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FORMULATION AND *IN-VITRO* EVALUATION OF VERAPAMIL HCl FAST DISINTEGRATING TABLETS USING *OCIMUM GRATISSIMUM* SEED MUCILAGE POWDER AND *CUCURBITA MAXIMA* PULP POWDER

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ABSTRACT

Verapamil HCl belongs to the BCS class 2 drug, hence its oral bioavailability is poor. Bioavailability is very important for every drug to get good biological activity. Dissolution is directly proportional to the bioavailability and disintegration is directly proportional to the dissolution. Hence, in this current study i*n-vitro* dissolution was increased with the help of increasing disintegration. Fast disintegrating tablets of verapamil HCl were designed with the help of *Ocimum gratissimum* seed mucilage powder and *Cucurbita maxima* pulp powder as natural super disintegrants at 2.5, 5 & 10% w/w per tablet and compared with croscarmellose sodium, a synthetic super disintegrant. And found that *Ocimum gratissimum* seed mucilage powder had best *in-vitro* disintegration and dissolution characteristics compared to other two super disintegrants and at 10% w/w per tablet i.e., F10 formulation had shown best *in-vitro* dissolution compared to croscarmellose sodium and was considered as final formulation.

Keywords: Fast disintegrating tablets, natural disintegrants and synthetic super disintegrant.

INTRODUCTION

Newly discovered drugs are tried to formulate as tablets, because of possibility of self-administration and doesn't require any technician. And tablets are the best formulations among the solid oral dosage forms with respect to the dose accuracy. They are pilfering proof dosage forms; the incorporated dose to the tablet dosage form is completely available to the systemic circulation if drug doesn't suffer from solubility. If drug suffers from the solubility, then it suffers from oral bioavailability. The drug bioavailability may be increased by enhancing solubility by various methods like decreasing crystallinity, converting crystalline drug to amorphous solid, by increasing disintegration and by increasing dissolution. Enhancement of disintegration is one of the mostly used method for enhancing drug bioavailability by enhancing drug dissolution. This technique is used widely for the greatest number of drugs that are suffered from poor solubility[1].

BCS Class II drugs and Class IV drugs suffers from oral bioavailability problems because of their poor aqueous solubility[2]. Verapamil HCl belongs to such a class of drug belongs to BCS Class II drugs and it is used in the treatment of hypertension as a calcium channel blocker. Its oral bioavailability is poor because of its poor aqueous solubility. In current study, it was selected as a model drug and its aqueous solubility was increased with the help of natural super disintegrants. *Ocimum gratissimum* seed mucilage powder and *Cucurbita maxima* pulp powder were tried as natural super disintegrating agents to enhance the bioavailability of verapamil HCl. These natural agents enhance the aqueous solubility of verapamil HCl by promoting its disintegration[3].

Natural excipients are widely employing in various dosage forms because of their least toxicity and high efficiency i.e., they are promoting desired characteristics of a drug. Their interruption with biological activity of drug is very less compared to the synthetic one. As universally their applicability is more and their recognition is also very more to consider them as excipients. Hence, in this study they are preferred and evaluated for the desired characteristic. Verapamil HCl fast disintegrating tablets were prepared with the help of natural disintegrating agents and synthetic disintegrating agent and compared among them to evaluate the best characteristic i.e., *in-vitro* disintegration and *in-vitro* dissolution[4].

All the tablets were prepared by employing direct compression method because of good flow properties and good binding characteristics of the tablet mixtures for compression. Direct compression method is very economical method consists of very a smaller number of steps for tablet compression and requires very a smaller number of labors for manufacturing of tablets. Hence, direct compression method was adopted for manufacturing of tablets[5].

