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FeniCaff: Mouth-Dissolving Caffeine Tablets Utilizing Fenugreek Mucilage as a Natural Superdisintegrant

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Abstract:
The demand for mouth-dissolving tablets (MDTs) has increased due to their convenience for patients with dysphagia, pediatric, and geriatric populations. This study focuses on the formulation and evaluation of mouth-dissolving caffeine tablets using fenugreek mucilage as a natural superdisintegrant Strong muscle relaxant caffeine helps control elevated muscular tone linked to spasticity. This study examined and compiled eight different formulations of mouth-dissolving tablets (FDTs) containing caffeine. These tablets were made using super disintegrants, following official guidelines and standards. A 2-level, 3-factorial design was employed to optimize the formulation parameters, investigating the effects of fenugreek mucilage concentration, caffeine dose, and compression force on tablet properties. The prepared tablets were evaluated for disintegration time, wetting time, drug release profile, and mechanical strength to determine their efficiency in rapid drug delivery. Results indicated that fenugreek mucilage significantly enhanced disintegration and dissolution rates, making it a promising natural alternative to synthetic superdisintegrants. The optimized formulation met pharmacopeial standards and demonstrated improved caffeine release, highlighting the potential of fenugreek mucilage in MDT formulations.

Keywords: Mouth-Dissolving Tablets, caffeine, Fenugreek Mucilage, Superdisintegrant, Factorial Design, Rapid Drug Delivery System.

1. INTRODUCTION

Mouth-dissolving tablets (MDTs), also known as orally disintegrating tablets (ODTs) or fast-dissolving tablets, are a novel drug delivery system designed to dissolve or disintegrate rapidly in the oral cavity without the need for water. These tablets offer a convenient alternative for patients who experience difficulty in swallowing conventional tablets or capsules, including paediatric, geriatric, and bedridden patients. MDTs enhance patient compliance and provide faster onset of action by allowing drug absorption through the oral mucosa. Caffeine is a widely recognized central nervous system stimulant, known for its ability to enhance alertness, combat fatigue, and improve mental focus. In modern pharmaceutical formulations, mouth-dissolving tablets (MDTs) offer a convenient and innovative method for delivering caffeine quickly and effectively. Caffeine is a widely recognized central nervous system stimulant, known for its ability to enhance alertness, combat fatigue, and improve mental focus. In modern pharmaceutical formulations, mouth-dissolving tablets (MDTs) offer a convenient and innovative method for delivering caffeine quickly and effectively. Due to their simplicity of self-administration, precise dosing, and ease of

manufacture, tablets are the most widely used dosage form in the world. Despite all of these benefits, children and elderly patients may find it challenging to swallow traditional tablets.1-2The mouth dissolving tablet is a unique medicine delivery mechanism that scientists have created to overcome these problems. Mouth-dissolving tablets dissolve in the mouth within seconds when they come into contact with saliva, without needing any extra water. Mouth-dissolving tablets (MDTs) offer several advantages, such as a quicker onset of action, improved patient compliance, and enhanced bioavailability. Caffeine, commonly found in beverages like coffee and tea, as well as in pain-relief medications, acts as a stimulant that helps increase alertness. Additionally, it is used to treat and prevent pulmonary problems resulting from preterm birth. Caffeine belongs to the methyl-xanthine class of compounds. It is used to treat various conditions, such as breathing problems in premature babies, pain relief, and preventing drowsiness. Since caffeine stimulates the body, it helps in these treatments: the central nervous system, it increases alertness and can occasionally lead to agitation and restlessness.

2. MATERIAL AND METHODS

A. MATERIAL:

Caffeine mouthwash tablets were made using the direct compression method. For each formulation, the necessary quantity of medication and excipients was taken (Table No. 1). Using a mortar and pestle, the powdered medication, MCC, and lactose were thoroughly combined while triturating continuously. After adding the necessary amount of sucralose and super disintegrate (Fenugreek Mucilage Powder) to each recipe, and thoroughly mixing them, magnesium stearate were added. For every intended formulation, a batch of 50 tablets of each formulation was made. Prior to tablet production or punching, compatibility studies (IR) and precompression characteristics such as Hauser's ratio, bulk density, taped density, compressibility index, and angle of repose were applied to the mixture blend of all suggested formulations.7–10.

