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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL TABLETS OF PROPRANOLOL PREPARED USING NATURAL POLYMER

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Keywords:

Mucoadhesive buccal tablets, Wet granulation method, Hypertension, *Vigna mungo* powder, Propranolol

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ABSTRACT: Propranolol is beta-blocker and it is widely used in the management of hypertension. Propranolol is used to treat tremors angina, hypertension, heart rhythm disorder and other heart or circulatory conditions. The mucoadhesive buccal tablets of propranolol were papered by wet granulation method using natural polymer like *Vigna mungo* powder. The compatibility studies of drug and excipient were performed by FT- IR spectroscopy and DSC. After examining the flow properties of the powder blends the results were found to be within prescribed limits and indicated good flowing property, hence it was subjected to compression. The tablets were evaluated for post-compression parameters like weight variation, hardness, thickness, friability, drug content uniformity, surface pH, *in-vitro* studies like swelling, mucoadhesive strength, residence time and drug release. Formulation (F6) containing *Vigna mungo* showed good mucoadhesive strength (21.75g) and maximum drug release of 89.31% in 12 h and residence time (6.9 h). The drug content shown 92.19%, surface pH was found to be 6.9. All the evaluation parameters given the positive result and comply with the standards. The results indicated that the mucoadhesive buccal tablets of propranolol may be good choice to bypass the extensive hepatic first pass metabolism with an improvement in bioavailability of propranolol through buccal mucosa.

INTRODUCTION: Oral route of administration of drugs is most preferred to the patient and the clinician also. However, per oral administration of drugs has disadvantages such as hepatic first pass metabolism and enzymatic degradation within the GI tract, that prohibit oral administration of many drugs. Due to this other absorptive mucosa are considered as potential sites for drug delivery offer ′ s distinct advantages over per oral administration for systemic drug delivery.

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Further oral trans-mucosal drug delivery bypass first-pass effect in the GI tract and liver and avoids GI side effects [2]. Mucoadhesive drug delivery system are utilizes the property of bioadhesion of certain polymers. Bioadhesion is defined as an ability of a material to adhere a particular region of the body for extended period of material to adhere a particular region of local targeting of drugs but also for better control of systemic delivery.

Mucoadhesion is defined as the interaction between a mucin surface and a synthetic or natural polymer [1, 3]. Propranolol is beta-blocker. Beta- blocker affects the heart and circulation (Blood flow through arteries and veins). Propranolol is used to treat tremors angina (chest pain) hypertension (high blood pressure) heart rhythm disorders and other heart or circulatory conditions.

It is also used to treat or prevent heart attack and reduces the severity and to reduce the severity and frequency of migraine headaches. Propranolol is highly lipophilic and almost completely absorbed after oral administration however, it undergoes high first pass metabolism by the liver and an average, only about 25% of propranolol reaches the systemic circulation, peak plasma concentration occurs about 1 to 4 h after an oral dose.

After oral administration, propranolol is almost completely and rapidly absorbed from the gastrointestinal tract. However, because of the high first - pass metabolism and hepatic tissue binding, the absolute bioavailability is only about 30% and varies greatly between individuals. Peak plasma concentration occurs one to two hours after administration. The physicochemical properties of propranolol, its suitable half-life (4 h) and its low molecular weight 295.81 gm/mol makes it suitable for administration by the buccal route [5].

MATERIALS AND METHODS:

Material: Proparnolol was gifted by (Sai Supreme Chemicals, Tamil Nadu). AvicelPh 102, Magnesium stearate, Talc were gifted by (SD Fine chemicals, Mumbai).

Preparation of Seed Flour of Black Gram: [6, 7, 8, 9] The dehusked seed of black gram were properly washed with distilled water and dried in oven temperature less than 50 ºC. The dried seeds were powdered in mixer and passed through #120 sieve using sieve shaker and stored in desiccators until further use.

