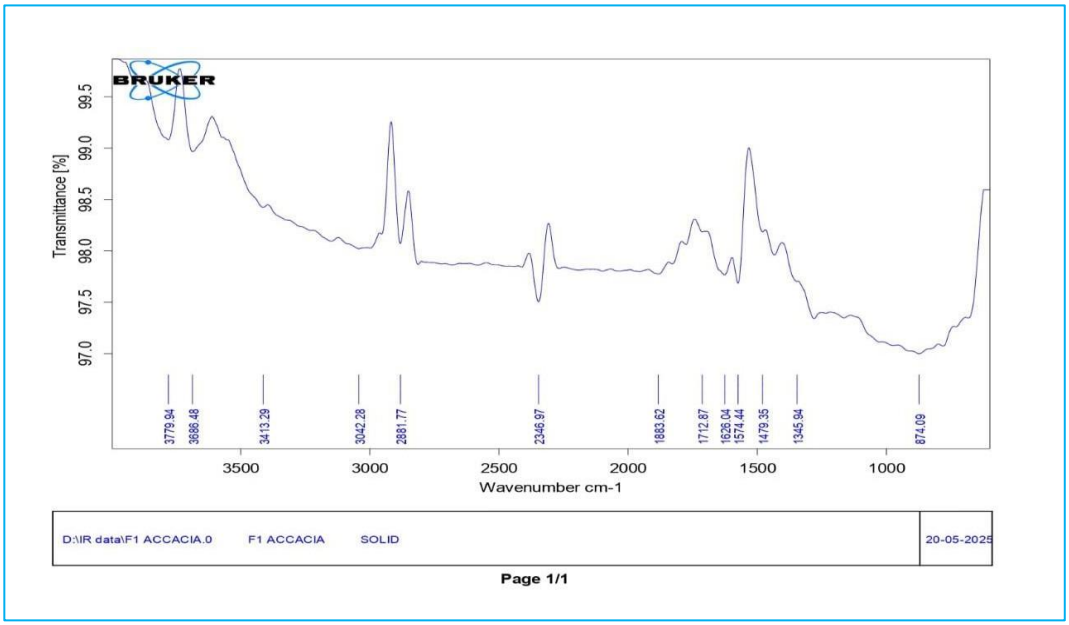
Ingredients	F1	F2	F3
Turmeric	9.7	9.7	9.7
Fennel	19	19	19
Ginger	30	30	30
Cumin	18	18	18
Stevia	10	10	10
Mannitol	233	233	233
Mcc	77	77	77
Citric acid	19	19	19
Starch Paste	qs	-	-
Acacia Paste	-	qs	-
HPMC	-	-	qs
Methyl Paraben	1	1	1
Mg Sterate	20	20	20
Talc	22	22	22
Black salt	38	38	38

