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Formulation and Evaluation of Mouth Dissolving Tablets for Halitosis (bad Odour)

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ABSTRACT
Halitosis is associated with bad breath, which may be due to various reasons such as the food consumed or due to a deep-set pathological problem. However, halitosis has a psychological embarrassing social impact with social restrictions. If halitosis is not treated it may lead to chronic bad breath and ill health. Many resources have been spent to treat halitosis with products like chewing gums, mouthwash, etc. However, The present study was aimed to formulate and evaluate mouth dissolving tablets for halitosis by direct compression method using two different flavoring agents such as peppermint oil or cinnamon oil in a different concentration 0.25%, 0.5%, 0.75% & 1%. FTIR studies showed that there was no interaction between the flavoring agent and the excipients used for formulation. Eight formulations were prepared, labeled was F1-F8 and evaluation for hardness, weight variation friability, wetting time, disintegration time and In vitro spoon test among the eight formulation F2 formulation containing 0.5% peppermint oil showed less wetting time 23.2 seconds, less disintegration time 23.2seconds, Invitro spoon test show as good peppermint flavor. The stability studies for optimized formulation F2 were performed for 30 days, at 25°C/60RH and 40°C/75RH. The formulation F2 was found to be stable and showed no significant change in physical appearance, weight uniformity, wetting time, disintegration time, and In vitro spoon test during the study period. Hence, formulation (F2) containing 0.5% peppermint oil was identified as ideal and better formulation among all formulation developed mouth dissolving tablets and may be useful for halitosis.

KEYWORDS: Halitosis, Mouth dissolving tablet, Flavouring agent, Peppermint oil, Cinnamon oil.

I. INTRODUCTION

Oral route of administering the drug had been widely accepted i.e. up to 50-60% of total dosage forms. Among all the dosage forms solid dosage forms are popular because of advantages like easy in the administration, self-medication, accurate dose, pain avoidance and patient compliance. Tablets and capsules are one of the most popular solid dosage forms. But the main disadvantage of this dosage form for some patients is little difficulty to swallow. People frequently experience difficulty in swallowing conventional dosage forms such as tablet when the water is not available to them, in the period of the motion sickness and sudden incidence of coughing during the common cold, and in allergic condition. For these reasons, tablets which can rapidly dissolve or disintegrate in the oral cavity without any water have attracted the attention of the researchers. Mouth dissolving tablets are not only formulated for people who have difficulties in swallowing, but also are best for active people. A solid dosage form that dissolves and disintegrates rapidly in the oral cavity, resulting in solution or suspension without the need of water and therefore known as fast dissolving tablets. Fast dissolving tablets are also known by other name as mouth-dissolving tablets, which melts-in mouth. Oro-dispersible tablets, porous tablets, rapimelts, quick dissolving etc. Fast dissolving tablets are those tablets when they are kept on tongue disintegrates instantaneously and releases the drug which dissolve or disperses in the saliva. The quicker the drug gets dissolved, quicker will be the absorption and onset of clinical effect. Few examples of fast dissolving tablets are ondestron tablets, famotidine, few examples of sublingual tablets are nitroglycerine tablets, abstral tablets, few examples of dispersible tablets are disprin, amoxilline and few examples of chewable tablets are multivitamin/fluoride, caffeine chewable tablets.

VARIOUS CRITERIA FOR THE MOUTH DISSOLVING DRUG DELIVERY SYSTEM: [1-3]

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The tablets however do require water to swallow, but it should disintegrate or dissolve itself within the mouth in few seconds.Be compatible with masking the taste,convenient without weakness worry,have a satisfying mouth feel,leave minimum residue in the mouth after administration orally, exhibit low sensitive to environmental condition as humidity and temperature and allow the manufacturing of the tablets using conventional process and packaging equipments at a low cost.

