ORIGINAL ARTICLE

Development of Fast-dissolving Oral Dosage Form as Tablet using Binder as *Vigna Mungo* Mucilage and Oral Film using Solvent Casting Technique: Comparative Study

Nilesh S. Kulkarni[1], Vidyaranee B. Ingle[1], Shashikant N. Dhole[1], Rahul H. Khiste[2], Rahul S. Shivarkar[1], Manoj K. Munde[3]

[1]Department of Pharmaceutics, PES Modern College of Pharmacy (For Ladies), Moshi, Pune Affiliated to Savitribai Phule Pune University, Pune, Maharashtra, India, [2]Department of Pharmaceutical Quality Assurance, Marathwada Mitra Mandals College of Pharmacy, Thergaon, Pune affiliated to Savitribai Phule Pune University, Pune, Maharashtra, India, [3]Department of Pharmaceutical Chemistry, Raigad College of Pharmacy, Mohpre Mahad, Raigad Affiliated to Dr. Babasaheb Ambedkar Technological University, Lonere, Maharashtra, India

Abstract

Aim: Oral route is the most common route of delivery which is used for drug administration. Oral solid dosage forms are the most preferred oral dosage forms as tablets and novel drug delivery as oral films. Sumatriptan succinate is a new generation anti-migraine agent; Oral bioavailability of sumatriptan succinate is low due to its severe first-pass metabolism. **Materials and Methods:** An attempt was made to develop fast-dissolving and disintegrating oral tablet and oral film for the sumatriptansuccinate to avoid first-pass metabolism. To develop a fast-dissolving tablet a natural mucilage powder extracted from *vigna mungo*. The tablet formulations were prepared using 2, 4, and 6% mucilage solution as a binder. Similarly, the oral films containing polyvinyl alcohol: soluplus or hydroxypropyl methyl cellulose: Soluplus were prepared by solvent casting method. The differential scanning calorimetry and fourier transform infrared spectroscopy was carried out for plain drugs, blend of drugs with mucilage, formed granules andoral film. The developed oral fast-dissolving tablet and oral fast-dissolving film formulations were evaluated for drug content, *In vitro* dissolution study. **Results and Discussion:** Tablets formulated with 2% mucilage (B1) binder require less disintegration time and 100% drug dissolution within 10 min. Film formulations containing HPMC K100M with soluplus containing 100 mg and 675 mg, respectively, resulted disintegration within 25 seconds and 96% of drug dissolution within 5 min. **Conclusion:** Hence, the fast-dissolving dosage form was successfully developed as film formulation as compared to tablets for the sumatriptan succinate.

Key words: First pass metabolism, mucilage, oral film

INTRODUCTION

Large advancements and developments in the region of pharmaceutical dosage forms have been seen over the last few decades. Solid dosage forms are most preferred oral solid dosage forms are popular and among them, tablets are mostly used. To avoid experiencing difficulty in swallowing oral solid medicament by geriatric and pediatric patients, patients who are suffering from illnesses that cause difficulty in swallowing, and bedridden patients. Advancement and development are also required to obtain faster and instant action of medicament and to overcome problems related to bioavailability. To overcome or minimize disadvantages some sort of modification is needed. International oral dosage form for gaining that desired effect for the intended onset of action

Address for correspondence:
Dr. Nilesh S. Kulkarni, Department of Pharmaceutics, PES Modern college of Pharmacy (For Ladies), Moshi, Pune, Maharashtra, India. E-mail: nileshpcist@gmail.com

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and bioavailability fast-dissolving systems were evolved. The oral cavity has a unique environment than the other body parts and that uniqueness is beneficial for the rapid absorption of the drug. pH of this region is slightly acidic to neutral due to salivary secretion and in this pH range, most of the drugs are stable. Mucosal region shows less enzymatic activity than other parts of the gastrointestinal tract, so enzymatic degradation of a drug is avoided. Due to the direct entrance of drugs into the systemic circulation, there is avoidance of risk of first-pass effect.[1,2]

Sumatriptan succinate is new generation anti-migraine drug which relieves pain of migraine by producing its vasoconstricting action by binding to 5-HT1D receptor and constricting cerebral blood vessels also inhibits pro-inflammatory neuropeptides. It is highly metabolized by cytochrome P450 enzyme in first-pass metabolism.[3] Due to that only 14.3 % of the drug is avail at systemic circulation. The aim of the present work is to develop an orally disintegrating dissolving tablet and film formulation for rapid absorption to avoid the first pass effect and to avail the maximum amount of drug for absorption.[4]

MATERIALS AND METHODS

Sumatriptan succinate was a gift sample from Emcure Pharmaceuticals, Pune. Hydroxy propyl methyl cellulose (K 100M) and soluplus was received as a gift sample from Colorcon India Ltd., Goa, India, and BASF, India. Urad dal was purchased from the local market of Pune, Maharashtra, India.

