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FORMULATION AND EVALUATION OF SUSTAIN RELEASE MATRIX TABLET OF FLUVOXAMINE MALEATE USING *MORINGA OLEIFERA* GUM

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Keywords:

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ABSTRACT: Fluvoxamine Maleate, an oral serotonin reuptake inhibitor, has been used widely for the treatment of anxiety. Sustained-release matrix-type drug delivery system has advantages over conventional modes of drug administration, enhancing drug bioavailability as it avoids the first-pass metabolism and improves patient compliance. Optimization of the formulation was performed by varying the concentration of natural polymer *Moringa oleifera* gum and HPMC K100, *i.e.*, releases retarding polymers. Sustain release matrix tablets were formulated, and the drug release profiles of formulations F3 and F6 were found to be 93.8008% and 96.94108%, respectively.

INTRODUCTION: Oral administration of a drug has been the most convenient and commonly employed route of drug delivery as it offers them greater flexibility in the dosage form design [1]. The design of sustained-release systems depends upon various factors as the route of administration, the type of delivery systems, the disease being treated, the patient, the length of therapy, and properties of drug [2]. Plant gums and mucilage are being used due to their abundance in nature, safety, and economy [3]. *Moringa oleifera* gum performed as a good muco-adhesive polymer, disintegrating agent, and binder [4]. Development of sustained-release oral dosage form for fluvoxamine maleate would result in a reduction in the drug blood concentration fluctuations, especially in long-term therapy, which will lead to the minimization of the drug side effect and patient compliance [5].

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MATERIALS AND METHODS: Pure sample of Fluvoxamine Maleate was obtained as a gift sample from Zydus Pharmaceutical Ltd. Mumbai. HPMC K100, Starch, Talc, Magnesium stearate were obtained from Modern science, Nashik. *Moringa oleifera* gum was naturally collected.

EXPERIMENTAL METHOD:

U. V. Spectroscopy: [6]Accurately weighed 10 mg of Fluvoxamine Maleate in 100 ml water in a volumetric flask to obtain a stock solution of 100µg/ml. appropriate aliquots were taken into different volumetric flasks, and volume was made up to 10 ml with water so as to get drug concentrations of 5 to 25 µg/ml. Absorbance was measured.

FT-IR Spectroscopy: [7] The FT-IR spectrum of Fluvoxamine Maleate was recorded using FTIR spectrophotometer (Shimadzu 8400S) using KBr pellet technique. The peaks are shown in **Fig. 1**.

Differential Scanning Calorimetry (DSC): [7] DSC analysis was performed using Shimadzu-Thermal Analyzer DSC 60 on 2-5mg samples. Samples were heated in an open aluminum pan at a rate of 10

°C/min conducted over a temperature range of 30 to 300 °C under a nitrogen flow of 2-bar pressure. The thermogram is shown in **Fig. 6**.

Identification of polymers HPMC K 100 and *Moringa oleifera* was subjected to Organoleptic properties, melting point, and FTIR spectroscopy as mentioned in **Fig. 7**, **Fig. 8**.

Formulation Development: Tablet formulation was prepared by wet granulation technique. Granules were compressed using 10 - station rotary press using round-shaped punches. Punches measuring 7 mm diameter were used for compression of the tablets.

TABLE 1: FORMULATION DEVELOPMENT FLUVOXAMINE MALEATE SUSTAIN RELEASE TABLET

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Fluvoxamine Maleate	100	100	100	100	100	100	100	100	100	100
HPMC K100	-	-	-	30	50	80	15	15	40	40
MoringaOleifera	30	50	80	-	-	-	15	40	15	40
Magnesium Stearate	2	2	2	2	2	2	2	2	2	2
Starch	5	5	5	5	5	5	5	5	5	5
Talc	2	2	2	2	2	2	2	2	2	2
MCC	61	41	11	61	41	11	61	36	36	11
Total weight	200	200	200	200	200	200	200	200	200	200

(Note: all quantities are in mg)

Evaluation Parameters:

Evaluation of Granules Flow Properties: [8] The flow properties of granules were characterized in terms of angle of repose, Carr's index, Hausner's ratio, bulk density, tapped density, Compressibility index. Results are mentioned in **Table 2**.

Evaluation of Fluvoxamine Maleate Sustains Release Matrix Tablets: [8, 9, 15-18]

Thickness: The thickness of the tablets was measured using vernier calipers. Results are mentioned in **Table 3**.

Hardness Test: The hardness was tested using Monsanto tester. "Hardness factor", the average of the six determinations, was determined. Results are mentioned in **Table 3**.