B. PRE-FORMULATION STUDIES:

Angle of Repose (θ): The maximum angle that can exist between the powder pile's surface and its horizontal plane is known as the angle of repose. The angle of repose ascertained using the funnel method that scientist Newman proposed. The following formula determines the angle of repose.

Bulk Density: Weight per unit volume is the definition of density. The mass of the powder divided by its bulk volume yields the bulk density, which is represented as gm/cm^.A powder's bulk density is mostly determined by the size, shape, distribution, and inclination of its constituent particles to stick together. Two varieties of bulk density exist.

Tapped Density (DT): It was the index representing the ratio of the powder's total mass to its tapped volume. By tapping the powder 500 times and recording the tapped volume, volume was reported. It was stated as follows, with an expression in g/ml. Dt= M/Vt ,Where, M is the mass of powder, Vt is the tapped volume of the powder.

Carr's index (or) % compressibility: Carr's index indicates powder flow properties. It is expressed by percentage and is given by: I=Dt−Db/Dt×100, Where, DT denotes the tapped density of the powder And Db is the bulk density of the powder.

Hausner ratio: Hausner ratio is an indirect index of ease of powder flow properties. It is calculated by the following formula: Hausner ratio=Dt/Db, Where, DT show the tapped density, Db is the bulk density. Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)

3. EVALUATATION OF TABLET

The following parameters were assessed for all manufactured caffeine tablets in accordance with IP guidelines; the results of all calculations are shown in table No. 3.

WEIGHT VARIATION: - From each formulation, twenty tablets containing the caffeine formulation were chosen at random, and each tablet's weight was recorded using Citizen Digital Balance.

HARDNESS: - Hardness of the Caffeine tablet was measured with the tablet hardness testing apparatus known as Monsanto tablet harness tester.

FRIABILITY: - The friability of the Caffeine tablet, a sample of twenty tablets was measured using USP type Roche Friabilator. The tablets were dusted reweighed and percentage weight-loss was calculated.19 %Friability= Initial Weight−Final Weight * 100/ Initial Weight

Wetting Time :- A tiny Petri dish (ID = 9 cm) filled with 6 ml of pH 6.8 phosphate buffer was used to hold a piece of tissue paper (12 cm by 10.75 cm) that had been folded twice. A tablet was placed on the paper, and the amount of time it took for it to fully wet was recorded. Every formulation had three tablets chosen at random, and the average wetting time was recorded.

DISINTEGRATION STUDY: - Disintegration time study was carried out by selecting 6 tablets of Caffeine and performed disintegration test using 900 ml distilled water at temperature (370C±20C)

DISSOLUTION STUDY: - Phosphate buffer was used as the dissolution medium in the in-vitro dissolution study, which was conducted in the USP (United States Pharmacopeia) dissolution test apparatus type 2, also known as the paddle dissolution apparatus. A vessel containing 900 ml of PH 6.8 was filled, and the temperature was kept at 37±0.50C.

Table No. 1 Formulation of Mouth dissolving tablet of Caffeine

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8
Caffeine	50	50	50	50	50	50	50	50
Lactose	230	370	370	230	370	370	230	230
MCC	151	41	49	181	19	11	189	159
Fenugreek Mucilage	50	20	20	20	50	50	20	50
Mg. Stearate	12	12	4	12	4	12	4	4
Sucralose	7	7	7	7	7	7	7	7
Total Weight	500	500	500	500	500	500	500	500

4. RESULT AND DISCUSSION

Table No. 2 Pre-compression parameters of Caffeine FDTs

Parameters / Formulation	Bulk Density (mg/ml)	Tapped Density (mg/ml)	Hausner's Ratio	Carr's Index (%)	Angle of Repose
F1	0.472	0.521	1.103	9.40	24.19
F2	0.461	0.543	1.177	15.10	25.30
F3	0.451	0.506	1.121	10.86	24.45
F4	0.401	0.425	1.270	21.66	24.14
F5	0.401	0.327	1.311	23.24	24.98
F6	0.396	0.556	1.200	16.98	23.12

F7	0.481	0.529	1.099	9.07	24.52
F8	0.492	0.565	1.148	12.92	28.11

Table No. 3 Post-Compression parameters of Caffeine FDTs

Parameters Formulation	Thickness (mm)	Avg.Weight (mg)	Hardness (Kg/cm2)	Friability (%)	Disintegration Time (Sec)
F1	3.2	500	3.5	3.42	259.8
F2	3.1	501	3.9	2.85	19
F3	3.0	499	4.0	0.55	18
F4	3.4	500	3.0	3.99	68.4
F5	3.3	500	3.9	0.57	15
F6	3.1	501	3.0	5.05	23
F7	3.5	500	3.2	1.61	90
F8	3.6	500	3.5	1.15	225