Solubility estimation of sumatriptan succinate

The solubility of sumatriptan succinate was tested in various solvents such as distilled water, hydrochloric acid pH1.2, phosphate buffer pH 6.8, and phosphate buffer pH 7.4. Fifty experimental work PES MCPL, Moshi, Pune 46 mg of drug was added to 50 ml of distilled water, hydrochloric acid pH 1.2, phosphate buffer pH 6.8, and phosphate buffer pH 7.4, respectively. The solutions were kept for stirring on a mechanical shaker for 2 h at room temperature. After completion of 2 h, solutions were filtered by Whatman filter paper. The filtrates were diluted by respected buffer solutions. Suitable dilutions were made and the absorbance of final solutions was recorded using a UV spectrophotometer at λmax 282 nm.

Extraction of mucilage from *vigna mungo* (urat dal)

Vigna mungo is referred to as the urd bean, urad dal, urid, black gram, black lentil, or white lentil. Vigna beans have grown in the region of Southern Asia. In contact with water, the seed flour of *vigna mungo* swells and forms a gelatinous mass. It is hydrophilic in nature. It is a rich source of protein albumin and globulin as well as methionine, lysine, and tryptophan. It contains about 60% of soluble sugar, starch, fibers, and carbohydrates. Furthermore, contains minerals such as calcium, zinc, iron, magnesium, and potassium. About 80% phytate phosphate is present, form complex with protein. In pharmaceuticals, it is used as a binder, thickening agent, suspending agent, stabilizing agent, and release retardant. The method for the preparation of mucilage powder is described[4] in Figure 1.

Evaluations of extracted mucilage

Ruthenium red test

50 mg of dried mucilage was dissolved in 2 mL of distilled water. Then, few drops of ruthenium red solution were added to the solution. Red color of the solution indicates the presence of mucilage.

Loss on drying

50 mg of dried mucilage was taken in a porcelain dish and kept in a hot air oven for 3 h at 120°C. After 3 the weight of mucilage was taken and moisture content was calculated as:

$$Moisture\,Content = \frac{\left(Inititial\,Weight - Final\,Weight\right)}{Final\,Weight} \times 100$$

Swelling index

25 mg of dried mucilage was placed in a petri plate containing 10 mL of distilled water for 1 h. After 1 h mucilage absorbs the water and the remaining water in the petri plate was removed and the weight of mucilage was taken. The swelling index was calculated as:

$$Swelling\,Index = \frac{\left(Final\,Weight - Initial\,Weight\right)}{Initial\,Weight} \times 100$$

Solubility testing

The solubility of mucilage was tested using different solvents such as cold water, hot water, ethanol, and chloroform.

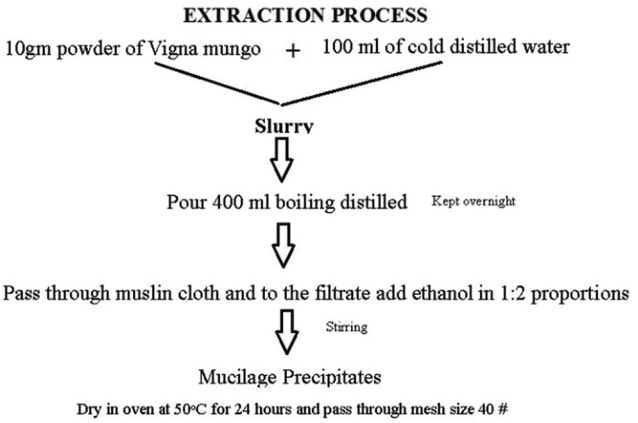

Figure 1: Isolation/extraction of mucilage from *vigna mungo*

Formulation of orally disintegrating tablet

Orally disintegrating tablets for sumatriptan succinate were prepared using the wet granulation technique. Mucilage from a natural source, that is, *vigna mungo* was used for formulating granules. Sumatriptan succinate, microcrystalline cellulose, and mannitol was passed through the sieve and then mixed. Powder mixture was converted into a damp mass by adding 2%/4%/6% mucilage solution, respectively [Table 1]. Mass was then passed through the 20-mesh sieve and allowed to dry in a hot air oven. Granules were formulated into tablet formulation using a tablet punching machine.