Uniformity of Weight: Twenty tablets were weighed individually. The average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the acceptable limits (+5%).

The percent deviation was calculated using the following formula,

% Deviation = Individual Weight – Average Weight × 100

Average weight Results are mentioned in **Table 3**.

Friability Test: Roche Friabilator was used to measure the friability of the tablets. Ten tablets were weighed collectively and placed in the chamber of the Friabilator. It was rotated at a rate of 25 rpm. In the Friabilator, the tablets were exposed to rolling, resulting from the free fall of tablets within the chamber of the Friabilator. After 100 rotations (4 min), the tablets were taken out from the Friabilator, and intact tablets were again weighed collectively. The permitted friability limit is 1.0%. The percent friability was determined using the following formula. Results are mentioned in **Table 3**.

% Friability = (W1 – W2) × 100 / W1

Where, W1 = weight of the tablets before test, W2 = weight of the tablets after test

Measurement of Bioadhesive Strength of Tablet (Detachment Force): [10-12] The mucoadhesive forces of the tablets were determined by the measuring device shown in the following figure.

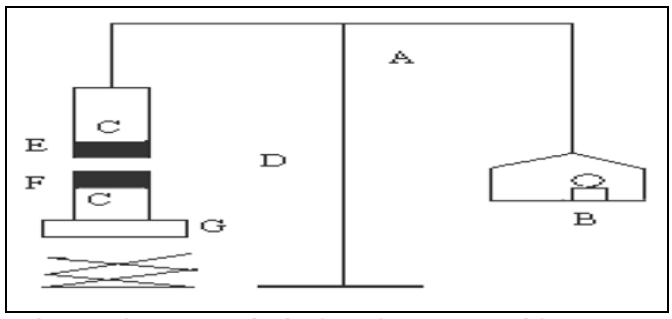

FIG. 1: MODIFIED BALANCE FOR THE MEASUREMENT OF BIOADHESIVE STRENGTH; B, WEIGHTS; C, GLASS VIAL; D, BIOADHESIVE TABLET; E, INTESTINE TISSUE; F, SUPPORTIVE ADHESIVE TAPE; G, HEIGHT-ADJUSTABLE PAN

% Swelling Index Studies: [13, 14] The swelling studies of the tablets were determined at room temperature. The swelling study of the tablets was individually weighed and placed separately in Petri dishes with 5 ml of phosphate buffer of pH 6.8. At time intervals 2, 4, 6, 8, 10 h; the tablets were removed from Petri dish and excess water was removed carefully using the filter paper and weighed. The characteristics of the tablets were expressed in terms of % swelling as,

% swelling = Weight of the swollen tablet- Initial weight of the tablet × 100 / Initial weight of the tablet

Swelling indices of different formulations are shown in **Fig. 10**; Results are mentioned in **Table 5**.

***In-vitro* Dissolution Study:** [13, 14] *In-vitro* drug release study of the samples was carried out using USP – type I dissolution apparatus (Basket type). The dissolution medium, 900 ml of simulated gastric fluid (without enzyme), was placed into the dissolution flask, maintaining the temperature of 37 + 0.5 °C and rpm of 50. One Fluvoxamine Maleate tablet was placed in each basket of the dissolution apparatus. The apparatus was allowed to run for 12 hours. Samples measuring 5 ml were withdrawn after every hour manually, and samples were filtered. The fresh dissolution medium was replaced every time with the same quantity of the sample withdrawn. Collected samples were analyzed at 246 nm using 6.8 phosphate buffer as blank. The cumulative percentage of drug release was calculated. Results are mentioned in **Fig. 11** and **Table 6**.

RESULTS AND DISCUSSION:

UV Spectroscopy and Beer – Lambert's Plot: In UV spectroscopy study, the maximum wavelength (λ_{max}) of Fluvoxamine Maleate in water was found to be 244 nm. The reported λ_{max} of Fluvoxamine Maleate in water is 246 nm.

FTIR Analysis of Drug: Major functional groups present in Fluvoxamine Maleate show characteristics peaks in IR spectrum.