Formulation of Propranolol Mucoadhesive Buccal Tablet: Proparnolol mucoadhesive buccal tablets were prepared by wet granulation technique using varying concentration of *Vigna mungo* seed powder as polymer and isopropyl alcohol as binding agent as mentioned in **Table**. To the *Vigna mungo* powder, proparnolol and Avicel pH 102 were added and triturated properly to form a uniform blend. The powdered blend then subjected to granulation by using isopropyl alcohol as granulating agent. The wet powder mass was passed through sieve no. 12 and the granules obtained were dried at 45 ºC for 30 min. the dried granules were passed through sieve no. 16 and lubricated with magnesium stearate and talc.

The blended granules were finally compressed in to tablets of desired weight (500 mg) and hardness by 8 mm flat faced punch on 10 stages rotary tablet compress machine.

TABLE 1: COMPOSITION OF FORMULATIONS

Ingredients	F-1	F-2	F-3	F-4	F-5	F-6
propranolol	20	20	20	20	20	20
Vigna mungo powder	350	355	360	365	370	375
Avicel Ph 102	110	105	100	95	90	85
Magnesium stearate	10	10	10	10	10	10
Talc	10	10	10	10	10	10
Total weight	500	500	500	500	500	500

Pre-formulation Study of Pre-compression Parameters:

Bulk Density: [3, 11] It is the ratio of mass to bulk volume. It is required to decide appropriate packing of dosage forms. An accurately 10 gm of sample was weighed and transferred to a 50 ml measuring cylinder. The volume was noted. The Bulk density was obtained by dividing weight of the sample in grams by final volume in cm^3 and it was determined by equation given below:

$$\text{Bulk density} = \frac{\text{Mass}}{\text{Bulk volume}}$$

Tapped Density: [3, 11] Accurately weighed quantity of powder was carefully poured in to graduated 50 ml measuring cylinder through large funnel. The cylinder was then tapped 100 times from a constant height and the tapped volume was read. This is expressed in gm / ml and determined by the following formula:

$$\text{Tapped density} = \frac{\text{Weight of the powder}}{\text{Tapped volume}}$$

Angle of Repose: [10, 11] A funnel was kept vertically in stand at a specified height above a paper placed on horizontal surface. The bottom was closed and 10 gm of sample powder was filled in funnel. The funnel was opened to release the powder on paper to form a smooth conical heap. The height of heap was measured using the scale. A border of heap was marked circularly and its diameter was measured at four points. The angle of repose was calculated using following formula:

$$\text{Tan } \theta = \frac{h}{r}$$

Where;

θ= angle of repose
r=radius of the base
h=height from tip of funnel to the surface of graph paper.

Carr's Index: [10, 12] It is also one of the simple method to evaluate flow property of a powder by comparing the bulk density and tapped density. Carr's index is an indication of the compressibility of a powder. It is expressed in percentage and determined by the following formula:

% Car's consolidation index =

$$\frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 10$$

Hausner Ratio: [12] A small index like percentage compressibility index has been defined by Hausner. Values less than <1.25 indicates good flow, where as greater than 1.25 indicates poor flow. Added glidant normally improves flow of the material under study. Hausner's ratio can be calculated by;

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}} \times 100$$

Evaluation of Buccal Tablets:

Hardness: [13, 14, 15, 16] Hardness (diametric crushing strength) is a force required to break a tablet cross the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during handling and transportation. The degree of hardness varies with the different manufactures and with the different types of tablets. The hardness was tested by using Monsanto hardness tester.

Thickness: [13, 14, 16, 17] Three tablets from each batch of formulation were collected and the thickness of the tablets was measured with the help of venires calliper. The average thickness was calculated.

Friability: [13, 18, 15, 19] Roche friability test apparatus was used to determine the friability of the tablets. Twenty pre-weighed tablets were placed in the apparatus and operated for 100 revolutions and then the tablets were reweighed. The percentage friability was calculated according to the following formula:

$$\% \text{ Friability} = \frac{\text{Initial weight - final weight}}{\text{Initial weight}} \times 100$$

Weight Variation: [20] The weight of tablet is measured to ensure that a tablet contain the proper amount of drug. Randomly selected twenty tablets form each batch were subjected to weight variation test as per Indian Pharmacopoeia 2007. Not more than two individual weight deviate from the average weight by more than 5% percentage deviation.