MATERIALS

The following materials were used for the current work along with sources as shown in **table 1.**

NAME OF THE INGREDIENT	MANUFACTURES NAME
Verapamil HCl	S.K. HealthCarePvt. Ltd., Hyd.
Ocimum gratissimum seeds	LocalSources, Pulimeru.
Cucurbita maxima Fruits	Local Sources, Pulimeru.
Crosscarmellose sodium	SiriChemicals, Rjy.
Magnesium stearate	SiriChemicals, Rjy.
Microcrystalline cellulose	SiriChemicals, Rjy.
Talc	SiriChemicals,Rjy.

METHODS

I. Preparation of Natural Super Disintegrants

For formulation of verapamil fast disintegrating tablets, the natural excipients prepared as follows

1. Preparation of *Ocimum gratissimum* seed mucilage powder

The *Ocimumgratissimum* seeds were purchased from local store and cleaned them properly to remove unnecessary debris. Then the seeds were socked in distilled water for 24 hours and then stirred them intermittently for 20 minutes. The resultant dispersion was passed through the muslin cloth and was collected into a 500 ml beaker. Acetone was added to the beaker until all the mucilage get precipitated, then precipitate was separated with the help of muslin cloth and was spread on glass plates to dry at 40 ^{0}C for one hour. The resultant dried product was placed in a beaker and purified by adding 20% ethanol first to separate impurities in dispersion and later on the concentration enhanced to 60%, where all the mucilage gets precipitated. The precipitated mucilage was filtered and washed with acetone to remove water from it. Then the mucilage was dried in hot air oven at 40 ^{0}C until we get dry powder and passed through the sieve number 80.

2. Preparation of *Cucurbitamaxima* pulp powder

The *Cucurbitamaxima* pulp was separated from the fruits. Then the pulp was sun shade dried for twenty days and grinded in a domestic grinder. The resultant powder was passed through the sieve number 80.

II. Analytical Method

Analytical method was developed to measure the drug present in dosage forms accurately with the help of UV- Spectro photo meter and the procedure as follows

1. **Preparation of stock solutions**

10 mg of drug was added to the 10 ml volumetric flask and dissolved in pH 6.8 phosphate buffer to get 1000 µg/ml. This was considered as stock solution-I. From stock solution I, one ml was withdrawn and added to the 10 ml volumetric flask and dilutes with the help of pH 6.8 phosphate buffer to get 100 µg/ml. This is considered as stock solution II. From stock solution II, 0.5 ml, 1 ml, 1.5 ml, 2 ml, 2.5 ml and 3 ml solutions were withdrawn and diluted to 10
ml in 10 ml volumetric flask with the help of pH 6.8 phosphate buffer to get 5 µg/ml, 10 µg/ml, 15 µg/ml, 20 µg/ml, 25 µg/ml and 30 µg/ml concentration solutions.

2. **Construction of linearity curve**

The prepared solution having concentration between 5 to 30 µg/ml, were scanned with the help of Double Beam Spectro Photo Meter (Lab India) at 278 nm and the linearity curve was constructed by taking concentration in µg/ml on X- axis and absorbance on Y- axis as shown in **figure 1**.

III. Formulation of Verapamil HCl Fast Disintegrating Tablets

The tablets were prepared by using direct compression method, all the drug and excipients shown in **table 2** were passed through sieve number 40 individually. First the verapamil HCl, diluent (Microcrystalline cellulose) and disintegrant (Croscarmellose sodium/ *Cucurbitamaxima* pulp powder/ *Ocimumgratissimum*seed mucilage Powder) were passed into a polybag and mixed them for five minutes. Then, lubricant (Mg. Stearate) and glidant (Talc) were added and mixed for five minutes to reduce frictional characteristics of the tablet mix. One tablet equivalent weight of powder from above mix was weighed and compressed as tablet with the help of 16-station compression machine such as to obtain enough hardness. The ingredients used for tableting were as followed in **table 2.**

F1 formulation was tableted without disintegrant, F2-F4 formulations were tableted with the help of natural super disintegrant i.e.,*Cucurbitamaxima* pulp powder at 2.5 w/w, 5% w/w and 10% w/w per tablet concentration, F5-F7 formulations were tableted with the help of synthetic super disintegrant i.e.,croscarmellose sodium powder at 2.5 w/w, 5% w/w and 10% w/w per tablet concentration and F8-F10 formulations were tableted with the help of natural super disintegrant i.e., *Ocimumgratissimum* seed mucilage powder at 2.5 w/w, 5% w/w and 10% w/w per tablet concentration[6] (Table 2).