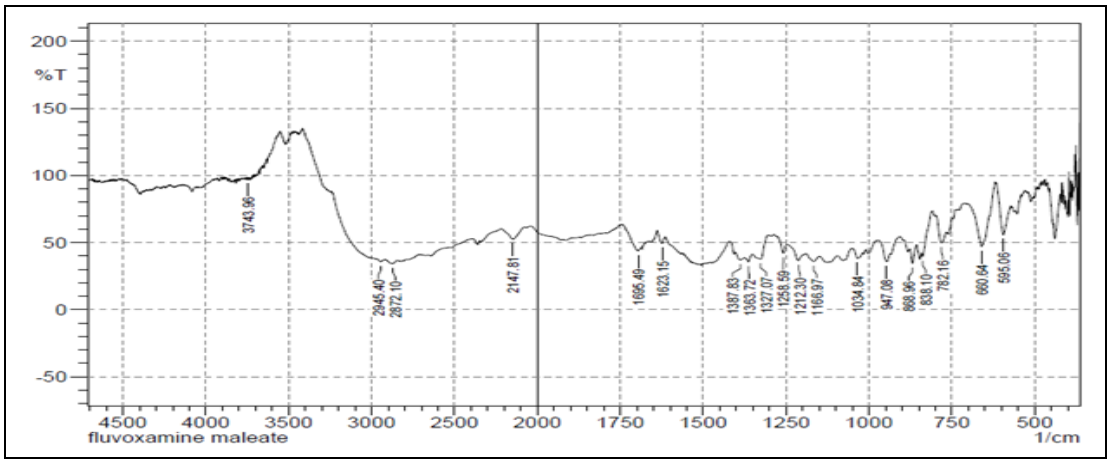

FIG. 2: FTIR SPECTRUM OF FLUVOXAMINE MALEATE

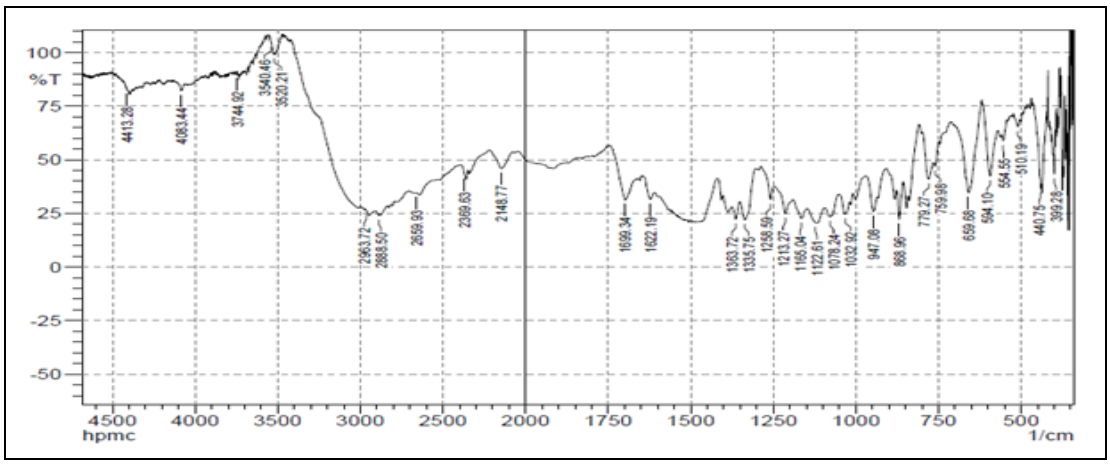

FIG. 3: FTIR SPECTRUM OF HPMC K100

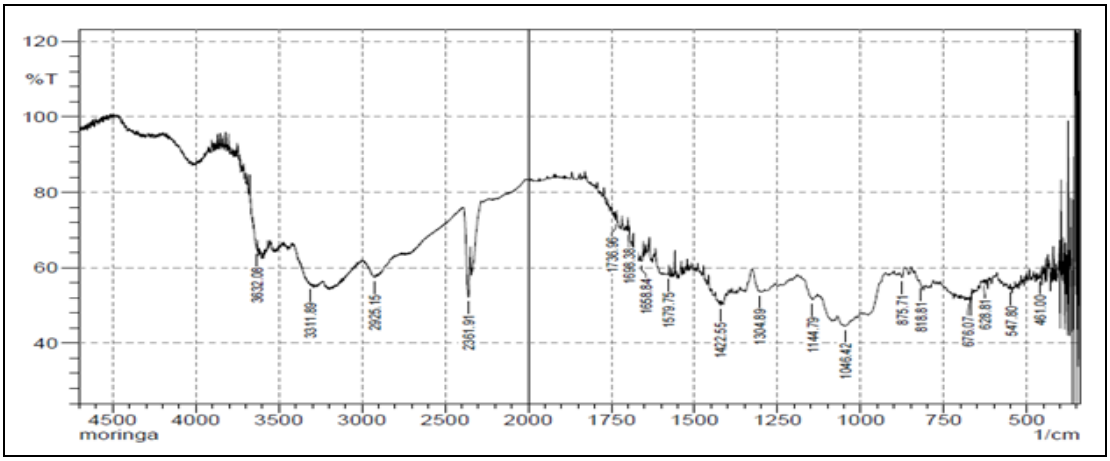

FIG. 4: FTIR SPECTRUM OF *MORINGA OLEIFERA* GUM

Characterization of Polymers and Identification of Polymers: Results of identification tests of HPMC K100 and *Moringa oleifera* gum were compared with the reported standards. The results obtained were found to be matched with the standards or reported