Uniformity of Content: [11, 5] Drug content uniformity was determined by dissolving the tablets in ethyl alcohol and filtering with whattman filter paper. The filtrate was evaporated and drug residue dissolved in 100ml phosphate buffer pH 6.8. The 5 ml solution was then diluted with phosphate buffer pH 6.8 to 20 ml, filtered through whattman filter paper, and analyzed at 289 nm using UV double beam spectrophotometer.

Swelling Studies: [21, 22, 23] The degree of swelling of bioadhesion polymers is an important factor affecting adhesive. For conducting the study, a tablet was weighed and placed in petridish containing 5 ml of phosphate buffer at pH 6.8 for 6 hrs, the tablets were taken out from the petridish and excess water was removed carefully by using filter paper. The swelling index was calculated using the following formula:

$$\text{Swelling index} = \frac{Wt - Wo}{Wo} \times 100$$

Wt = weight of swollen tablet at each time interval
Wo = weight of initial tablet

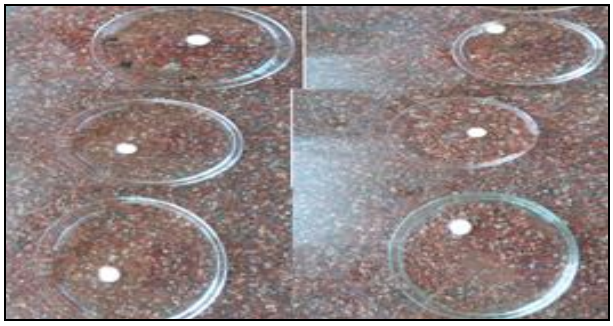

FIG. 1: SWELLING STUDY OF TABLETS

Surface pH: [10, 24, 15, 16] The surface pH of the buccal tablets was determined in order to investigate the possibility of any side effects *in-vivo*. Since an acidic or alkaline pH may cause irritation to the buccal mucosa, so it was determined to keep the surface pH as close to neutral as possible. A combined glass electrode was used for this purpose. The tablet was allowed to swell by keeping it in contact with 1 ml of distilled water for 2 h at room temperature. The pH was measured by bringing the electrode in contact with the surface of the tablet and allowing it to equilibrate for 1 minute.

FIG. 2: pH METER FOR THE MEASUREMENT OF pH

Measurement of Adhesion Force: [3, 25, 26, 27] Measurement of adhesion force was determined by using bovine buccal mucosa which was obtained from slaughter house. The underlying tissues were separated and washed thoroughly with phosphate buffer solution (pH 6.8). The membrane was then tied to the bottom of the lower vial using rubber band. The vial was kept in glass bottle which was filled with phosphate buffer solution at 37 ± 1 ºC in such way that buffer just reaches the surface of mucosal membrane and kept it moist. The tablet to be tested was stuck on the lower side of the hanging Glass vial by using adhesive tape and the weight (2 gm) on the right pan was removed.

FIG. 3: BIOADHESION TEST ASSEMBLY

This lowered the left side of the pan along with tablet over the mucosa. It was kept undisturbed for three minutes and the weights were added on right side of pan till the tablet just separated from the membrane surface. The excess weight on the right pan *i.e.* total weight minus 2 gm was taken as measure of bioadhesive strength. Bioadhesive force was calculated by using following equation.

$$\text{Bioadhesive force} = \frac{\text{Bioadhesive strength x } 9.81}{100}$$

Residence Time: [28, 25, 18] The *ex-vivo* residence time was determined using a locally modified USP disintegration apparatus. The disintegration medium was composed of 900 ml (pH 6.8) of phosphate buffer maintained at 37 ± 1 ºC. The bovine buccal mucosa was tied to the surface of a wooden scale, vertically attached to the disintegration apparatus. The buccal tablet was hydrated using phosphate buffer (pH 6.8) and the hydrated surface was brought in contact with the mucosal membrane by keeping the backing membrane outside. The wooden scale allowed moving up and down, so that the tablet was completely immersed in buffer solution at the lowest point and was out at the highest point (**Fig**). The time taken for complete displacement of the tablet from the mucosal surface was noted and repeated thrice.