Table 2: Formulation table for verapamil HCl fast disintegrating tablets

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
VerapamilHCl	20	20	20	20	20	20	20	20	20	20
Cucurbitamaxima pulp powder	-	5	10	20	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	-	5	10	20	-	-	-
Ocimumgratissimum seed mucilage Powder	-	-	-	-	-	-	-	5	10	20
MCC	176	171	166	156	171	166	166	171	166	166
Mg.Stearate	2	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2	2
Total weight of the tablet	200	200	200	200	200	200	200	200	200	200

IV. Evaluation of Verapamil HCl Fast Disintegrating Tablets

1. **Pre-compression parameters**

a. **Angle of repose**

The angle of repose was performed with the help of fixed height method[7]. The glass funnel was fixed to burette stand with the help of a clamp such that the bottom of the tip is exactly two centi-meters from the bottom. A graph paper was place underneath the funnel and tablet mix was passed through the glass funnel until flow strops. The radius of pile was measured and angle of repose was determined using following formula

$$\theta = \text{Tan}^{-1} (h/r)$$

h= Height of the pile
r= radius of the pile

Specification

Table 3: Limits for angle of repose

S. No.	Hausner's Ratio	Flowability
1	< 30	Free flowing
2	30-40	Good
3	>40	Poor

b. Carr's Index

Carr's Index is used to evaluate the flow properties of tablet mix to be compressed as tablet. When flow properties are good the tablet mix is feasible to compress as tablet. The procedure for evaluation of Carr's Index was as follows, 10 ml of measuring cylinder was weighed and taken that weight as $W_1$and filled the measuring with tablet mix to 10 ml, then weight was taken as W_2 and by using these parameters bulk density and tapped density were calculated using following equations

Bulk Density = $(W_1 – W_2)$/Bulk volume
Tapped Density = $(W_1 – W_2)$/Tapped volume

With the help of bulk density and tapped density the Carr's index was calculated using following formula

Carr's Consolidation Index = [(Tapped Density – Bulk Density) / Tapped Density] x 100

Specifications

Table 4: Limits for Carr's Index

S. No.	% Compressibility	Flowability
1	5-15	Excellent
2	12-16	Good
3	18-21	Fairly Passable
4	23-35	Poor
5	33-38	Very Poor
6	<40	Very, Very Poor

c. **Hausner's Ratio**

Hausner's ratio is also used to know the flow properties of tablet mix as such Carr's index. Hausner's ratio was calculated based on tapped density and bulk densities. And the formula for calculation of Hausner's ratio was as follows

Hausner's Ratio = Tapped density/Bulk density

Specifications

Table 5: Limits for Hausner's ratio

S. No.	Hausner's Ratio	Flowability
1	<1.15	Excellent
2	1.15-1.25	Good
3	1.25-1.45	Moderate/passable
4	>1.45	Poor

2. Post-compression parameters

a. Weight variation: Weight variation governs the dose accuracy and drug activity. This test was performed following procedure. 20 tablets were randomly selected from the batch and their individual weights were checked and calculated the average weight of the tablet. The weight variation was calculated by following formula,

Weight variation = [(Individual weight- Average weight)/ Average weight] x 100

Specifications

Table 6: Weight variation specifications (IP)

S. No	Tablet weight (mg)	% Variation (±)
1	130	10
2	130-250	7.5
3	250	5

b. Hardness

Hardness is a non-compendial test used to test to get reproducible and desired drug effect and the procedure for hardness testing was as follows. Five tablets were taken randomly from a batch, their individual hardness was tested using Monsanto hardness tester and average weight was calculated.