values. FTIR spectrum of a received sample of polymers (HPMC K100 and *Moringa oleifera* gum) shown in **Fig. 3**, **Fig. 4**.

Compatibility Study of Drug with Polymers:

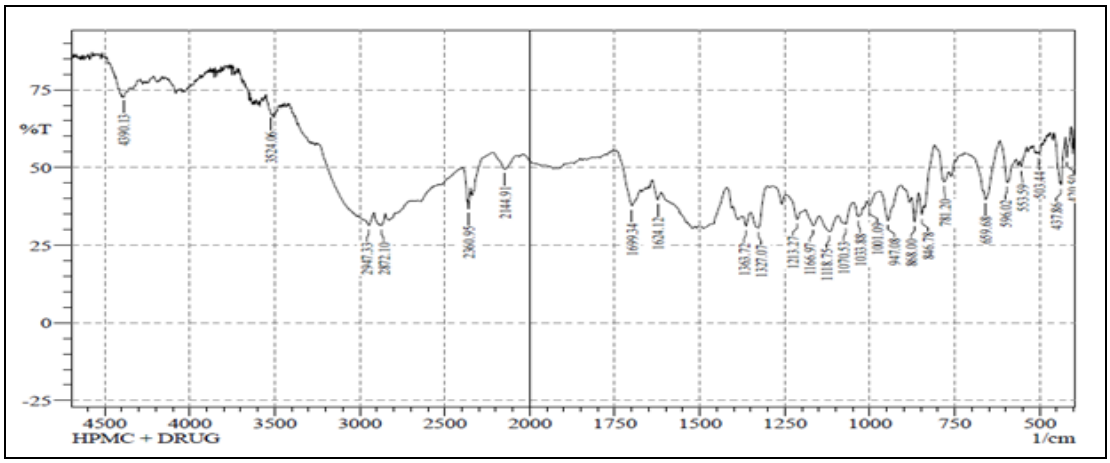

FIG. 5: FTIR OF FLUVOXAMINE + HPMC K100

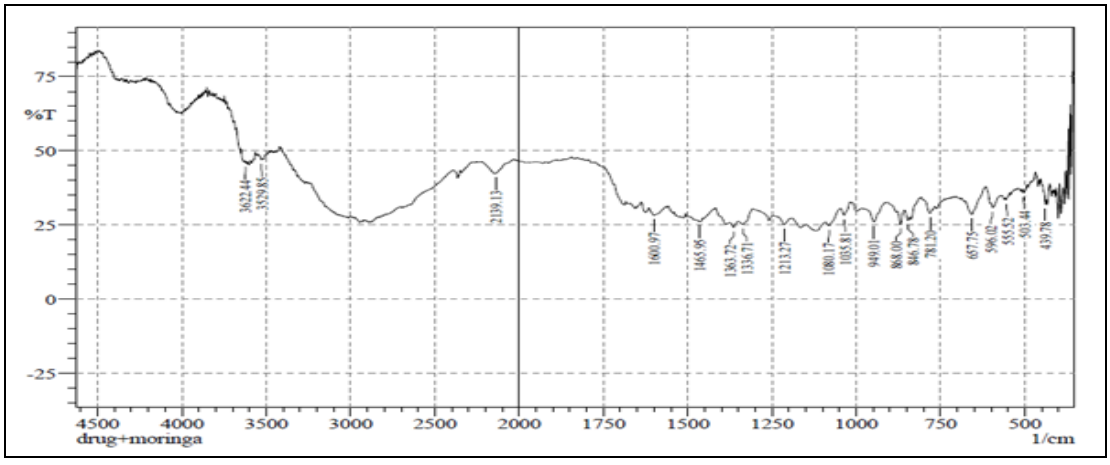

FIG. 6: FTIR OF FLUVOXAMINE MALEATE + *MORINGA OLEIFERA*

There were no variations in the IR spectrums of drug and drug-polymer/excipients mixture compared to the initial. So there was no interaction between the materials.