FIG. 4: MODIFIED DISINTEGRATION APPARATUS FOR MEASUREMENTS OF *EX- VIVO* RESIDENCE TIME

***In-vitro* Dissolution Studies:** [4, 5, 11] The United State Pharmacopeia (USP) type II dissolution apparatus was used to study the release of drug from buccal tablets. The dissolution medium consisted of 900 ml of phosphate buffer (pH 6.8). The release was performed at 37 ± 0.5 ºC, at a rotation speed of 50rpm Samples (5 ml, at each time) were filtered with fresh medium. The samples were filtered through Whattman filter paper no. 41 with appropriate dilutions with phosphate buffer (pH 6.8) and were assayed spectrophotometeically at 289 nm against phosphate buffer as blank.

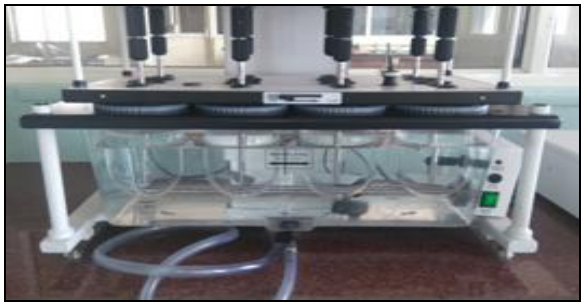

FIG. 5: *IN-VITRO* DISSOLUTION STUDY

RESULTS AND DISCUSSION:

Calibration Curve of Propranolol:

TABLE 2: OBSERVATION FOR STANDARD CALIBRATION CURVE OF PROPRANOLOL

S. no.	Concentration (µg/ml)	Absorbance
1	0	0
2	2	0.061
3	4	0.104
4	6	0.144
5	8	0.195
6	10	0.252
7	12	0.289
8	14	0.336
9	16	0.380
10	18	0.414
11	20	0.460

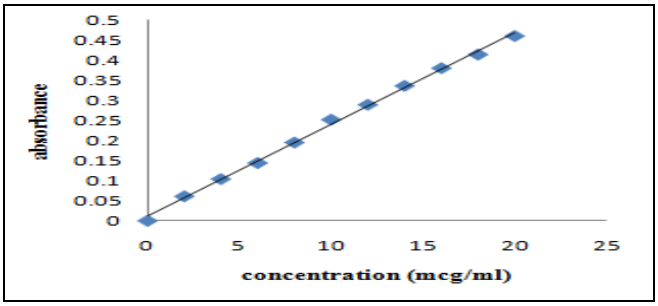

FIG. 6: CALIBRATION CURVE OF PROPRANOLOL IN PHOSPHATE BUFFER pH 6.8

TABLE 3: STANDARD CURVE STATISTICS

S. no	Parameters	Observations
1	Absorbance maximum	289
2	Slope	0.0228
3	Intercept	0.0115
4	Coefficient of correlation (r^2)	0.9978

Infrared Spectrum Analysis: The infrared spectrum of pure drug propranolol was studied and it was found that all the important peaks that correspond to various functional groups present in the structure of propranolol were present. The drug exhibits peaks due to the N-H, C-H stretch, aryl O-CH_2. In the IR study, it was found that there was no interaction exhibited between propranolol and excipients used.

