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Research Article

Development and Evaluation of Mango Pulp Powder as Pharmaceutical Excipient

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ABSTRACT

The study was aimed extraction of mango powder from mango pulp; The presence of carbohydrate was confirmed by phytochemical analysis. The drugs and extract were found to be compatible as confirmed by IR spectral studies. The mango powder was evaluated for its micromeritic properties viz. bulk density, tap density, angle of repose, Hausners's ratio, Carr's index and the results indicated good flow properties. The formulations were prepared using mango pulp powder and other excipient. The prepared granules were free flowing and the compressed tablets showed good friability and hardness. The drug content of all the prepared formulations was ranging from 96.5- 100.0%. This study confirmed that the mango pulp can be used as an effective release retardant and can be successfully used in development commercial products.

INTRODUCTION

Mango is a tropical fruit of the mango tree. The mango obtained from *mangifera indica*, having family *Anacardiaceae* [1, 8]. The mango is the most commonly eaten fresh fruit worldwide. It believed to be rich of nutritional source, containing many vitamins, minerals, and especially antioxidants, as well as enzymes such as magneferin and lactase which aid in digestion and intestinal health [2]. Raw mango with 100g has 65 calories and about half the vitamin C found in oranges [3]. It also contains more vitamin A than most fruits. The mature mango can be recognized when it has a characteristic fragrance and smooth, thin and tough skin [4]. The color of ripe flesh mangos is pale yellow to orange. Likes another popular fruits, mango can be eaten raw as fruit or can be processed to various products such as juice, jams, jellies [5]. It can control the moisture content by either removing moisture or binding it so that the food becomes stable to both microbial and chemical deterioration [6]. The modern techniques such as spray drying, freeze drying and so on can be applied for this method [7].

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MATERIALS AND METHODS

Materials

The mango fruit was obtained local market (shirpur. Maharashtra) Nimesulide obtained as gift sample from Denizen pharma. Ltd, (New Delhi). Micro crystalline cellulose obtained Famy car Ltd, (Mumbai), Magnesium stearate Talc from S.D.fine chem.Ltd. (Mumbai), Lactose obtained from Ranbaxy Chemical (Mumbai). Sodium hydroxide, Hydrochloric acid at Loba chemical (Mumbai India) All others chemical used were of analytical grade.

Preparation of lyophilized mango pulp powder

The mango fruits were collected from the local market and thoroughly washed with portable water. Peels were removed from pulp and scrap out pulp, cut into small pieces with the help of knife. The mango pulp was homogenized by using mixer grinder and mechanical stirrer. The homogenized mango juice was frozen in defreeze. The frozen mango pulp was kept in freeze dryer at -45°C. The frozen sample was allowed to sublime at – 75°C under vacuum. This process was continued up to 48 hr. up to getting dry mango powder [1, 9].

Formulation of tablets

The tablets were prepared by direct compression technique using Four hundred milligram (400

mg) nimesulide tablets were manufactured using a 10-station Rimek multi press (Karnavati Engineering) fitted with 10 mm standard concave tooling varying concentrations of mango pulp powder and other excipient as mentioned in Table 1. Mango powder, nimesulide (model drug) and all other excipients was added and passed through sieve no. 80 and used for direct compression of tablets.

Evaluation of lyophilized mango powder

Phytochemical examination

Molisch's test was performed to confirm the presence of Polysaccharide. To 2-3 ml. aqueous mixture of powder, add few drops of alpha naphthol solution in alcohol, shake and add conc. $H_2 SO_4$, from sides of the test tube. Violet ring is formed at the junction of two liquids

Micromeritic properties of mango powder

Bulk density, tap density, angle of repose, Hausner's ratio and Carr's index were determined.

Bulk density

Apparent bulk density was determined by placing excipients blend into a graduated cylinder and measuring the volume (V) and weight (M).

$$\text{Bulk Density} = \frac{\text{Mass of powder (M)}}{\text{Bulk volume of the powder (V)}} \ldots . (1)$$

Tapped density

The measuring cylinder containing a known mass of blend was tapped for a fixed number of taps. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (ρt) was calculated using following formula.

$$\text{Tapped Density} = \frac{\text{Weight of powder (M)}}{\text{Tapped Volume of the powder (Vt)}} \ldots . (2)$$

Angle of repose

The angle of repose was determined by the funnel method. The blend was poured through a funnel that can be raised vertically until maximum cone height 2 cm. (h) was obtained. Radius of the heap (r) was measured and angle of repose (q) was calculated using the following formula. [10-12].

$$q = tan^{-1} h/r \ldots (1)$$

Hausners Ratio

Hausners ratio was determined by following equation [13].