BENEFITS OF MOUTH DISSOLVING TABLETS:

• Can be administered without water ,suitabilityfor geriatric and pediatric patients, who experiencedifficulties in swallowing and for the other groups that may experiences some troubles using conventional oral dosage form, due to being mentally ill, the development disabled and the patients who are un-cooperative, or are on reduced liquid intakes plans or are nauseated.Beneficial in cases such as sudden motion sickness, sudden episodes of allergic attacks or coughing, where an ultra rapid onset of action is required.An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets. Stability for a longer period of time, since the drug continuously remains in the solid dosage form till it is consumed. So, it combines benefits of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

LIMITATIONS OF MOUTH DISSOLVING TABLETS:

• The tablets generally have insufficient mechanical strength. Hence, these tablets are required to be handled cautiously. The tablets may leave unpleasant taste in the mouth if it is not formulated suitably.

II. MATERIALS AND METHODOLOGY

Materials

Methodology

Fourier-Transform Infrared Spectroscopy (FT-IR) study [4]

In the preparation of mouth dissolving tablets, drugs is in intimate contact with one or more excipients It is very important to study the compatibility of the drug with the various excipients used. In the formulation drug and excipients compatibility study was carried out using FTIR. Sample and KBr way fing!y grounded using mortar and pestle at the ratio of respectively. A small amount of mixture was placed under hydraulic press, compressed at 10 kg/cm2 to form a transparent pellet. The pellet was kept in the sample holder and scanned from 4000 cm-I to 400 cm" in Shimadzu FTIR spectrophotometer infrared spectrum of pure drug alone and along with excipients was taken, drug compatibility with excipients was assessed based on the IR s m obtained.

PREPARATION OF MOUTH DISSOLVING TABLET FOR HALITOSIS (bad odour)

Mouth dissolving tablet for halitosis (bad odor) were prepared by using different superdisintegrant like SSG by direct compression method. For preparation of tablets previously sieved (Sieve no. 25) ingredients were mixed according to formula specified in formulation table. Binder like microcrystalline cellulose were used for the preparation of the tablets. Sweetening agents like Sodium Saccharine, Mannitol were used. Flavoring agents like Peppermint oil and cinnamon oil were used.

PREFORMULATIONSTUDY: [1, 5]

1. **Angle of repose:** Angle of repose was determined using fixed funnel method. The granules were taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the drug powder. The powder was allowed to flow through the funnel freely onto surface. The height (h) and diameter of the powder cone was measured and angle of repose was calculated by following formula:

Angle of repose (θ) = tan-1 (h/r)

2. **Bulk density:** Loose bulk density (LBD): LBD was determined by placing granules into a graduated cylinder and measuring the volume and weight as it is.

LBD = Mass/Volume

3. **Tapped bulk density (TBD):** Weighed granules were transferred to a graduated cylinder and were tapped for a fixed time or for a fixed number of taps. The TBD was determined by using the following formula:

TBD = Weight of granules/Tapped volume

4. **Compressibilityindex:** Based on LBD and TBD, the % compressibility of the powder mixture was determined by the following formula:

Compressibility index = (TBD - LBD) × 100/ TBD

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5. **Hausner's ratio:** It is determined by the following formula:

Hausner's ratio = TBD/LBD

POSTCOMPRESSION STUDIES: [1, 5]

1. **Hardness test:** Monsanto or Pfizer hardness tester was used for the measurement of hardness. The tablet to be tested was held between a fixed and a moving jaw and reading of the Indicator adjusted to zero. The force applied to the edge of the tablet is gradually increased by moving the screw knob forward until the tablet breaks. The reading is noted from the scale which indicates the pressure required in kg or lb to break tablets. The unit for hardness is kg/cm2 or lb/cm^2.
2. **Tablet thickness and diameter**: Thickness and diameter of tablets was important for uniformity of tablet size. Thickness and diameter were measured by using Vernier calipers on 3 randomly selected samples. The unit is centimeter or millimeter.
3. **Weight variation:** 10 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P. is shown in Table-8 Weight Variation Specification as per IP.
4. **Friability test:** Roche's friabilator was used for testing the friability of prepared tablets. Twenty tablets were weighed accurately and placed in the friabilator and rotated at 25 rpm for a period of 4 min. Tablets were dedusted using soft muslin cloth and weighed again. Percentage weight loss was determined by using following formula. The weight loss should not be more than 1% to pass the test.