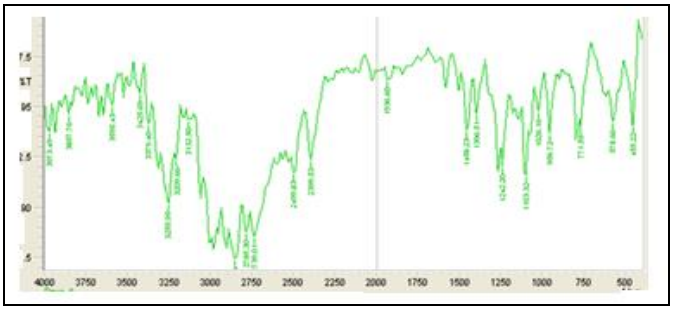

FIG. 7: INFRARED SPECTRUMOF PROPRANOLOL PURE DRUG

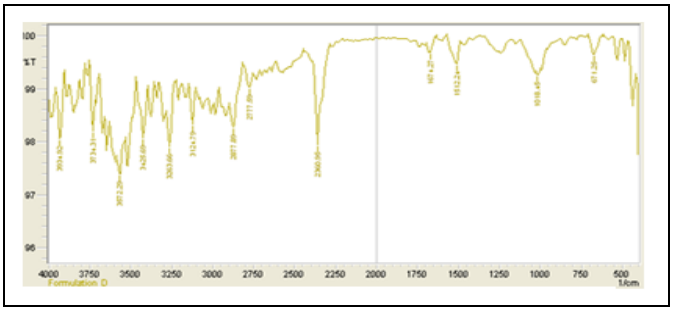

FIG. 8: IR SPECTRUM OF TABLET

TABLE 4: INTERPRETATIONOF IR SPECTRUM CHARAC-TERISTICS PEAKS OF THE FORMULATION F6

S. no	Wave number (cm^{-1})	Interpretation	Peak observed		
			cm^{-1}	Drug	tablet
1	3500 -3180	N-H stretch	3263.66	YES	YES
2	2950 -2800	C-H stretch	2877.89	YES	YES
3	3400 -2400	O-H stretch	3572.29	YES	YES
4	1260 -1000	Aryl O-CH_2 Symmetric	1018.45	YES	YES

The results of the granules evaluation suggested that all the granules exhibited the good flow properties. The formulation blends were directly compressed using 8 mm flat faced punch on 16 stages rotary tablet compress machine and *in- vitro* drug release studies were performed.

TABLE 5: EVALUATION PRE-COMPRESSION PARAMETERS OF POWDER BLEND

Formulation code	Bulk density (gm/cc)	Tapped density (gm/cc)	Hausner's ratio	Compressibility index	Angle of repose (°)
F-I	0.32 ± 0.00	0.38 ± 0.00	1.16 ± 0.05	17.16 ± 0.84	28.58 ± 0.84
F-II	0.30 ± 0.00	0.33 ± 0.00	1.09 ± 0.05	9.58 ± 0.87	24.79 ± 1.47
F-III	0.27 ± 0.00	0.31 ± 0.00	1.1 ± 00	11.72 ± 0.78	24.9 2± 1.45
F-IV	0.26 ± 0.00	0.28 ± 0.00	1 ± 00	8.2 ± 0.59	25.21 ± 0.64
F-V	0.24 ± 0.00	0.27 ± 0.00	1.1 ± 00	9.96 ± 0.65	27.07 ± 2.20
F-VI	0.23 ± 0.00	0.26 ± 0.00	1.06 ± 0.05	9.30 ± 1.40	26.26 ± 2.51

All the prepared mucoadhesive buccal tablets of propranolol were evaluated for thickness, hardness, friability, weight variation and drug content and data is shown in **Table**.

TABLE 6: EVALUATION POST COMPRESSION PARAMETERS OF PROPRANOLOL MUCOADHESIVE BUCCAL TABLETS

Formulation no	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	% Friability	%Drug content
F1	Passes	7.3±0.24	4.2±0.15	0.99±0.00	89.01±0.47
F2	Passes	7.4±0.32	4.5±0.1	0.94±0.00	90.30±0.34
F3	Passes	7.7±0.21	4.5±0.1	0.86±0.00	91.43±0.34
F4	Passes	6.9±0.53	4.1±0.15	0.93±0.00	92.04±0.45
F5	Passes	7.3±0.16	4.4±0.15	0.77±0.00	89.84±0.69
F6	Passes	7.8±0.20	4.3±0.2	0.76±0.00	92.19±0.94