Table No. 4 In-Vitro Drug Release of Formulated Tablets

Formulation	% Drug release				
	Time (min)				
	5 min	15 min	30 min	45 min	60 min
F1	61.8	80.1	85.5	86.6	92.4
F2	40	50	69	78	87
F3	30	45	60	70	89
F4	55	60	66	75	84
F5	65.8	80.1	85.5	86.6	92.4
F6	64	79	84	88	94
F7	45	54	66	76	89
F8	68	77	87	89	93

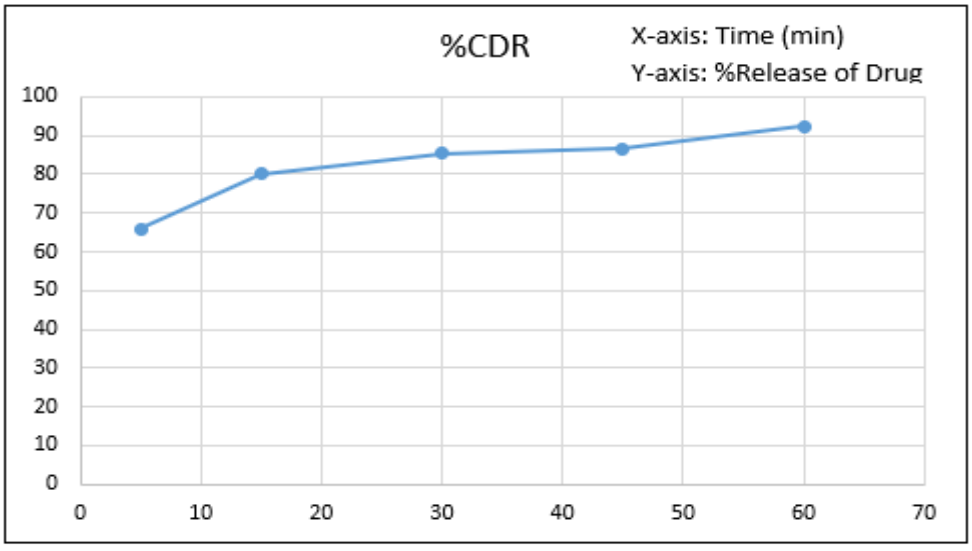

Figure-1. %CDR Graph

The in-vitro release profile (Figure 6.1) of batch – 6 demonstrates a progressive increase in drug release over time, reaching a substantial percentage of the total drug released within the 60-minute observation period. As the drug is released more than 80% in less than 60 minutes, so the tablet can be considered as immediate – release dosage form or mouth dissolving dosage form.