Evaluations for formulated tablets

Precompressional evaluations

Formulated granules were evaluated for pre compressional parameters. Bulk density, tapped density, compressibility index, hausner ratio, angle of repose, and drug content. These parameters were checked with standard ranges.[5,6]

Post compression evaluations

Weight variation, thickness, hardness, friability, disintegration test, *In vitro* dissolution.

In vitro drug dissolution

Dissolution profile of sumatriptan succinate oral fast-dissolving developed tablets was carried out in 900 ml of the phosphate buffer pH 6.8 as a dissolution medium, maintained at 37.5±0.5°C using United State Pharmacopeia (USP) type II paddle apparatus operated at 50 rpm. Aliquots of the medium were withdrawn at regular intervals of 5 min, 10 min, 15 min, 30 min, 45 min, and 60 mins. Samples were analyzed for the cumulative percentage of drug dissolved by Shimadzu UV-visible spectrophotometry at 282 nm. Three trials were carried out for all the samples and an average was taken.

Formulation of an oral fast-dissolving film by solvent casting method

Solvent casting methods were used for formulation of oral fast-dissolving film formulation. Weighed quantity of polyvinyl alcohol/hydroxypropyl methyl cellulose was dissolved in 15 mL of water by slow addition of polyvinyl alcohol in water with continuous stirring with a magnetic stirrer. After the complete addition of PVA, a clear solution of polyvinyl alcohol was formed. In that solution, soluplus was added to make a solution, and then a calculated quantity of drug and other excipients was added to make a solution. To the prepared solution, 0.6 mL of ethanol to promote evaporation which helps the drying of films, and plasticizer- propylene glycol 0.6 mL was added. Prepared solution was kept for settling for a few hours to cause defoaming and then the clear solution was poured into the petri plate [Table 2]. Petri plate was placed for drying and after drying film was peeled off from petri plate. Cutted into 2 × 2 cm containing 25 mg sumatriptan succinate in each 2 × 2 cm film.[7,8]

Evaluations of prepared oral film formulation

Transparency

Transparency was evaluated by the visual appearance of oral film and categorized into various levels such as transparent, translucent, and opaque.

Weight variation

Prepared films were weighed individually and their mean weight was calculated for each batch.

Thickness

For evaluation of film thickness three films of each formulation were taken and the film thickness was measured using a micrometer screw gauge at three different places and the mean thickness of films was calculated and reported.

Surface pH

One 2 × 2 cm film was taken and the surface of the film was wetted by distilled water. Digital pH meter was calibrated using a pH 7 phosphate buffer and then an electrode of the digital pH meter was placed on the wetted surface of the oral film and pH was noted. pH paper may also be used for pH determination.

Drug content

One strip of 2 × 2 cm size containing 25 mg of sumatriptan succinate was dissolved in a solvent and filtered through the

Table 1: Composition of orally disintegrating tablet

Ingredients	Formulation B1	Formulation B2	Formulation B3
Sumatriptan succinate	250 mg	250 mg	250 mg
Microcrystalline cellulose	125 mg	125 mg	125 mg
Mucilage Powder (binder solution)	2% (Q.S)	4% (Q.S)	6% (Q.S)
Mannitol	15 mg	15 mg	15 mg
Magnesium stearate	5 mg	5 mg	5 mg
Talc	5 mg	5 mg	5 mg

Table 2: Composition of oral fast-dissolving film

Batch code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Sumatriptan succinate (mg)	250	250	250	250	250	250	250	250	250
Hydroxypropyl methylcellulose K 100 (mg)	-	-	-	-	-	-	-	300	100
Polyvinyl alcohol (mg)	300	450	200	150	600	450	200	-	-
Soluplus (mg)	675	675	675	675	675	675	400	400	675
Propylene glycol (mL)	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Ethanol (mL)	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Mannitol (mg)	15	15	15	15	15	15	15	15	15
Citric acid (mg)	75	75	75	75	75	75	75	75	75
Water (mL)	15	15	15	15	15	15	15	15	15