Specification: ±5% of standard value

c. *In-vitro* Disintegration test

Disintegration test was performed to know the correlate the rate of drug release from the tablet with its biological activity. Because disintegration is proportional to the drug biological activity. The disintegration test was performed with the use of disintegrator (Kshitiz Innovation Pvt. Ltd.) and the procedure as follows. Six tablets were placed in disintegrator that was dipped in pH 6.8 phosphate buffer and the time required for complete disintegration was observed. Then, the average disintegration time was calculated from sum of individual tablets and considered as batch's disintegration time[8].

Specifications

Table 7: *In-vitro* disintegration specifications (IP)

S. No	Tablet type	Disintegration time (min)
1	Uncoated	<30
2	Film Coated	<60
3	Sugar coated	<60
4	Enteric coated	<120

d. *In-vitro* wetting time

Wetting time also used to correlate the biological activity as such disintegration. Wetting time is proportional to the disintegration and biological activity of the drug. If wetting time is good for a drug, its disintegration and dissolution is good and these two are directly proportional to the bioavailability by that to the biological activity also. The procedure for wetting time was as follows, a petri-dish plate was covered with a circular filter paper, then six ml of water was placed on filter paper and time was noted down to wet all the tablet. The test was repeated three times and average value was taken as wetting time for the tested tablet batch[9].

e. *In-vitro* dissolution studies

In-vitro dissolution studies were directly proportional to bioavailability of the drug and the procedure as follows for the studies. Six tablets were placed in six individual dissolution flasks consisting of 900 ml of pH 6.8 phosphate buffer maintained at body temperature i.e., 37 ± 0.5 ^{0}C with the agitation of 50 rpm. The samples were withdrawn at five minutes regular intervals for 30 minutes i.e., 1, 3, 6, 9, 12 and 15 minutes. Five ml of sample was withdrawn and the same volume was replaced to the dissolution flask and samples were analyzed at 278 nm using double beam UV- Spectrophotometer.

f. Dissolution efficiency ($DE_{15\%}$)

The $DE_{15\%}$for all verapamil HCl fast dissolving tablets were performed to know the best formulation among formulated one. The $DE_{15\%}$ was calculated following formula with the help of *in-vitro* dissolution data[10].

$$DE_{15\%} = \{[AUC]_0^{15}/1500\} \times 100$$

Where, AUC is calculated by trapezoid rule i.e.,

$$AUC = 1/2(C_1 - C_2)(t_2 - t_1)$$

Where, C_1& C_2 are drug concentrations and t_1& t_2 are time intervals

RESULTS &DISCUSSION

1. Analytical Method

Results

The standard calibration curve values were as follows

Table 8: Standard calibration curve for verapamil HCl in pH 6.8 phosphate buffer at 273 nm

Concentration(µg/ml)	Absorbance
0	0
5	0.123
10	0.228
15	0.337
20	0.456
25	0.563
30	0.674