% Friability = (Initial wt. of tablets – Final wt. of tablets)* 100/Initial wt. of tablets

5. **Wetting time:** A piece of tissue paper folded double was placed in a Petri plate (internal diameter is 8.5 cm) containing 6ml of SSS pH 7.4. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds.
6. **In vitro dispersion time:** Tablet was placed in 10 ml SSS pH 7.4. Time required for complete dispersion of a tablet was measured in seconds.
7. **In-vitro disintegration time:** The in-vitro disintegration time of the tablet was determined using disintegration test apparatus. One tablet was placed in each of the 6 tubes of the basket a disc was added to each tube and the apparatus was run using pH 7.4 (simulated saliva fluid) maintained at 37±20C as the immersion liquid. The time in seconds taken for complete disintegration of the tablet was noted when no palpable mass was remaining in the apparatus and recorded.
8. **Stability study:** The mouth dissolving sublingual tablets were packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines [40 °C ± 2 °C and 75 ± 5 % RH.(Q1C)]. The tablets were withdrawn after a period of 30 days and analyzed for physical characterization (Hardness, Disintegrations and Dissolution, wetting time etc.) and drug content.
9. **In vitro Spoon test:** The spoon test was performed by taking nine 20ml beakers, into each beaker 10ml of the simulated saliva having a PH of 6.7 was poured.1gm of onion was crushed and placed in each of the nine beakers. The contents were mixed with a stainless steel spoon and the spoons were allowed to be in the beaker for 5minutes. In the first four beakers, the formulations (F1-F4) containing peppermint were added (one tablet of each formulation in each beakers) and in the next four formulations (F5-F8) containing cinnamon were added. The nineth beaker the marked product S-mint, one tablet was placed. After two minutes the spoon were removed from the beakers and the odour for onion was checked. It was found that the spoon in formulation f2 had the same smell as that of the spoon in marked product the spoon cinnamon formulation had pungent odor. So the formulation F2 was selected as masked the onion odor.

III. RESULTS AND DISCUSSION:

1. Angle of repose

Table No 1: Angle of repose

Sl. No	Angle of repose	Type of flow
1	<25	Excellent
2	25-30	Good
3	30-40	Passable

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4	>40	Very poor

2. Compressibility index and Hausner's ratio

Table No 2: Compressibility index and Hausner's ratio

% compressibility	Flow ability	Hausner's ratio
5-12	Excellent	Excellent
12-16	Good	Good
18-21	Fair passable	Fair passable
23-35	Poor	Poor
33-38	Very poor	Very poor
<40	Very very poor	Very very poor

3. Organoleptic properties of Peppermint oil: The peppermint oil sample was analysed for physical appearance and odour.

RESULT: The available sample of peppermint oil was found to be a yellow -greenish liquid and, strong peppermint odour.

4. Organoleptic properties of cinnamon oil: The cinnamon oil sample was analysed for physical appearance and odour.

RESULT: The available sample of cinnamon oil was found to be yellow liquid and pungent odour.

5. Compatibility studies: Compatibility studies were performed using IR spectrophotometer. The IR Spectrum of pure flavoring agent and excipient were studied and characteristic absorption peak were obtained.