Differential Scanning Calorimetry (DSC): Thermal analysis of drugs was carried out using DSC. The DSC curve of Fluvoxamine Maleate profiles a sharp endothermic peak at 121 °C, correspondings to its melting point and indicating its crystalline nature and purity of the sample. The heat required for melting was -76.76J/g. The DSC thermogram is shown in **Fig. 7**.

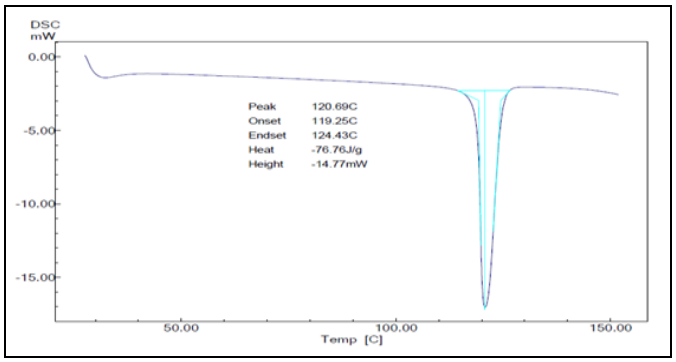

FIG. 7: DSC THERMOGRAM OF FLUVOXAMINE MALEATE

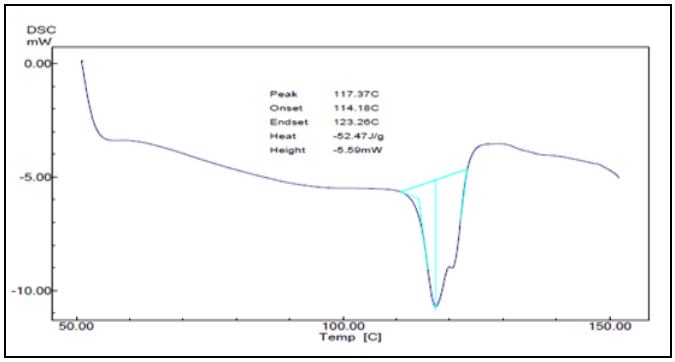

FIG. 8: DSC OF FLUVOXAMINE MALEATE + *MORINGA OLEIFERA*

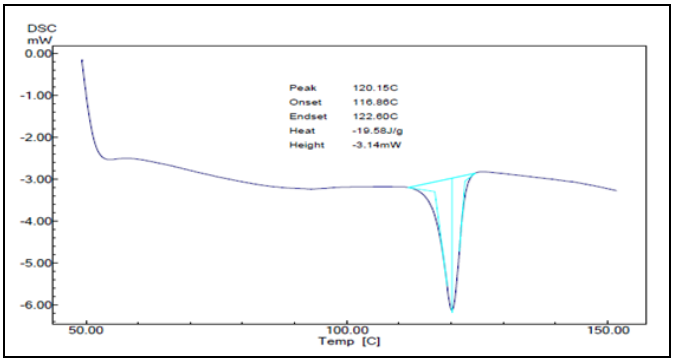

FIG. 9: DSC OF FLUVOXAMINE MALEATE AND MIXTURE

There were no variations in the melting point of Fluvoxamine Maleate from drug-polymer mixture compared to the melting point of Fluvoxamine Maleate. So there was no interaction between the materials.

Evaluation of Granules for Flow Properties: The granular characteristics of the drug affect the formulation of tablets. The results shown in **Table 2** indicated that granules had good flow properties. The angle of repose ranged from 23.70 to 28.26, and the compressibility index ranged from 13.13 to 16.73. The Bulk density and tapped density of the powder blend ranged from 0.387 to 0.392 and 0.450 to 0.466, respectively.