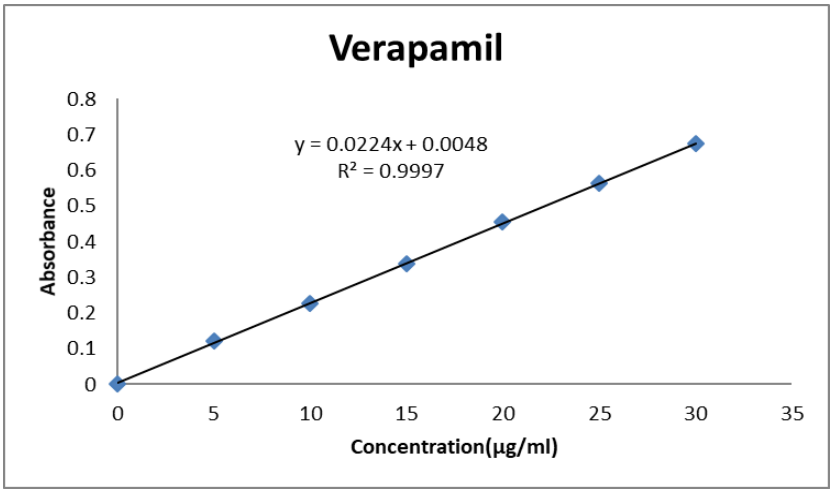

Fig. 1: Standard calibration curve for verapamil HCl in pH 6.8 phosphate buffer at 273 nm

Discussion

From the **table8** & **figure 1**, it was observed that, the correlation co-efficient value was found to be 0.9997. The correlation co-efficient value was between 0.997-0.999 and was following Beer-Lambert's law over the concentration range between 5-30 µg/ml. Hence, the chosen UV-Spectro photo meter can be effectively used to determine drug concentration in solutions, which were scanned under the equipment

2. Evaluation of verapamil HCl fast disintegrating tablets
Results

a. Pre-compression parameters of verapamil HCl fast disintegrating tablets
Table 9: Pre compression parameters of verapamil HCl fast disintegrating tablets

Formulation	Angle ofrepose(°)	Carr'sIndex(%)	Hausner'sratio
F1	31.44	10.25	1.11
F2	24.72	7.14	1.07
F3	27.58	12.19	1.13
F4	25.52	9.37	1.10
F5	28.73	11.86	1.06
F6	26.43	6.13	1.13
F7	24.67	8.26	1.25
F8	25.45	6.21	1.11
F9	24.67	12.15	1.21
F10	23.85	9.12	1.06

b. Post compression parameters of verapamil HCl fast disintegrating tablets
Table 10: Post compression parameters of verapamil HCl fast disintegrating tablets

Formulation	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Disintegration time(sec)	Wetting Time(sec)	Avg. wt (mg)
F1	3.1	2.84	0.50	45	38	199.98
F2	3.0	2.93	0.50	25	23	200.02
F3	3.1	2.94	0.49	24	22	199.91
F4	3.1	2.93	0.48	22	20	200.04
F5	3.1	2.95	0.50	26	24	200.05
F6	3.0	2.94	0.49	24	22	199.96
F7	2.9	2.95	0.50	21	19	199.93
F8	3.0	2.95	0.49	22	20	200.01
F9	3.1	2.94	0.47	20	18	200.00
F10	3.1	2.93	0.49	17	15	199.95

c. *In-vitro* dissolution data for verapamil HCl fast disintegrating tablets
Table 11: *In-vitro* dissolution data for verapamil HCl fast disintegrating tablets

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	8.37	3.31	3.710	2.37	1.03	1.58	6.63	4.026	3.79	3.08
3	9.47	14.84	10.66	9.71	7.66	10.45	23.68	9.16	10.81	16.03
6	14.4	22.42	17.76	17.60	9.00	17.84	41.29	10.74	16.42	41.21
9	18.95	27.79	28.42	32.29	13.89	21.39	48.31	13.74	28.18	50.92
12	22.26	31.89	35.92	44.29	17.29	25.03	50.60	17.76	43.26	56.84
15	25.26	33.55	36.08	46.42	19.74	23.53	51.87	20.53	48.71	58.66