Figure 2: Extracted mucilage from *vigna mungo*

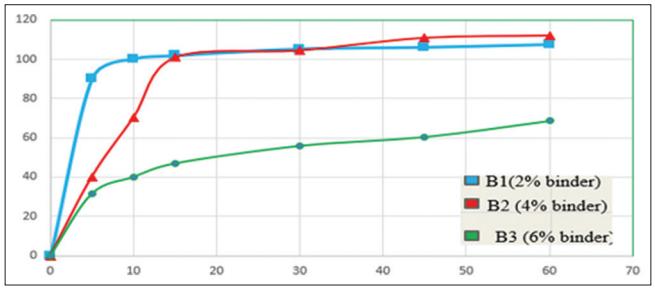

Figure 3: Percent drug dissolution for various batches prepared using 2%, 4%, and 6% powder mucilage as a binder

Whatman filter paper to get the clear solution and transferred to a 25 mL volumetric flask and volume made up to 25 mL with solvent. Absorbance of the prepared solution was taken at 282 nm on a UV spectrophotometer and drug content was estimated.

Disintegration test

For the oral fast-dissolving film, the time of disintegration should be in the range of 5–30 s. USP disintegration apparatus was used to study disintegration time. The disintegration time for formulations (F 1, F 7, F 8, and F 9) was visually determined by dipping the film in

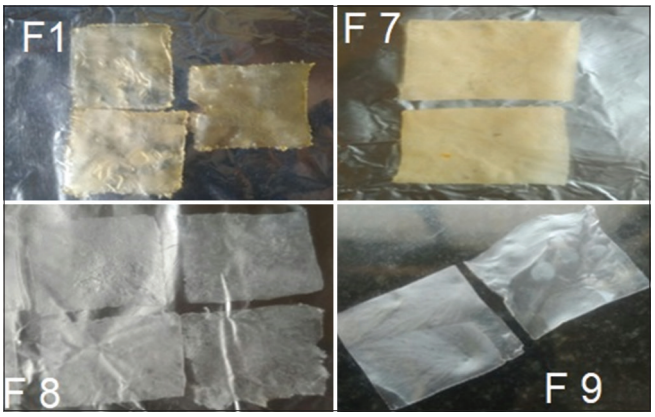

Figure 4: Formulated batches of fast-dissolving films

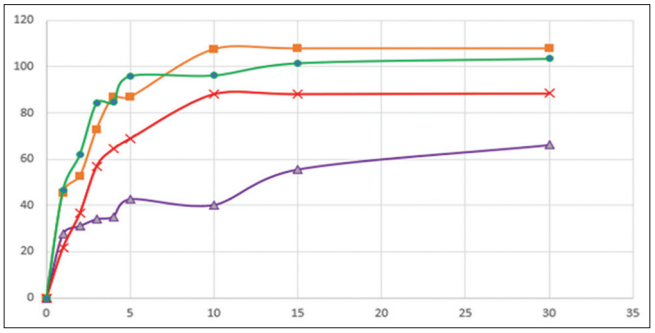

Figure 5: % Cumulative drug release of fast-dissolving films

25 mL water in a beaker. The beaker was shaken gently and the time was noted when the film starts to breaks or disintegrates.[9,10]

In vitro drug dissolution

Dissolution profile of sumatriptan succinate oral mouth dissolving film was carried out in 900 ml of the phosphate buffer pH 6.8 as a dissolution medium, maintained at 37.5±0.5°C using USP type II paddle apparatus operated at 50 rpm. Aliquots of the medium were withdrawn at regular intervals of 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, and 30 min. Samples were analyzed for the cumulative percentage drug dissolved by Shimadzu

UV-visible spectrophotometry at 282 nm. Three trials were carried out for all the samples and an average was taken.[11,12]

Table 3: Solubility of sumatriptan succinate in a different medium

Solvent	Solubility (mg in 50 mL solvent)
Water	39.5
pH 6.8 phosphate buffer	29.02
pH 7.4 phosphate buffer	34.03
pH 1.2 phosphate buffer	32.05

Table 4: Solubility of *vigna mungo* mucilage

Solubility test: Solvent	Solubility
Cold water	Swells in cold water
Hot water	Insoluble
Ethanol	Slightly soluble
Chloroform	Insoluble

Table 5: Physicochemical parameters of *vigna mungo* mucilage

Evaluation parameters	Results
Ruthenium red test	Appearance of a red color after the addition of ruthenium red solution indicates the presence of mucilage
Loss on drying (%)	25%
Swelling index (%)	56%
pH value	4.54