TABLE 2: EVALUATION OF GRANULES FOR FLOW PROPERTIES

Formulation	Angle of repose (θ)	Bulk density (gm/ml)	Tapped density (gm/ml)	Compressibility Index (%)	Hausner's Ratio
F1	26.10 ± 0.23	0.392 ± 0.004	0.461 ± 0.002	14.09 ± 0.803	1.17 ± 0.005
F2	23.75 ± 0.39	0.391 ± 0.0021	0.460 ± 0.007	15.06 ± 0.26	1.17 ± 0.003
F3	24.70 ± 0.12	0.391 ± 0.0007	0.456 ± 0.003	14.25 ± 0.50	1.16 ± 0.003
F4	24.70 ± 0.12	0.388 ± 0.005	0.460 ± 0.001	15.06 ± 0.509	1.18 ± 0.006
F5	24.22 ± 0.35	0.387 ± 0.0021	0.466 ± 0.0021	16.73 ± 1.10	1.20 ± 0.006
F6	23.26 ± 0.9	0.389 ± 0.0007	0.451 ± 0.005	13.72 ± 0.26	1.15 ± 0.003
F7	22.29 ± 0 .49	0.388 ± 0.002	0.457 ± 0.004	15.09 ± 0.017	1.17 ± 0.002
F8	25.64 ± 0.32	0.390 ± 0.0007	0.466 ± 0.066	16.32 ± 0.05	1.19 ± 0.008
F9	25.62 ± 0.31	0.391 ± 0.0042	0.450 ± 0.0024	13.13 ± 0.24	1.15 ± 0.003
F10	24.22 ± 0.6	0.391 ± 0.0042	0.460 ± 0.007	13.72 ± 0.26	1.20 ± 0.006

Evaluation of Final Formulation Tablets: The tablet formulations were subjected to various evaluation tests, such as thickness, Diameter, content uniformity, weight variation, hardness, friability, and *in-vitro* dissolution. The results for all the formulations are shown in **Table 3.**

TABLE 3: EVALUATION OF FINAL FORMULATION TABLETS

Formulation	Hardness Kg/cm^2	Friability (%)	Weight variation (gm)	Content uniformity (% w/w)	Thickness (mm)
F1	5.2 ± 0.11	0.13 ± 0.15	200.6 ± 0.13	96.78 ± 0.15	5.05 ± 0.032
F2	5.5 ± 0.13	0.16 ± 0.12	200.7 ± 0.37	97.32 ± 0.16	5.10 ± 0.129
F3	6.5 ± 0.16	0.17 ±0.061	197.5 ± 0.16	95.13 ± 0.18	5.20 ± 0.074
F4	5.0 ± 0.10	0.17 ± 0.06	195.3 ± 0.21	96.45 ± 0.13	5.05 ± 0.011
F5	5.2 ±0.11	0.15 ± 0.06	198.4 ± 0.18	98.99 ± 0.21	5.15 ± 0.05
F6	5.3 ± 0.16	0.18 ± 0.09	200.2 ± 0.14	97.34 ± 0.15	5.11 ± 0.012
F7	5.7 ± 0.15	0.20 ± 0.063	197.6 ± 0.11	95.67 ± 0.16	5.22 ± 0.043
F8	6.0 ± 0.30	0.15 ± 0.06	198.5 ± 0.15	95.34 ± 0.24	5.10 ± 0.083
F9	5.5 ± 0.13	0.13 ± 0.15	197.8 ± 0.18	98.29 ± 0.32	5.15 ± 0.024
F10	5.3 ± 0.16	0.18 ± 0.13	198.3 ± 0.13	95.45 ± 0.16	5.02 ± 0.129

The tablet hardness of all the formulations was determined, and it was found in the range of 5-6.5 kg/cm^2. Another measure of tablet hardness was friability. Compressed tablets that lose less than 1 % of their weight are generally considered acceptable. For all formulations tried here, the weight loss was less than 1 %, hence acceptable.

Measurement of Bioadhesive Strength of Tablet (Detachment Force): *Moringa oleifera* and HPMC K100 exhibiting inheriting bioadhesion was chosen as drug retreading polymers. It was observed that optimized formulation has adhesion force 2.25 and 2.40 dyne/cm^2. The above study shows that the tablet will remain intact with the gastric mucosa and remain to adhere with mucosa to keep the tablet remain in the stomach as the drug is better absorbed.

TABLE 4: DETACHMENT FORCE OF DIFFERENT FORMULATIONS

Formulation	Bioadhesion Strength (dyne/cm^2)	Formulation	Bioadhesion Strength (dyne/cm^2)
F1	1.17 ± 0.16	F6	1.52 ± 0.16
F2	1.60 ± 0.18	F7	1.81 ± 0.09
F3	2.25 ± 0.23	F8	2.40 ± 0.17
F4	1.91 ± 0.05	F9	1.96 ± 0.15
F5	1.47 ± 0.17	F10	1.71 ± 0.08

Determination of Swelling Index:

TABLE 5: SWELLING INDICES OF DIFFERENT FORMULATIONS

Formulation	%Swelling index					
	2 h	4 h	6 h	8 h	10 h	12 h
F1	80.12	88.12	96.07	103.03	109.14	118.11
F2	101.85	118.20	132.46	142.61	163.45	188.50
F3	165.55	185.43	196.34	223.25	246.75	264.30
F4	103.70	120.94	133.34	151.38	165.65	189.29
F5	122.20	145.11	161.65	188.92	205.25	230.33
F6	185.63	223.30	240.25	188.92	282.55	307.40
F7	125.89	154.15	175.33	197.47	217.28	233.25
F8	174.25	197.85	216.66	233.50	254.35	276.22
F9	178.25	199.85	218.50	237.66	257.17	281.22
F10	188.25	227.35	245.45	269.17	290.53	315.34