$$\text{Hausner's ratio} = \frac{\text{TBD}}{\text{LBD}} \ldots . (3)$$

Where,

TBD= Tapped Bulk density

LBD= Loose Bulk density

Carr's index

The compressibility index of all ingredients was determined by following equation [13].

$$\text{Carr's index} = \frac{\text{TBD} - \text{LBD}}{\text{TBD}} \text{x}100 \ldots (4)$$

Fourier Transform Infrared Spectroscopy (FTIR)

The FTIR study of MPP was carried out to identify the functional group present in Material. For FTIR spectroscopy, MPP and dried KBR were mixed in ratio 1:100. Then small fraction of mixture was compressed on Automatic IR Press (Kimaya Engg, Thane, India), at pressure 10 tones to form transparent pellet. Then the IR spectrum of pellet was taken on FTIR spectrophotometer.

Evaluation of Tablets

Post compression analysis

The prepared tablets were evaluated for thickness, hardness, friability, weight variation, drug content determination, dissolution according to pharmacopoeia.

Thickness

Ten tablets were selected randomly from individual formulations and thickness was measured by using vernier caliper scale, which permits accurate measurement of the tablet.

Hardness

Ten tablets were randomly selected and the crushing strength of the tablets was measured by using Monsanto hardness tester. The average values were recorded.

Friability

Ten tablets were weighed and placed in a Roche friabilator and the equipment was rotated at 25 rpm for 4 min. The tablets were taken out, dedusted and reweighed. The percentage friability of the tablets was measured as per the following formula,

$$\% \text{ Friability} = \frac{(\text{Initial Weight} - \text{final weight})}{(\text{Initial weight})} \text{x } 100$$

Table 1: Composition of tablet formulation

Sr. No	Content's(mg)	F-1	F-2	F-3	F-4	F-5	F-6
1	Nimesulide	100	100	100	100	100	100
2	MCC	00	25	50	50	100	50
3	Mango powder	50	50	50	75	50	125
4	Mg. sterate (1%)	4	4	4	4	4	4
5	Talc (2%)	8	8	8	8	8	8
6	Lactose	238	213	188	163	138	113
7	Total	400	400	400	400	400	400

Weight variation

Weight variation test was performed by weighing 20 tablets individually; calculating the average weight and comparing the individual tablet weight to the average.

Drug content determination

Ten tablets of each formulation were powdered. Powder equivalent to 50 mg of nimesulide was weighed accurately and transferred to two 100ml volumetric flasks separately. To the flask 100 ml of methanol was added and shaken thoroughly. The resulting solution was filtered, diluted and the drug content was estimated at230 nm for nimesulide using UV spectrophotometer (model) using methanol as blank.

***In-vitro* drug release**

Drug release studies were carried out using USP-II dissolution test apparatus-II (Electro lab, Mumbai, India). The study was conducted at 37^{o}C and 50 rpm. The dissolution medium used was 900ml of phosphate buffer pH 1.2 and study was carried up to 2.30 hours. 5ml of sample was withdrawn at different time intervals and replaced with fresh medium in order to maintain sink condition. The withdrawn samples were diluted suitably and drug content was estimated spectrophotometrically at 230 nm for nimesulide.

RESULTS AND DISCUSSION

The yield of mango pulp powder was 25%. The identification of the polysaccharide was confirmed by Molisch's test as there was formation of violet ring at the junction of the liquids. The results of micromeritic properties of mango powder were shown in Table 2. The supplied drug passed the various tests of identification and analysis. The pure drug nimesulide and mango pulp powder as excipients used in the preparation of tablet formulations were characterized by FT-IR spectroscopy to know the compatability, figure-2. The FT-IR study did not show any possibility of interaction between nimesulide and mango pulp powder used in the tablets. Since the flow properties of the mango pulp powder are important for the uniformity of the mass of the tablets, the flow of the mango pulp powder was analyzed before compression of the tablets. The results of angle of repose and compressibility index (%) ranged from (20.80 ± 0.72 to 25.54 ± 0.23) and (20.00 ± 0.87 to 26.66 ± 0.28), respectively. The results of loose bulk density and tapped bulk density ranged from (0.11 ± 0.27 to 0.13 ± 0.43) and (0.15 ± 0.48 to 0.17 ± 0.31), respectively. The results of angle of repose (<30) indicate good flow properties of granules. This was further supported by lower compressibility index values. The lowest compressibility index is 5- 15 % which indicates excellent flow properties (Table 2).

Table 2: Characterization of lyophilized mango powder

Sr. No.	Parameter	Values observed*
1	Bulk density (g/cc)	0.553
2	Tap density (g/cc)	0.638
3	Angle of repose(θ)	22.78
4	Hausner's ratio	1.153
5	Carr's index (%)	13.23

Evaluation of compressed tablet

General appearance

Yellow colour with uniform colour distribution, surface was smooth without fracture.