Table 6: Micromeritic properties of mucilage powder and prepared granules

Evaluation parameters	Mucilage powder	B1	B2	B3
Bulk density (gm/cm^3)	0.5	0.429	0.453	0.423
Tapped density (gm/cm^3)	0.625	0.491	0.529	0.500
Compressibility index (%)	20	12.62	14.36	15.4
Hausners ratio	1.25	1.14	1.16	1.18
Angle of repose (°)	39	28	29.30	29

Characterization FTIR and differential scanning calorimetric (DSC)

Fourier transform infrared spectroscopy study

The drug sumatriptan succinate, physical mixture (sumatriptan succinate: HPMC K100: Soluplus), powder mucilage, physical mixture (sumatriptan succinate: mucilage), and granules (B 1) formulation were scanned on Shimadzu (FTIRNITY1) with IR resolution software. It was scanned over a wave number range of 4000–400 cm^{-1} with a diffraction reflectance scanning technique.

Differential scanning calorimetry study

DSC measurements were carried out on a modulated DSC (Mettler Toledo). 20–30 mg samples were placed in aluminum pans and sealed. The probes were heated from 30°C to 300°C at a rate of 10°C/min under a nitrogen atmosphere at the rate of 40 mL/min. The drug sumatriptan succinate, physical mixture (sumatriptan succinate: HPMC K100: Soluplus), powder mucilage, physical mixture (sumatriptan succinate: mucilage), granules (B 1) formulation and film formulation (F 9) samples were studied for DSC.

RESULTS

Solubility study

Solubility study for sumatriptan succinate was observed in distilled water, pH 6.8 phosphate buffer, pH 7.4 phosphate buffer, and pH 1.2 phosphate buffer.

DISCUSSION

Solubility study: Solubility study for sumatriptan succinate was observed in distilled water, pH 6.8 phosphate buffer, pH 7.4 phosphate buffer, and pH 1.2 phosphate buffer [Table 3].

Evaluations of *vigna mungo* mucilage

The solubility of extracted mucilage was found be insoluble in hot water and swell in cold water [Table 4 and Figure 2].

Physicochemical evaluations

The physicochemical evaluation of mucilage powder was carried out and it showed presence of mucilage as red color

Table 7: Weight variation, thickness, hardness, disintegration, drug content for the prepared tablets

Batch code	Weight variation (%)	Thickness (mm)	Hardness (kg/cm^2)	Disintegration time	Drug Content
B1	3.39	0.34	3.6	55 s	99.68
B2	1.46	0.35	3.9	5 min 05 s	97.59
B3	1.91	0.34	4	8 min 33s	97.60