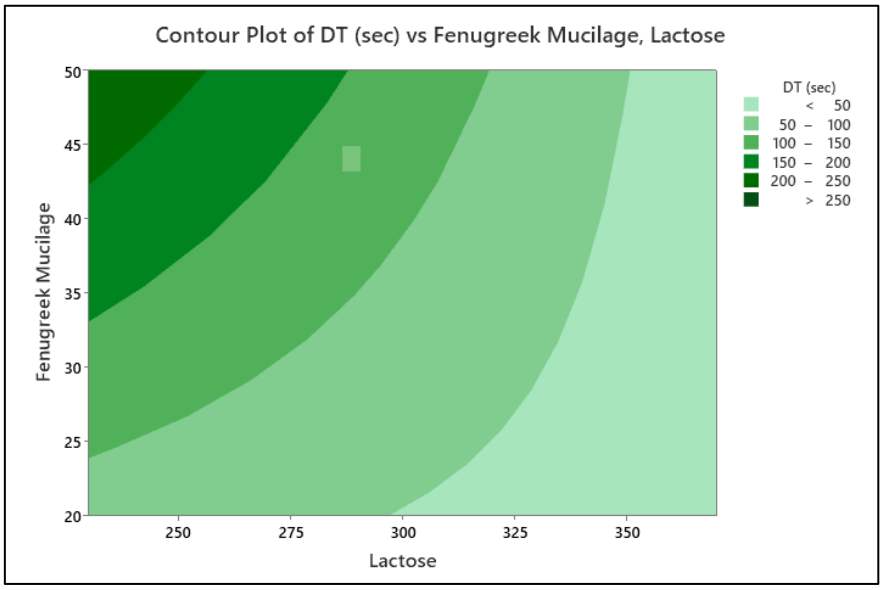

Figure-2: Contour Plot DT (sec) vs Fenugreek Mucilage, Lactose

The contour plot demonstrates the relationship between fenugreek mucilage, lactose concentrations, and disintegration time (DT). DT increases with higher concentrations of fenugreek mucilage, indicating stronger tablet binding and slower disintegration. Conversely, DT decreases slightly with increasing lactose levels due to its water solubility and ability to enhance disintegration through wicking action. The fastest disintegration (lowest DT) occurs at low mucilage and high lactose concentrations (bottom-right region). The slowest disintegration (highest DT) is observed at high mucilage and low lactose concentrations (top-left region). The interaction between these two excipients is crucial for optimizing tablet disintegration time based on the desired formulation goals.

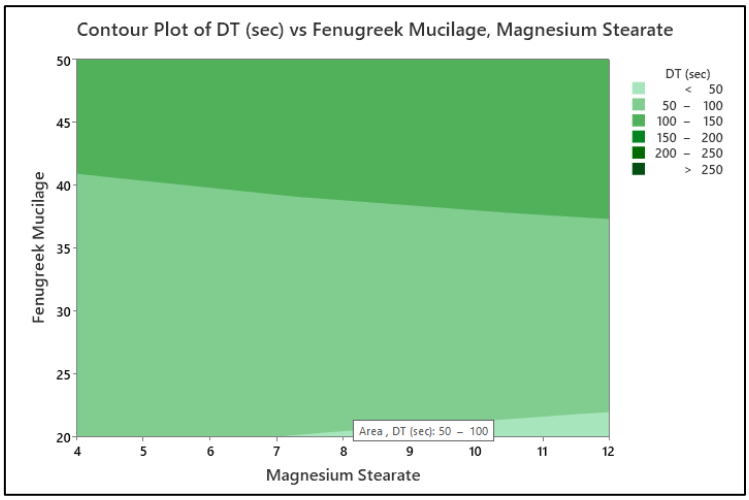

Figure-3: Contour Plot DT (sec) vs Fenugreek Mucilage, Magnesium Stearate

This contour plot illustrates the combined effect of fenugreek mucilage and magnesium stearate concentrations on tablet disintegration time (DT). Disintegration time (DT) increases with higher concentrations of fenugreek mucilage, likely due to its binding properties, which result in stronger tablet matrices and slower disintegration. On the other hand, magnesium stearate shows a relatively moderate effect on DT, with a slight increase in DT observed as its concentration increases. The lowest DT values (50–100 sec) are found in regions with low fenugreek mucilage (20–30 units) and moderate magnesium stearate levels (around 8–10 units). The highest DT values (>200 sec) appear in areas with high fenugreek mucilage (above 40 units), regardless of magnesium stearate concentration. The plot suggests that fenugreek mucilage has a more significant influence on DT compared to magnesium stearate.

Figure-4: Visual representation of Final Batch Tablets

5. CONCLUSION

This study aims in formulating an effective and attractive dosage form in juvenile to adults and elderly. Formulated and evaluated mouth-dissolving caffeine tablets utilizing fenugreek mucilage as a natural superdisintegrant. The use of a 2-level, 3-factorial design approach allowed for systematic optimization of formulation parameters, ensuring rapid disintegration and effective drug release.

The results demonstrated that fenugreek mucilage significantly enhanced the disintegration time while maintaining tablet integrity, friability, and dissolution profile within the desired range. Variations in tablet weight, thickness, and hardness were effectively controlled to meet pharmacopeial standards. The optimized formulation achieved a disintegration time between 15-23 seconds, aligning with the requirements for mouth-dissolving tablets. Additionally, the dissolution studies confirmed that a high percentage of caffeine was released within 10 minutes, ensuring rapid onset of action. Evaluation parameters result shows that from the above formulation listed in the table F5 is the accurate formulation and describes the stability study faultlessly.

Overall, the study validates the potential of fenugreek mucilage as a promising natural superdisintegrant in the formulation of mouth-dissolving caffeine tablets. Future research can explore its applicability in other drug formulations to enhance patient compliance and therapeutic efficacy.

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