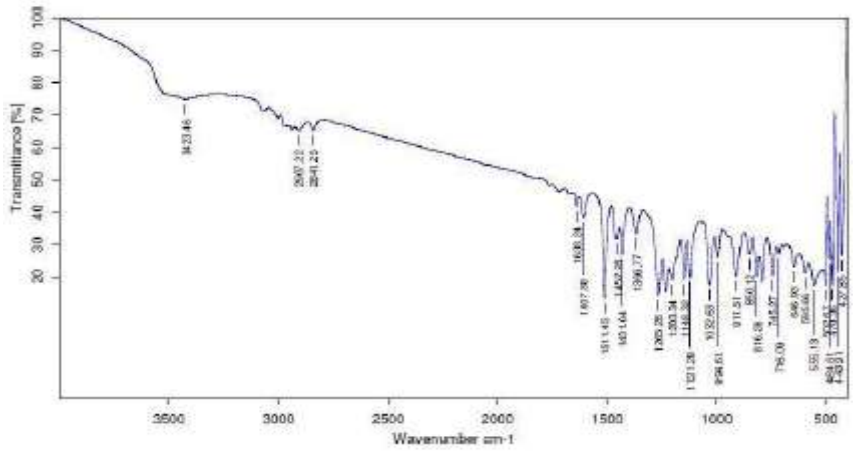

Figure 1: FT-IR spectra of cinnamon oil

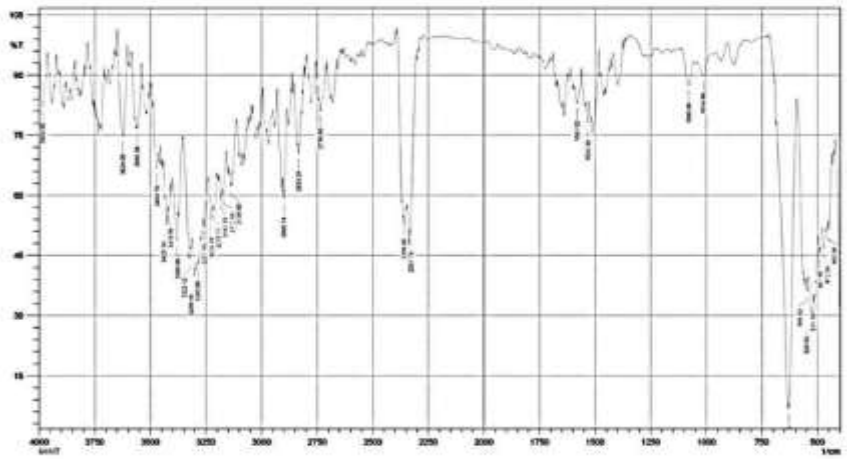

Figure 2: FT-IR spectra of peppermint oil and excipients

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Post compression studies

Table No 3: Post compression studies

Formulation	Thickness (mm) (±SD), n=3	Hardness (Kg/cm^2) (±SD), n=6	Friability (%) (±SD), n=10	Weight variation (%) (±SD), n=20
F1	3.23° ± 0.048	3.7±0.542	0.16±0.02	200.5±1.36
F2	3.15±0.067	3.98±0.622	0.23±0.04	200.1±1.67
F3	3.99±0.174	4.10±0.365	0.32±0.03	199.8±0.89
F4	4.03±0.067	4.13±0.279	0.18±0.03	200.5±0.65
F5	3.16±0.060	3.99±0.699	0.24±0.04	200.2±1.68
F6	4.03±0.15	3.97±0.360	0.32±0.03	200.08±0.65
F7	4.03±0.064	4.13±0.279	0.17±0.01	200.5±0.68
F8	4.01±0.015	3.98±0.147	0.31±0.04	199.8±0.67

Table No 4: Evaluation data of post compression properties

Formulation	Wetting time (sec) (±SD), n=3	Water absorption ratio (%)(±SD), n=3	Disintegration time (sec) (±SD), n=6
F1	28±0.58	17.01±0.55	22±1.644
F2	25±0.55	25.32±0.57	23±1.211
F3	33±3.00	26.42±0.73	26±1.97
F4	26±1.53	21.93±0.33	27±1.63
F5	26±0.54	26.32±0.54	23±1.94
F6	27±0.58	18.10±1.00	34±0.98
F7	26±1.58	21.92±0.33	27±1.63
F8	28±1.15	31.21±0.74	26±1.06