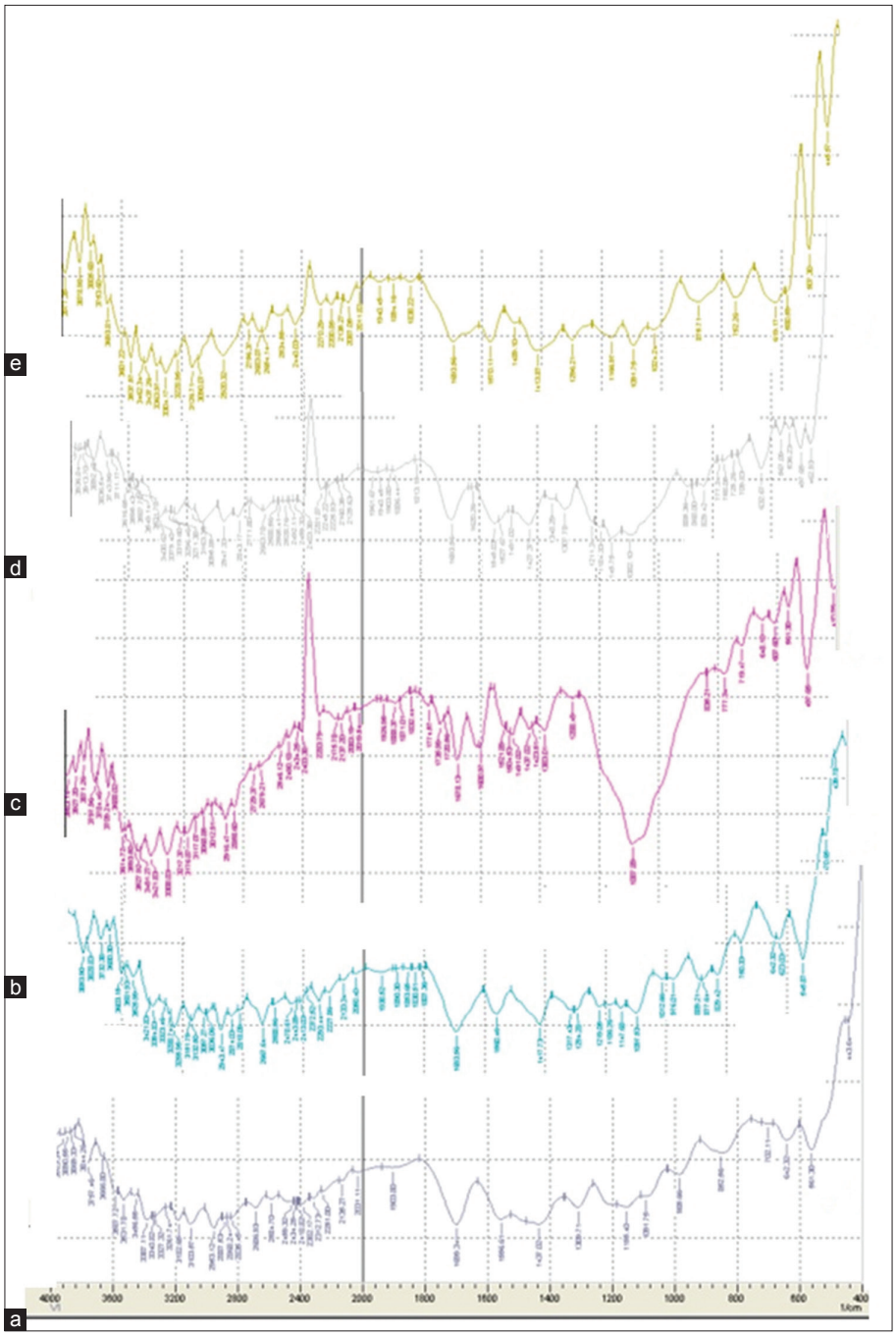

Figure 6: FTIR spectrum of a: Sumatriptan succinate; b: Physical mixture of sumatriptan succinate-HPMC K100-soluplus; c: Powder Mucilage; d: Physical mixture of sumatriptan succinate-powder mucilage; e: Granule formulation (B 1 batch)

Table 8: % cumulative drug release of tablets

Time (min)	%Cumulative drug release (%)		
	B1	B2	B3
5	90.13	40.18	31.53
10	100.12	70.26	40.08
15	101.79	100.79	47
30	105.14	104.42	55.91
45	106	110.85	60.40
60	107.41	112.02	68.54

appeared in ruthenium red test. The results of loss on drying, swelling index and pH is reported in Table 5.

Micromeritic properties of mucilage and granules

The flow properties of the mucilage and different granules were found to be in the range of acceptance criteria. For the mucilage compressibility index, Hausner's ratio and angle of repose were found to be in the passable range. The granules prepared (B1, B2, and B3) resulted in excellent with respect to the angle of repose (Standard limit 25–30). For hausners

ratio (standard limit 1.12–1.18) and compressibility index (standard limit 11–16) values found to be good. It suggests good compacatability for the prepared granules [Table 6].

Evaluations of orally disintegrating tablets

Weight variation

Weight variation of prepared batches of orally disintegrating tablets was performed [Table 7].

Thickness

The average thickness of tablets was noted as thickness in mm.

Hardness

Average hardness of all the batches of orally disintegrating tablets was found to be in the range of 3.6–4 (kg/cm^2).

Disintegration time

As the concentration of mucilage increases, disintegration time also increases. Disintegration time of formulated tablets was found to be from 55 s to 8 min. Rapid disintegration is desired for fast onset of action.

Drug content

The drug content of the prepared batches was found to be in the range of 97.68–99.68.

In vitro drug dissolution

In vitro drug release of formulated batches of orally disintegrating tablets was calculated which ranges from 68 to 112%. The B1 batch shows 100% drug release within 5 min min [Table 8 and Figure 3].

Evaluations of oral fast-dissolving films

Ease of handling

The formulated films were evaluated for ease of handling. F 1, F 7, F 8 and F 9 formulations were easy to handle [Figure 4, Tables 9 and 10].

Transparency

Formulated films were evaluated for transparency test by visual observation. All the formulations were found to be transparent only F7 was opaque and F1 was translucent.[13,14]

Mean weight, thickness, and surface pH

Average weight of the films of peeled-out batches was ranged 40–50 mg, thickness ranged from 0.121 to 0.127mm, and the surface pH of films ranged from 6.4 to 6.9.