The hardness of prepared mucoadhesive buccal tablets was range of 6.9 - 7.8 kg /cm^2 and hardness was increased as the concentration of *Vinga mungo* gum was increased in the formulation. The thickness of the tablets was in the range of 4.1 - 4.5 mm, which shows uniform thickness of the tablets. The friability was in the range of 0.76% to 0.99%. Less than 1% indicates good mechanical strength to withstand the rigors of handling and transportations. Weight of the prepared buccal tablets were found to be in the range of 493 to 496 mg. The drug content was in the range of 89.01% to 92.19%, suggesting uniform mixing of drug.

Thermal Analysis: From the **Fig. 9** of pure propranolol drug and propranolol with *Vigna mungo* excipient, the compatibility of propranolol drug is checked. The melting point of pure drug is in the range of 161-163 ºC. The above thermogram of pure drug shows three peaks. The thermogram of propranolol along with the excipient shows comparatively same peak onset and peak temperature as that of the pure propranolol drug.

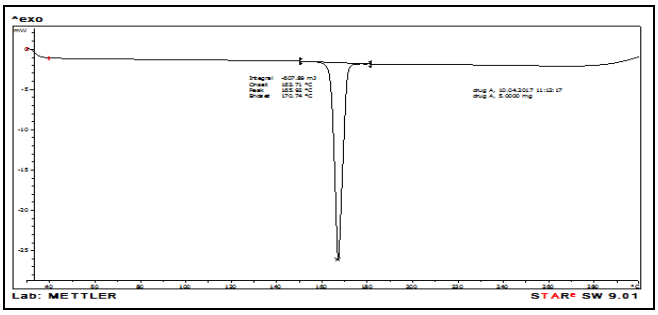

FIG. 9: DSC THERMOGRAM OF PURE PROPRANOLOL DRUG

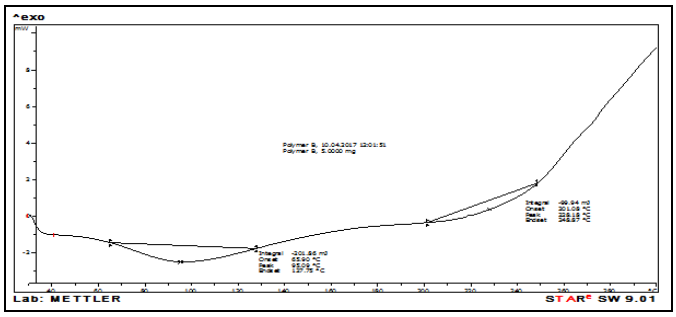

FIG. 10: DSC THERMOGRAM OF *VIGNA MUNGO*

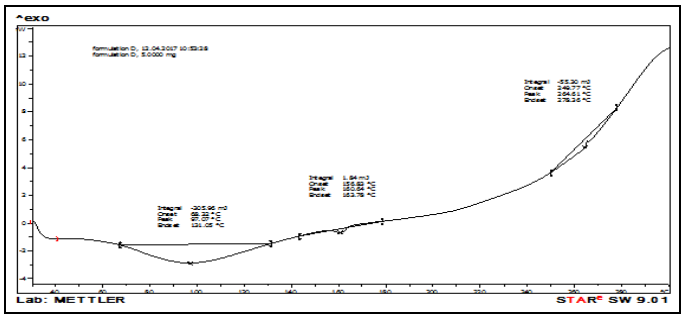

FIG. 11: DSC THERMOGRAM OF TABLET FORMULATION F6

Hence from **Fig. 11** of DSC thermogram we can conclude that the *Vigna mungo* sample is compatible with the propranolol drug.

Swelling Studies: The swelling index of all formulation was found in the range 14.42 % to 82.42% for 6 h. swelling studies indicates that swelling index of F5 and F6 was found to be higher followed by F4>F3>F2>F1. Swelling of tablets increases with increase in polymer concentration.