From **Table 5**, it was observed that F3 and F8 have a significant % swelling index due to the high concentration of HPMC K100 and *Moringa oleifera*. Swelling is vital factor to drug dissolution and also influences drug release kinetics. A greater extent of swelling is observed with the highest concentration of HPMC K100. Moringa oleifera led to an increase in tablet dimension, thus increasing diffusion pathways and decreasing drug release. % Swelling index was calculated at 2, 4, 6, 8, 10, 12 h; it has been observed that % S.I. increase with time. HPMC K100 and Fluvoxamine swell immediately, and this is assisted by CMTKP. Thus tablet swells continuously over 12 h.

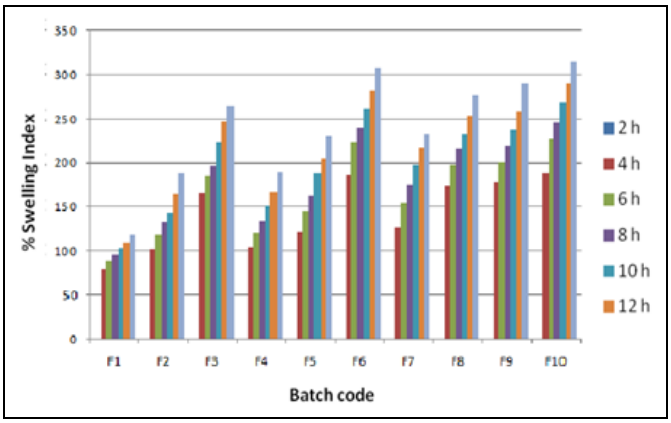

FIG. 10: SWELLING INDICES OF DIFFERENT FORMULATIONS

***In-vitro* Dissolution Study:** HPMC K 100 and *Moringa oleifera* are hydrophilic polymers. When these polymers come in contact with water, allow gradual hydration of the tablet matrix, leading to swelling of the tablet. Water decreases the glass transition temperature of the polymers to the experimental temperature. At this temperature, a glassy polymer is transformed into a rubbery state. Mobility of polymeric chains is enhanced in this state. This favors the transport of water into the tablet and consequently transport of the dissolved drug from tablet core to the dissolution medium. Drug release from matrix tablet is determined by drug characteristics, delivery system and destination (site of drug release). Drug content of each tablet was 100 mg and 900 ml of dissolution.

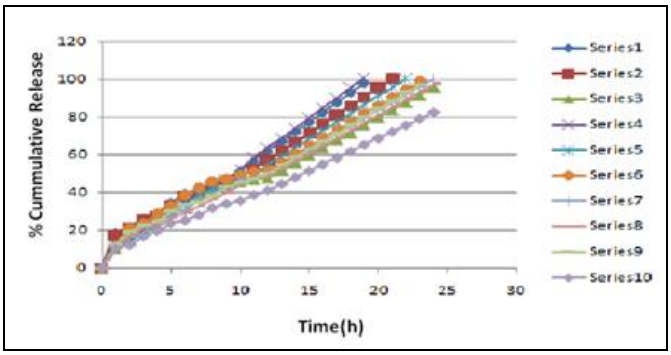

FIG. 11: DISSOLUTION PROFILES OF FORMULATION (F1 – F10)