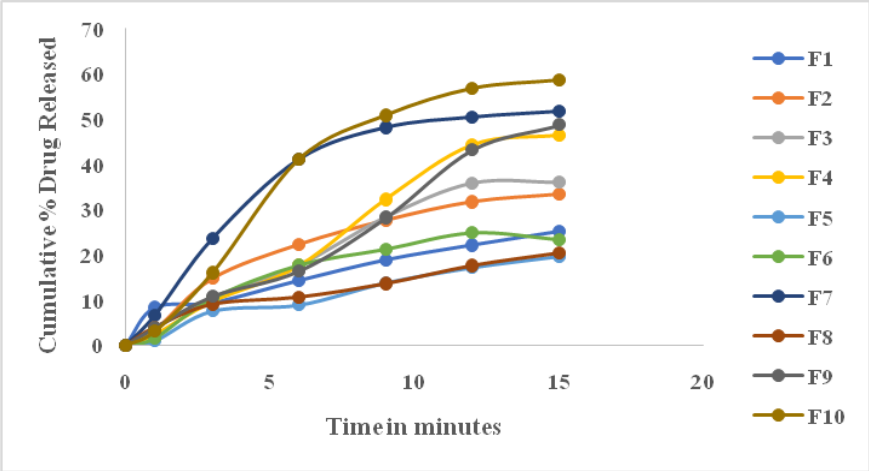

Fig. 2: *In-vitro* dissolution data for verapamil HCl fast disintegrating tablets

d. Dissolution efficiency ($DE_{15\%}$) values of verapamil HCl fast disintegrating tablets

Table 12: Dissolution efficiency ($DE_{15\%}$) values of verapamil HCl fast disintegrating tablets

Formulation	$DE_{15\%}$
F1	16.06
F2	22.57
F3	22.09
F4	25.366
F5	11.389
F6	17.10
F7	37.836
F8	12.43
F9	24.62
F10	38.639

Discussion

a. Pre compression parameters

From **table 9**, it was observed that the angle of repose values was between 23°-32°, Carr's Index values were between 6-13% and Hausner's ratio values were between 1-1.25 for all the verapamil HCl fast disintegrating tablet mixtures. Hence, we conclude that the verapamil HCl fast disintegrating tablet mixtures were having good flow properties as per the specifications given in **table 3, table 4** and **table 5**. Hence, all verapamil HCl tablet mixtures can be considered for compress as tablets.

b. Post compression parameters

From **table number 10** it was observed that, the hardness values were between 2.9to3.1kg/cm^2, thickness was between 2.84-2.95 mm, friability was between 0.47-0.5 %, disintegration time was between 17-45 seconds, wetting time was between 15-38 seconds and average weight of tablet of all batches of verapamil HCl fast disintegrating tablets were between 199.91-200.05 mg.

The hardness and thickness of all batches of verapamil HCl fast disintegrating tablets were not exceeding ±5%, and friability values were also below 1% so mechanical strength for all tablets were good. The weight of tablets was not deviating ±7.5% with respect to specifications given in **table 6**, hence tablets may be effectively incorporated with accurate dose. From the *in-vitro* disintegration time was below 30 seconds (Specification for uncoated tablet). Wetting of all tablets were correlating the *in-vitro*

disintegration time. From all these observations it is concluded that all the parameters were meeting the specifications.

The *in-vitro* wetting time and *in-vitro* disintegrating time for all tablets were as follows

F1 > **F5** > **F2** > **F3 & F6** > **F4 & F8** > **F7** > **F9** > **F10**

From the above observations, it was found that F10 is having low *in-vitro* wetting time and *in-vitro* disintegrating time. As well both are matching and showing in the same descending order. It was clearly evident that more the wetting more the disintegration from **table 10**.

c. *In-vitro* dissolution studies

From **table 11**& f**igure 2**, it was observed that the descending order *in-vitro* dissolution for all the verapamil fast disintegrating tablets were as follows

F10>**F7**>**F9**>**F4**>**F3**>**F2**>**F1**>**F6**>**F8**>**F5**

The pure verapamil HCl (F1) i.e., tablet except disintegrant have shown 25.26 % cumulative % drug release at the end of 15th minute, and all the tablets with high disintegrant concentration (F4, F7 & F10) have shown more cumulative % drug release at the end of 15th minute than pure drug.