Wetting time

Figure 3: Wetting time of formulation

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Dispersion time

Figure 4: Dispersion time of formulation

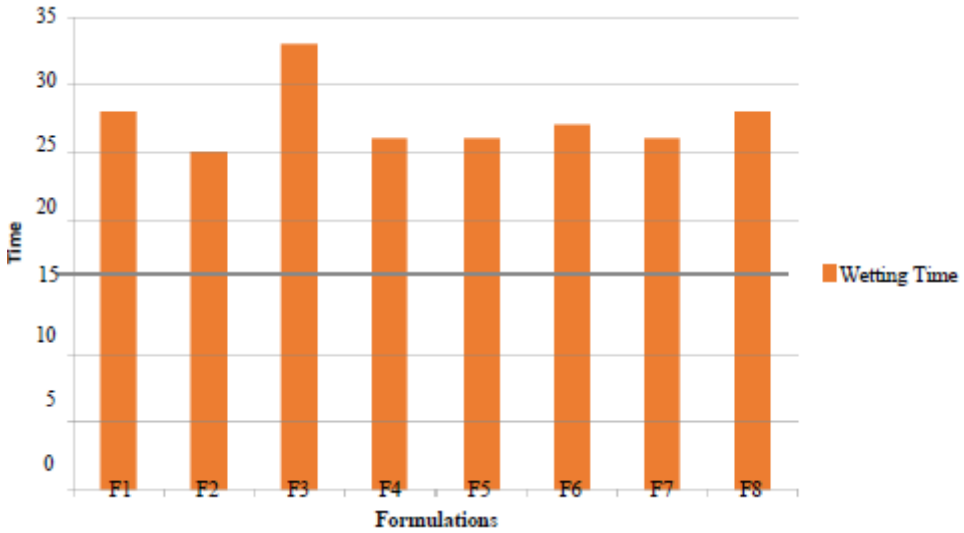

Figure 5: Comparison of disintegration time

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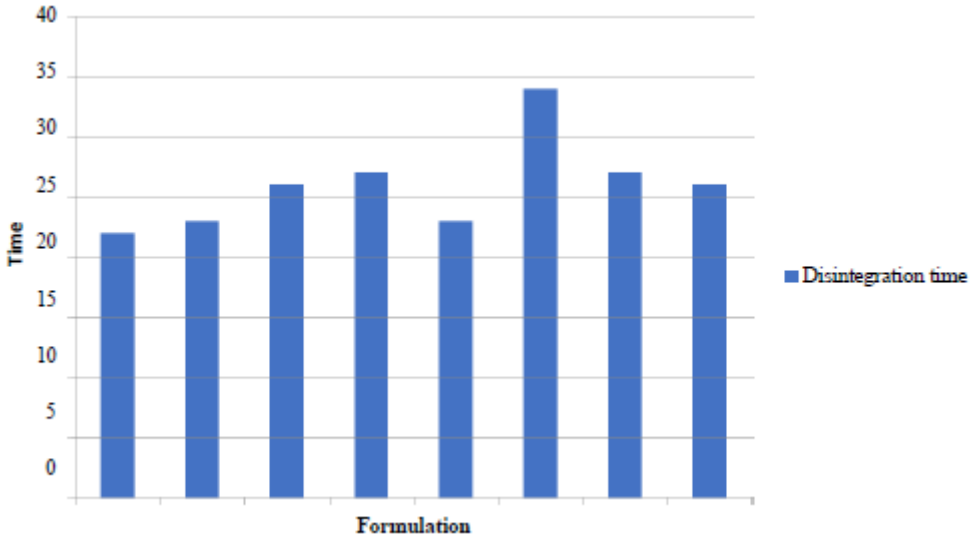

Figure 6: Comparison of disintegration time

In vitro spoon test:

Table 5: Evaluation of in vitro spoon test

Formulations	Onion odor	Peppermint oil flavor	Cinnamon oil flavor
F1	Slightly onion odor	Good	-
F2	No onion odor	Excellent	-
F3	No onion odor	Slightly more mint flavor	-
F4	No onion odor	More mint flavor	-
F5	Onion odor	-	Poor
F6	Slightly onion odor	-	Good
F7	No onion odor	-	Very good
F8	No onion odor	-	Slightly more cinnamon oil flavor

Stability study (25°C/60RH) after 30 days

Evaluation parameter	After 30 days
Hardness test	3.80Kg/cm^2
Wetting time	28sec
Disintegration time	23sec

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Stability study (40°C/RH) after 30 days

Evaluation parameter	After 30 days
Hardness test	3.88Kg/cm^2
Wetting time	23sec
Disintegration time	21sec

After stability testIn vitro spoon study

Optimum formulation	Onion odor	Peppermint oil flavor
F2	Slightly onion odor	Good

IV. DISCUSSION

Halitosis is associated with bad breath, which may be due to various reasons such as the food consumed or due to a deep-set pathological problem. However, halitosis has a psychological embarrassing social impact with social restrictions. If halitosis is not treated it may lead to chronic bad breath and ill health. Many resources have been spent to treat halitosis with product like mouth fresheners, chewing gums, mouthwash, etc. But there has not been a proper solution for this. However, this project aims to develop mouth dissolving tablet to overcome bed breath which would have a better patient compliance and will be cost effective.

In the development of mouth dissolving tablet for halitosis, the main challenges are palatability, mechanical strength, and aqueous solubility, size of the tablet, taste and mouth feel. Palatability, taste and mouth feel can be improved by adding sweeteners and flavors. Mechanical strength is managed by using optimum hardness which should not affect disintegration time. Tablet should disintegrate as fast as possible in mouth while coming in contact with the saliva. This is the main feature of the formulation and can be managed by using super disintegrants.

In the present study, the mouth dissolving tablet for halitosis were prepared by using various flavouring agent and other excipients as mentioned in the formulation chart (Table 3). A total number of eight(F1-F8) formulations were prepared by direct compression method. The preformulatory studies such as bulk density, tapped density, angle of repose, compressibility and Hausner's ratio were evaluated. All the Preformulation studies were found within the prescribed limits and indicated good to fare free flowing nature. The data obtained from physicochemical parameters such as hardness, friability, weight variation, wetting time, disintegration time, dispersion time and in vitro spoon test are shown in (Table 12,13,14).Out of all the eight formulations, F2 was found to be most satisfactory.

V. CONCLUSION:

Mouth dissolving tablet were prepared by direct compression method using peppermint oil and cinnamon oil for halitosis(bad odour).Peppermint oil, cinnamon oil and excipients compatibility were checked by FT- IR and found Compatibility with each other .the precompression parameters like Carr's index, Hauser ratio, and angle of repose were determined . the post compression paraeters like weight variation, hardness, friability, disintegration, wetting time and invitro spoon test were determined for all the formulation F1-F8 and the values were found to be within limits.The tablet thickness ranged between 3.25mm to 4.033mm,hardness ranged between 3.7Kg/cm² to 4.15Kg/cm²,friability ranged between 0.16% to 0.35%,disintergration time was between 22±1.644 to 34±0.98 seconds,wetting time was found to be 22±1.644 to 33±3.00 seconds , in-vitro spoon test formulation (F2) contain a concentration of 0.5% peppermint oil was identified as ideal and better formulation among all the eight formulation(F1-F8).The stability studies for optimized formulation F2 was performed for 30days,at 25c/60RH and 40c/RH and the result showed that the formulation was found to stable. The odour masking capacity of tablet F2 prepared was similar to the marketed product (s mint).It can concluded that, MDTs for halitosis containing 0.5% peppermint oil, can be prepared by direct compression and will be useful for paediatric and geriatric population at large.

CONFLICT OF INTEREST: No

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