The physical properties of different batches of tablets are given in (Table 3). Tablet mean thickness was almost uniform in all the formulations. The thickness varies between 4.0 ± 0.49 to 4.1 ± 0.23 mm. The prepared tablets in all the formulations possessed good mechanical strength with sufficient hardness in the range of 3.238 ± 1.4 to 3.731 ± 1.81 kg/sq cm.

Table 3: Evaluation of Tablet formulation

Parameters	F1	F2	F3	F4	F5	F6
Thickness ±S.D. mm(n=10)	4 ± 0.02	4 ± 0.04	4 ± 0.03	4 ± 0.02	4 ± 0.05	4 ± 0.03
Hardness ± S.D. (kg/cm²)	2 ± 0.3	2.5 ± 0.5	2.5 ± 0.2	2.5 ± 0.2	3.0 ± 0.2	2.0 ± 0.3
Friability (% w/w)	0.97± 0.04	0.97±0.06	0.97± 0.02	0.97±0.04	0.975± 0.08	0.975± 0.03
Average Weight variation (n=10)(400 mg)	398.13±1.5	397.9 ±1.6	397.14±1.4	387.32±1.3	394.2± 1.58	390.4 ± 1.60
Drug Content (%)	82.2 ± 1.20	86.6 ±1.46	93.2 ± 1.56	96 ± 0.92	84.2 ± 2.12	94.4 ± 0.55

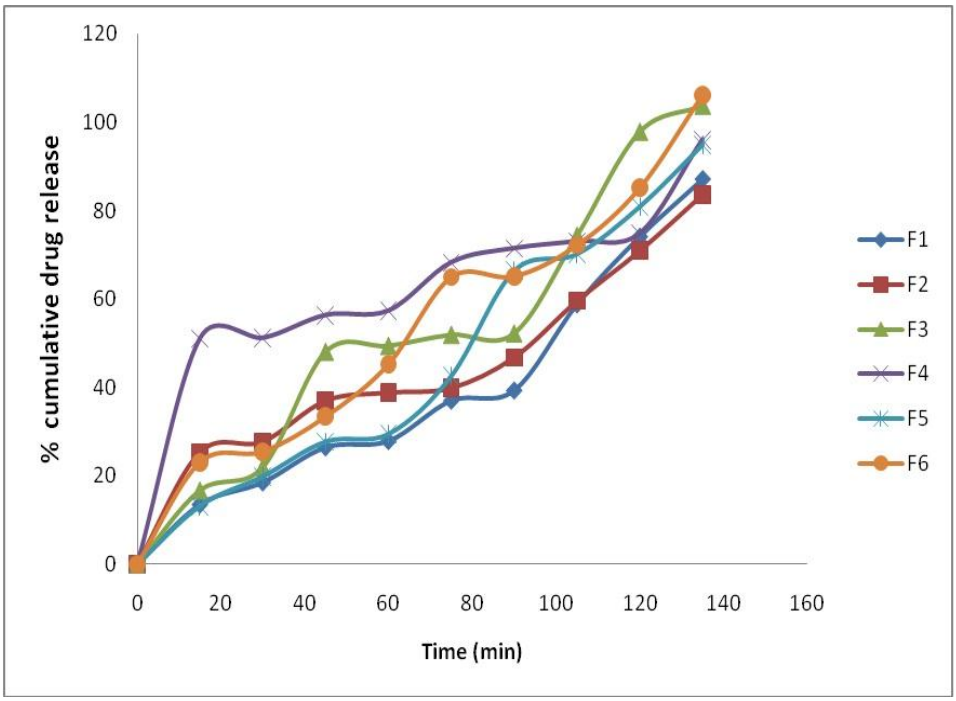

Figure 1: Cumulative % drug release of prepared tablet formulations

Friability values below 1% were an indication of good mechanical resistance of the tablets. Formulations prepared by sublimation method were found to be more friable. All the tablets from each formulation passed weight variation test, as the % weight variation was within the pharmacopoeial limits of ±7.5% of the weight. The weight variation in all the six formulations was found to be390.71 to 402.19 mg, which was in pharmacopoeial limits of ±7.5% of the average weight. The percentage drug content of all the tablets was found to be between 86.6 ±1.46 to 96 ± 0.92 % of nimesulide which was within the acceptable limits.

CONCLUSION

The mango pulp powder was found to be suitable release retardant for the tablet manufacturing, which showed good result as flavoring, coloring and diluents. Tablets were evaluated for physical characterization, drug release and content uniformity. The formulation which showed good general appearance, least friability, hardness, were further evaluated for drug content, *in vitro* dissolution time, *in vitro* drug release study, content uniformity, thickness, evaluation.

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