Among all the verapamil HCl fast disintegrating tablets F10 was showing highest cumulative % drug release than other. F10 was prepared by using *Ocimumgratissimum* seed mucilage powder as natural disintegrant at 10 % w/w per tablet. As well, F10 was showing more cumulative % drug release than the croscarmellose sodium, a synthetic super disintegrant. F10 was showing 1.13-fold cumulative % drug release than tablet with high croscarmellose sodium concentration(F7), hence we are concluding that tablet with *Ocimumgratissimum*seed mucilage powder (natural super disintegrant) had better disintegrating characteristic than synthetic super disintegrant. F10 formulation was showing 2.32-fold cumulative drug release compared to tablet except disintegrant.

As well, tablets with *Cucurbita maxima* pulp powder as natural disintegrant at moderate and high concentration (F3 & F4) have shown 1.33 & 1.43-fold increment in cumulative % drug release compared to tablet except disintegrant(F1). But they are not showing better dissolution characteristics than croscarmellose as disintegrant at its high concentration (F7).

d. Dissolution efficiency ($DE_{15\%}$)

The observed DE15% values for verapamil HCl fast disintegrating tablets from the **table 12**, were in the following descending order.

F10>**F7**>**F4**>**F9**>**F2**>**F3**>**F6**>**F1**>**F8**>**F5**

Among all the verapamil HCl fast disintegrating tablets, F10 was showing highest dissolution efficiency($DE_{15\%}$).

Out of all pre and post compressional parameters for all the verapamil HCl fast disintegrating tablets, it was observed that tablets with *Ocimumgratissimum* seed mucilage powder as disintegrant were showing better*in-vitro* wetting characteristics, in-vitro disintegration and *in-vitro* dissolution characteristics compared to *Cucurbita maxima* pulp powder, a co-natural disintegrant. As well, *Ocimumgratissimum* seed mucilage powder was showing better *in-vitro* wetting characteristics, *in-vitro* disintegration and in-vitro dissolution characteristics compared to croscarmellose sodium, a synthetic natural disintegrant.

Finally, it was found that *Ocimumgratissimum* seed mucilage powder had better *in-vitro* characteristics compared to other two super disintegrants namely *Cucurbita maxima* pulp powder & croscarmellose sodium and at its high concentration per tablet (10% w/w) have better *in-vitro* characteristics such as low wetting time and disintegration time and highest *in-vitro* cumulative % drug release compared to all verapamil fast disintegrating tablets.F10 was considered as best and final formulation because of its best *in-vitro* characteristics, especially because of its rapid disintegration time and wetting time i.e., 17 seconds & 15 seconds and highest in-vitro dissolution i.e., 58.66 % at the end of 15th minute & its highest DE15% value i.e., 38.63 %. As well, it has increased 2.32-fold *in-vitro* dissolution of verapamil HCl pure drug by enhancing disintegration. The mechanism of enhancement of disintegration is thought to be osmotic disruption of tablet, because mucilage may be rich in cellulose. Cellulose enhances the disintegration by osmotic disruption of tablet by water wicking.

CONCLUSION

Bioavailability is a very important characteristics, this is correlated with bioavailability. Bioavailability of oral dosage forms are depending upon solubility and permeability of the drug. Lack of any characteristics may decrease the bioavailability; especially oral bioavailability majorly depends on drug solubility.

Verapamil belongs to BCS Class 2 drug, it is lack of solubility, because of this it is having poor oral bioavailability. The bioavailability of such drug can be increased by increasing dissolution, in this current study dissolution of verapamil was increased by enhancing the disintegration with the help of natural super disintegrating agents and these are compared with the synthetic super disintegrating agent. Finally, it was found that natural super disintegrant had superior *in-vitro* disintegration and dissolution compared to synthetic one. *Ocimumgratissimum* seed mucilage powder was considered as best natural super disintegrant and at 10% w/w per tablet had better *in-vitro* performance compared to others, hence F10 was considered as final formulation for getting good oral bioavailability compared to other.

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