Drug content and disintegration time of peeled-off batches of the film

Drug content ranges from 98.17 to 104% and disintegration time lies between 25 s and 65 s.[15]

In vitro drug dissolution

Optimized batch F9 released about 96% of the drug within 5 min. Drug released from other batches of the film ranges from 40 to 86% at 5 min [Table 11 and Figure 5].

Characterization FTIR and DSC

FTIR

The FTIR spectrum of pure sumatriptan succinate showed strong absorption bands at a wave number of 3387, 2953, 1437, 2887, 1155, and 13090 cm^{-1}, corresponding to N-H stretch, O-H bending, C=C stretch, C-H stretch, C-N stretch, S=O stretch, respectively [Figure 6]. The FTIR spectrum of the physical mixture of sumatriptan succinate-HPMC K 100-soluplus showed strong absorption bands at a wave number of 1692, 2588, 1186, 1317, 1417, 2943, and 3394 cm^{-1}, corresponding to C=O stretch, O-H bending, N-C, S=O stretch, C=C stretch, C-H and -NH stretch, respectively. The FTIR of *vigna mungo* mucilage, which shows the presence of

Table 9: Ease of handling

Batch code	Ease of handling	Transparency
F1	Thin, easy to peel	Translucent
F2	Little difficult to peel	Transparent
F3	Little difficult to peel	Transparent
F4	Unable to peel from plate	Transparent
F5	Unable to peel from plate	Transparent
F6	Unable to peel from plate	Transparent
F7	Thin, easy to peel	Opaque
F8	Thin, easy to peel	Transparent
F9	Thin, easy to peel	Transparent

Table 10: Evaluation results for the developed films of Sumatriptan succinate

Batch code	Mean weight±SD (mg)	Thickness±SD (mm)	Surface pH±SD	Drug content (%)	Disintegration time (sec) ±SD
F1	50	0.127±0.03	6.7±0.13	98.17±0.2	65±3
F7	40	0.153±0.05	6.79±0.35	110.13±0.12	36±5
F8	42	0.210±0.01	6.4±0.12	97.37±0.48	44±3
F9	43	0.121±0.03	6.9±0.2	104±0.64	25±2