TABLE 7: SWELLING INDEX VALUES OF MUCO-ADHESIVE BUCCAL TABLETS

Formulation no	Time (h)					
	1	2	3	4	5	6
F1	14.42%	29.23%	28.34%	25.31%	34.94%	37.20%
F2	19.13%	32.16%	34.59%	30.49%	41.19%	43.65%
F3	31.34%	39.58%	41.83%	34.69%	53.00%	57.77%
F4	50.91%	48.91%	44.66%	40.76%	60.42%	70.47%
F5	59.11%	63.12%	67.01%	53.17%	64.13%	72.97%
F6	64.73%	70.21%	75.50%	77.85%	78.84%	82.42%

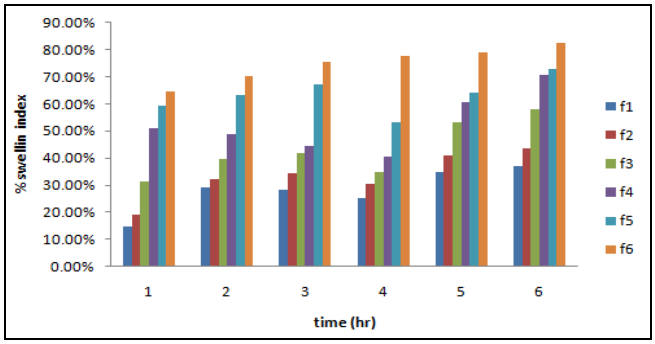

FIG. 12: SWELLING INDEX OF PROPRANOLOL TABLETS

Surface pH: The values of surface pH were in the range between 6.8 - 6.9 which indicates that all the formulation provides an acceptable pH in the range of salivary pH 5 -7.

TABLE 8: SURFACE pH STUDY

Formulation code	Surface pH
F1	6.8 ± 0.04
F2	6.8 ± 0.01
F3	6.8 ± 0.05
F4	6.9 ± 0.00
F5	6.8 ± 0.01
F6	6.9 ± 0.00

Mucoadhesive Strength and *Ex-vivo* Residence Time: The mucoadhesion of all the buccal tablets of varying ratio of polymers were tested and weight required to pull off the formulation from the mucous tissue was recorded as mucoadhesion strength in grams. The mucoadhesion of buccal tablets was found to be maximum in case of formulation F5 and F6 *i.e.* 20.16 and 21.75 gm respectively. The mucoadhesion was mainly due to the mucoadhesive nature of the polymer used. The residence time of buccal tablets ranged between 5.1 - 6.9 h and noted this much time required for buccal tablets to detach from the buccal mucosa.

TABLE 9: MUCOADHESIVE STRENGTH AND *EX-VIVO* RESIDENCE TIME

Formulation no	Mucoadhesive strength	*Ex-vivo* residence time (h)
F1	11.53±0.45	5.1±0.1
F2	12.98±0.99	5.0 ±0.47
F3	12.71±2.1	5.6±0.35
F4	14.19±0.7	5.8±0.50
F5	20.16±1.01	5.9±0.43
F6	21.75±1.1	6.9±0.31

The drug release pattern was studied for all formulations. (F1 to F6) for 12 h following standard procedure and the results are provided in **Fig**. The *in-vitro* cumulative drug release of formulation F1, F2, F3 at 9 h showed 71.59%, 70.22%, 74.31% and F4, F5 at 11 h showed 75.00% % 80.45%. And F6 formulation showed best result 89.31% drug release respectively. This may be attributed to increased hydration followed by increased swelling of polymer with increase in concentration of polymer.

The overall data on the *in-vitro* dissolution studies closely indicated that among the six formulations, the formulation F6 was found to be the best with high percentage of drug release (89.31%), with extended period of time for about 12 h.