FTIR of F1 Batch:-



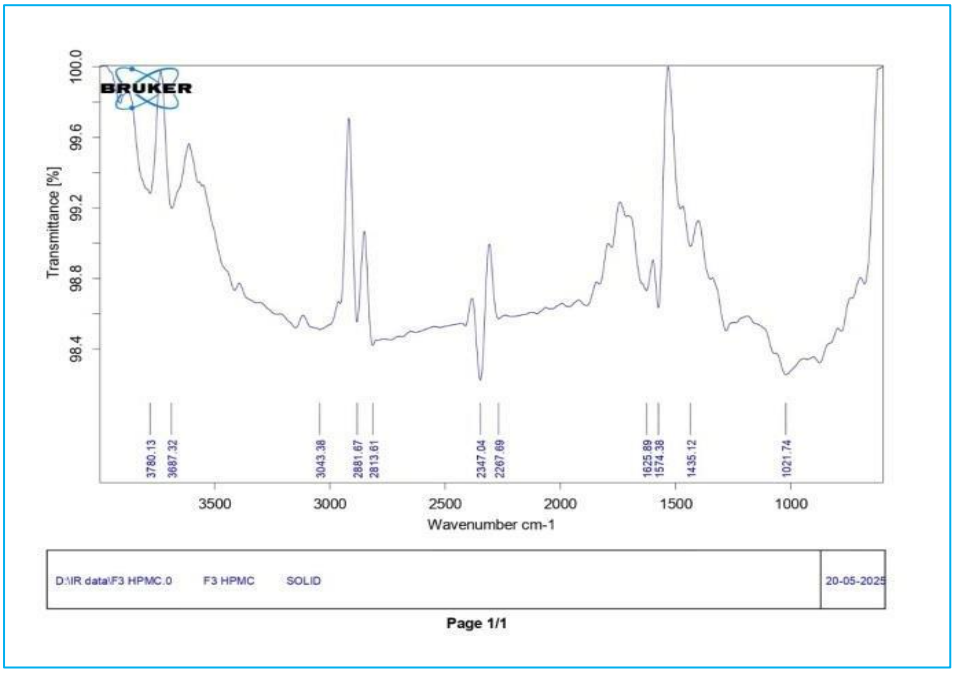
Type	Vibration mode	Frequency in cm^{-1}	
		Observed	Reported
Cuminaldehyde	C-H(Str.)	2881.67	3600-2850
Alkene (turmeric)	C=C(Str.)	1625.89	1680-1640
Ether (Fennel)	C-O(Str.)	1021.74	1250-1021
Alkene (Fennel)	=C-H	3043.38	3100-3000
Methyl	C-H(Str.)	2813.61	2960-2850
Aromatic	C-C(str in ring)	1435.12	1500-1400
Carboxylate (citric acid)	COO	1575.38	1610-1850

FTIR of F2 Batch:-



Type	vibration mode	Frequency in cm^{-1}	
		Observed	Reported
Alkene(Cumin)	C=C(Str.)	1626	1680-1640
Hydroxyl(Luteolin)	O-H(Str.)	3413	3500-3200
Aldehyde(Cuminaldehyde)	CHO(C-H) (Str.)	2881.77	2830-2695
Methoxy(Aromatic)	C-H(Str.)	874.09	900-675
Ether(Anthole)	C-O-C	1345.95	1320-100
Amine (Ginger)	N-H	1626.04	1650-1580
Alkene(Shagaols)	C=C(Str.)	1574.44	16801640
CH3(Acacia)	C-H (Bending)	1479	1470-1450
Ketones(Acacia)	C=O(Str.)	1712.87	1715
Phenol	Free O-H(Str)	3779.94	3640-3610
Phenol	Weakly H bonded	3686.48	-

FTIR of F3 Batch:-



Type	Vibration mode		
		Observed	Reported
Cuminaldehyde	C-H(Str.)	2881.61	3600-2850
Alkene	C=C(Str.)	1625.27	1680-1640
Hydroxyl(Luteolin)	O-H(Str.)	3414.03	3500-3200
Carboxylate (citric acid)	COO	1574	1610-1850
Ketones (Ginger)	C=O(Str.)	1712.82	1715
Alkene (Fennel)	=C-H(Str.)	3026.52	3100-3000
Ether(turmeric)	C-O(Str.)	1021.71	1250-1021

Evaluation of Granules

1. **Before Making Tablets (Pre-Compression):**[13]

- **Bulk Density:** Tells us how heavy the powder is without pressing it down.
  Formula :-BD= Mass\Volume
- **Tapped Density:** Shows how much the powder can be packed when tapped.
  Formula :-TD= Mass\Tapped volume
- **Carr's Index:** Helps us understand how well the powder flows.