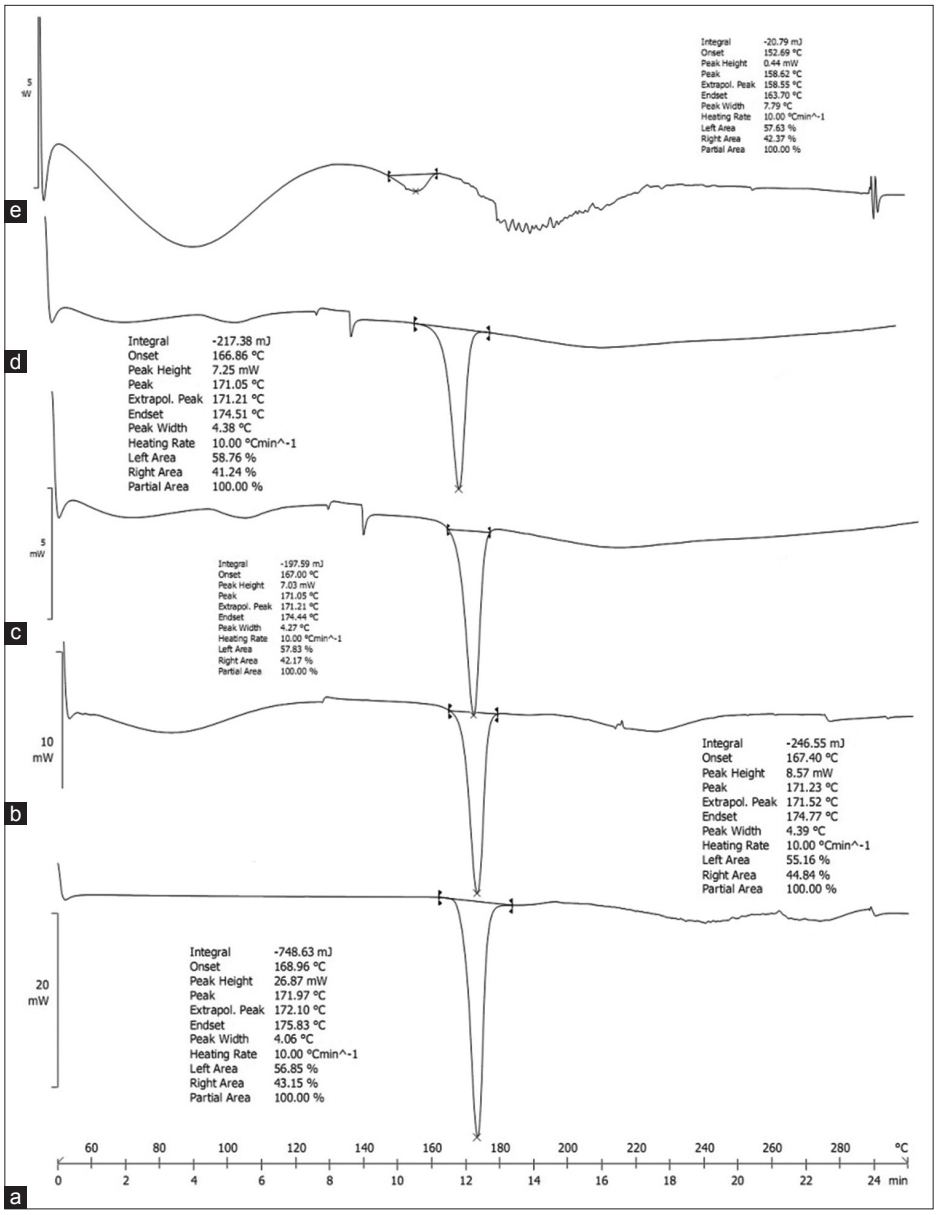

Figure 7: DSC thermogram of a: Sumatriptan succinate; b: Physical mixture of sumatriptan succinate-HPMC K100-soluplus; c: Physical mixture of sumatriptan succinate-powder mucilage; d: Granule formulation (B 1 batch); e: Film formulation (F 9)

Table 11: % cumulative drug release of fast-dissolving films

Time (min)	%Cumulative drug release (%)			
	F1	F7	F8	F9
0	0	0	0	0
1	27.62	45.40	21.76	46.60
2	30.97	52.46	36.55	61.95
3	34.04	72.83	56.93	84.27
4	35.16	86.79	64.46	84.55
5	40.18	86.79	68.93	96
10	42.69	107.44	88.18	96.27
15	55.53	107.72	88.18	101.58
30	66.13	107.72	88.46	103.53

C=O (ester), C=O (carbonyl), C≡C (alkyne), C=C(aromatic), O-H(alcohol), N-H functional groups at wavenumber 1087, 1678, 2137, 1413, 3614, and 3491 cm^{-1}. The physical mixture of sumatriptan succinate with excipients (HPMC K 100: Soluplus), sumatriptan succinate with powder mucilage, and granule formulation showed a summation effect for the presence of wavenumbers for a drug. It indicates compatibility with the selected excipients.

DSC

DSC studies indicated a sharp endothermic peak at 171.97°C corresponding to the melting point of pure sumatriptan succinate. The physical mixture of sumatriptan succinate-HPMC K100-soluplus, physical mixture of sumatriptan succinate-powder mucilage, and granule formulation (B

1 batch) showed sharp endotherm at 171.23°C, 171.21°C and 171.21°C, respectively [Figure 7]. It suggests no physicochemical interaction between the drug and selected excipients. The drug and excipients are compatible. For the film formulation, the reduction in peak area and disappearance of sharp endotherm for sumatriptan succinate suggest the drug is molecularly dispersed in the polymer matrix, changing in physical state.

CONCLUSION

Mucilage from its natural origin (*vigna mungo*) was extracted and used for the formulation of tablets. Tablets formulated from 2% mucilage (B1) showed less disintegration time and about 100% drug release within 10 min. Fast-dissolving oral films were formulated using a combination of different polymers in different concentrations. Films prepared from soluplus 675 mg and HPMC k100M 100 mg as a film former were shown the better mechanical properties, transparent, thin, and easy to handle. Film formulation containing HPMC k100M and soluplus combination (100 mg and 675 mg), that is, batch F9 shown disintegration within 25 s only and 96% of drug release within 5 min. From the present research work, it can be concluded that *vigna mungo* mucilage can be used for the formulation of orally disintegrating tablets for sumatriptan succinate. Combination of Soluplus and HPMC k100M produces oral fast-dissolving films with good mechanical properties. Fast-dissolving oral films produced more instant disintegration, dissolution, and maximum amount of drug release within a few minutes than orally disintegrating tablets.

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