TABLE 6: % CUMULATIVE DRUG RELEASE FROM FINAL FORMULATIONS

Time (hr)	Formulation									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
1	18.95 ±0.32	17.68 ±0.36	11.5 ± 0.67	12.89± 0.45	11.81± 0.28	12.09± 0.24	10.49± 0.20	10.90± 0.53	12.53± 0.32	10.79± 0.32
2	22.14± 0.61	21.40± 0.56	16.44± 0.54	15.45± 0.32	14.47± 0.46	21.33± 0.64	18. 0 ± 0.52	17.26± 0.77	19.27± 0.44	12.47± 0.56
3	26.57± 0.42	25.77± 0.27	18.56± 0.33	20.58± 0.55	19.30± 0.35	24 ± 0.52	21.41± 0.45	21.44± 0.87	22.85± 0.56	17.09± 0.42
4	28.96± 0.41	27.48± 0.35	24.70± 0.27	23.48± 0.65	22.83± 0.26	29.21± 0.84	25.74± 0.35	23.51± 0.65	24.92± 0.85	19.86± 0.55
5	34.65± 0.28	32.72± 0.45	29.21± 0.36	31.63± 0.23	30.73± 0.31	32.80± 0.42	29.60± 0.40	26.60± 0.49	30.14± 0.93	24 + 0.32
6	39.53± 0.23	37.94± 0.25	30.90± 0.65	35.08± 0.35	33.44± 0.45	38.67± 0.29	35.29± 0.33	29.43± 0.56	33.51± 0.67	25.46± 0.54
7	42.54± 0.32	40.00± 0.40	36.66± 0.45	40.31± 0.56	39.05± 0.70	42.64± 0.63	38.81± 0.15	32.85± 0.67	35.03± 0.53	28.29± 0.76
8	44.24± 0.23	43.69± 0.45	39.54± 0.53	43.07± 0.31	41.96± 0.31	45.86± 0.56	41.90± 0.35	36.71± 0.55	38.34± 0.69	31.98± 0.53
9	46.43± 0.45	45.40± 0.75	41.98± 0.91	46.73± 0.0.45	44.24± 0.55	46.22± 0.45	43.79± 0.66	39.92± 0.67	42.31± 0.58	33.23± 0.59
10	69.30± 0.69	47.60± 0.65	43.92± 0.83	63.27± 0.88	45.46± 0.35	47.36± 0.46	45.74± 0.45	41.23± 0.67	43.34± 0.45	34.21± 0.92
11	77.30± 0.55	69.60± 0.44	44.60± 0.77	66.08± 0.31	57.44± 0.41	47.67± 0.29	47.16± 50	44.34± 0.78	44.30± 0.59	36.15± 0.89
12	79.07± 0.76	75.88± 0.63	46.90± 0.45	70.17± 0.55	66.89± 0.35	48.47± 0.67	47.81± 0.52	45.55± 0.88	47.18± 0.93	38.54± 0.56
13	85.08± 0.82	80.01± 0.56	73.32± 0.49	80.63± 0.29	78.11± 0.78	85.28± 0.72	77.62± 0.67	65.71± 0.78	70.05± 0.67	56.58± 0.87
14	88.48± 0.85	87.39± 0.40	79.08± 0.77	86.15± 0.15	83.92± 0.67	91.73± 0.84	83.81± 0.45	73.43± 0.89	76.69± 0.88	63.97± 0.45
15	92.87± 0.49	90.80± 0.67	83.98± 0.37	93.47± 0.36	83.92± 0.93	92.45± 0.88	87.59± 0.50	79.84± 0.97	84.63± 0.78	66.4± 0.90
16		95.20± 0.49	87.85± 0.35		90.92± 0.57	94.73± 0.67	91.49± 0.67	82.46± 0.56	86.69± 0.27	68.43± 0.33
17			89.21± 0.26			95.35± 0.37	94.33± 0.78	88.68± 0.67	88.61± 0.85	72.30± 0.25
18			93.80± 0.26			96.94± 0.62	95.62± 0.56	91.11± 0.62	94.37± 0.25	77.09± 0.36

From **Fig. 11,** it was observed that (F1, F2, F3) as the concentration of *Moringa oleifera* increased, the drug release decreased. (F3, F4, F5) as the concentration of HPMC K100 increased, the drug release decreased. This leads to increase in diffusion path length thus decrease in dissolution rate. Formulations (F7, F8, F9 and F10) have the combination of HPMC K100 and *Moringa oleifera*

highest drug release retardant property. F3 shows 93.8008%, and F8 Shows 91.117% drug release over 24 h. It has a significant % swelling index and also maintains matrix integrity for 24 h. These findings are in compliance with the ability of HPMC to form a complex matrix network, which leads to an increase in the diffusion path so the amount of drug released decreases.

CONCLUSION: In conclusion, the research project was carried out with the objective of developing oral sustain release matrix tablet formulation of Fluvoxamine Maleate by using natural polymer *Moringa oleifera* gum and HPMC K100; and evaluation their sustain release potential. It can be concluded that,

- Increased polymer level in the formulation results in decreased drug released rates.
- Decreased concentration of polymer (*Moringa oleifera* gum and HPMC K100) results in reduced Hardness.
- Natural polymer *Moringa oleifera* gum has similar potential as that of HPMC K100 in the formulation of sustain release matrix tablet proven by drug release profiles F3 and F6 were 93.8008% and 96.94108%, respectively.

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