Formula:-CI= Tapped Density-Bulk Density\Tapped Density ×100

- **Hausner's ratio:-** To access the flow ability of powder

Formula :-Tapped Density\Bulk Density

Sr. no	Flow ability	Carr's Index (%)	Hausner's ratio
1	Excellent	0-10	1.00-1.11
2	Good	10-15	1.12-1.18
3	Fair	16-20	1.19-1.25
4	Passable	21-25	1.26-1.34
5	Poor	26-31	1.35-1.45

- **Angle of Repose**: Checks how easily the powder can slide or flow.
- **Formula:-** θ= tan¯1 h\r

Sr.no	Flow ability	Angle of repose
1	Excellent	<25
2	Good	25-30
3	Moderate	30-40
4	Poor	>40

2. After Making Tablets (Post-Compression)[13]

- **PH Determination:-** To ensure the tablet's pH is within a safe and effective range for stability, absorption, and patient safety.
- **Thickness/Diameter:-** To ensure uniformity, proper packaging, dose accuracy, and ease of chewing.
- **Tablet Hardness:-** check to ensure the tablet is strong enough for handling while still dissolving properly to deliver the correct drug dosage. It is done by Monsanto hardness tester.
- **Friability:-** The friability test for tablets measures their ability to resist abrasion and breakage during handling, using a device called a friabilator. Commonly used Roche friabilator.
- **Weight Variation:-** Makes sure all tablets weigh about the same.
  Formula:- weight variation (%)= individual tablet weight-average Weight \ average weight ×100

- **Disintegration test:-** To make sure the tablet disintegrates properly so the drug can be released and absorbed in the body.

RESULT AND DISCUSSION

1. Preformulation 1. F1

2. Table: Result of F1 batch.

Parameters	Observed values	Flow ablility
Bulk density	0.57	-
Tapped density	0.61	-
Carr's index	6.55	Excellent
Hausner ratio	1.7	Excellent
Angle of repose	30.54	Very good

1. **F2**

2. **Table: Result of F2 batch.**

Parameters	Observed values	Flow ablility
Bulk density	0.52	-
Tapped density	0.56	-
Carr's index	7.14	Excellent
Hausner ratio	1.07`	Excellent
Angle of repose	29.68`	Very good

3. **F3**

3. **Table: Result of F3 batch.**

Parameters	Observed values	Standards values
Bulk density	0.49	-
Tapped density	0.52	-
Carr's index	5.7	Excellent
Hausner ratio	1.06	Excellent
Angle of repose	29.6	Very good

2. Post formulation Evaluation test.

Table: Evaluation tests of F1, F2, F3 batches.

Parameter	F1	F2	F3	Results
Hardness	5.5kg/sq.cm	5kg/sq.cm	6kg/sq.cm	Pass
Friability	0.9	1.5	0.9	Pass
Weight variation	3.47	3.48	3.47	-
Thickness	1.1mm	1.1mm	1.1mm	-
disintegration	7 min	9 min	10 min	-
pH	4.3	4.5	4.1	Slightly acidic

Image of F1,F2,F3 Respectively

CONCLUSION

In the contemporary era, herbal products are increasingly regarded as safer alternatives compared to synthetic pharmaceuticals, which are often associated with adverse effects on human health and the environment. Historically, herbs have been valued for their medicinal, flavoring, and aromatic properties over centuries. Given their therapeutic potential and biocompatibility, there is a pressing need to promote and integrate herbal products into global healthcare and commercial markets. Hence from this research work we studied that , In chewable tablet formulations, starch is generally more effective than acacia or HPMC when considering key factors like taste, chewability, mouthfeel, and disintegration.

Parameters	Starch	Acacia	HPMC
Taste	Neutral	Slightly better	Slightly Mucilaginous
Mouth feel	Smooth	Slightly sticky	Gel like
Disintegration	Disintegrte easily when chewed		Slow and forms a gel, delaying breakdown
Chewablility	Excellent	Slow	Slow
Binding strength	Moderate, Ideal for chewable tablet	Strong	Strong
Main use	Binder, Disintegrant	Binder, Emulsifier	Binder, Film former

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