TABLE 10: *IN - VITRO* DISSOLUTION PROFILE OF FORMULATION F1 –F6

Time (h)	F 1	F 2	F 3	F 4	F 5	F 6
0	0 ± 00	0 ± 00	0 ± 00	0 ± 00	0 ± 00	0 ± 00
1	4.09 ± 2.04	7.5 ± 3.12	4.77 ± 3.12	6.13 ± 4.09	10.22 ± 2.04	12.95 ± 3.12
2	10.23 ± 4.25	15 ± 2.36	10.22 ± 2.04	11.59± 3.12	16.36 ± 4.09	20.45 ± 4.09
3	22.50 ± 1.62	21.81 ± 3.12	18.40 ± 5.41	19.09± 4.25	21.13 ± 3.12	25.22 ± 3.12
4	28.64 ± 7.08	29.31 ± 1.18	24.54 ± 4.09	26.59± 3.54	27.95 ± 3.12	32.04 ± 4.25
5	36.82 ±4.25	37.5 ± 3.12	34.09 ± 1.18	32.72± 2.04	34.09 ± 4.72	38.86 ± 3.54
6	47.05 ± 7.31	42.27 ± 3.12	40.90 ± 2.04	40.22± 3.12	40.90 ± 3.54	46.36 ± 4.25
7	55.23 ± 5.41	49.09 ± 4.09	48.40 ± 3.12	45 ± 2.04	47.72 ± 3.12	52.5 ± 4.25
8	59.32 ± 3.12	55.90 ± 6.24	57.95 ± 3.12	54.54± 3.12	53.18 ± 3.54	60 ± 3.12
9	65.45 ± 4.09	61.36 ± 5.41	64.09 ± 3.12	62.04± 1.18	61.36 ± 5.41	68.86 ± 3.12
10	71.59 ± 2.04	70.22 ± 1.18	74.31 ± 3.12	68.18± 2.36	70.22 ± 1.18	75 ± 3.12
11				75 ± 3.12	80.45 ± 4.25	80.45 ± 2.36
12					-	89.31 ± 3.12

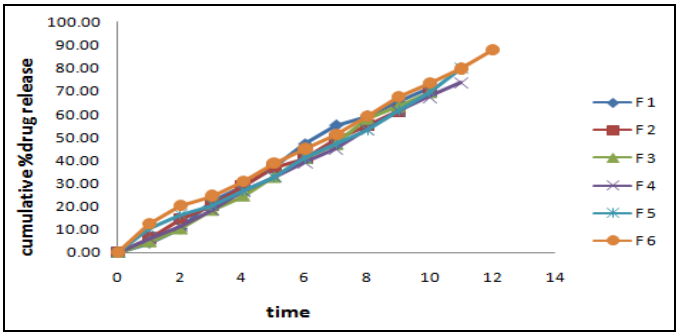

FIG. 13: *IN - VITRO* DISSOLUTION PROFILE OF FORMULATION F1 – F6

CONCLUSION: The present research was carried out to develop mucoadhesive buccal tablets of propranolol using natural polymers *Vigna mungo*. The preparation process was simple, reliable and

inexpensive. All the prepared tablet formulations were found to be good without capping and chipping. The mucoadhesive buccal tablets of propranolol could be prepared using *Vigna mungo* polymer by using wet granulation method. The prepared mucoadhesive buccal tablets subjected to infrared spectrum study suggested that there was no drug -polymer interaction. All the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability and drug content as per pharmacopeial specification. The surface pH of prepared buccal tablets was in the range of salivary pH, suggested that prepared tablets could be used without risk of mucosal irritation.

The buccal tablets showed good swelling up to 6 h in distilled water maintaining the integrity of formulation which is required for bioadhesion. The *in-vitro* release of propranolol was extended for 9 - 12 h. Formulations F6 batch shows good *in- vitro* drug release 89.95%. All the tablets showed good residence time 5 - 6.9 h indicated good adhesive capacity of polymer and all the tablets showed good mucoadhesive strength of 11.53 - 21.75g with high force of adhesion. DSC studies of tablet indicated that there was no drug excipient interaction.

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CONFLICT OF INTEREST: Nil

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