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FORMULATION AND EVALUATION OF SUBLINGUAL TABLET OF METOPROLOL SUCCINATE TO IMPROVE PATIENT COMPLIANCE AND BIOAVAILABILITY

Dodeja Priti * and Gangawane Ritul

Dr. Babasaheb Ambedkar Technological University, Lonere, Dhotre, Ahmednagar - 402103, Maharashtra, India.

Keywords:

Sublingual tablet, Hypertension, crospovidone, Compatibility studies, Direct compression

Correspondence to Author:
Priti Dodeja

Research Scholar,
Dr. Babasaheb Ambedkar Technological University, Lonere, Dhotre, Ahmednagar - 402103, Maharashtra, India.

E-mail: pritidodeja430@gmail.com

ABSTRACT: Metoprolol Succinate is an effective cardio-selective beta-1 blocker, that is used to treat acute disorders such as hypertension and cardiac diseases such as angina pectoris and cardiac heart failure (CHF). Oral route is the most convenient route for introducing different kind of drugs as it is preferred as the safest, cheaper & easiest route. Newly, researchers developed fast disintegrating tablets (FDT) with improved patient compliance. The main motto of this fast-disintegrating sublingual tablet is that is placed under the tongue &disintegrates rapidly within a short span of time in the presence of saliva. First-pass metabolism can be avoided by the sublingual route &the drug directly reaches into the systemic circulation. FDTs manage to overcome from hindrances such as dysphagia in pediatric, geriatric & unconscious patients. The FDTs were formed by different conc. Of super disintegrating agents such as crospovidone by direct compression method. The compatibility study of API & other excipients was studied & determined by DSC & FTIR techniques. The formulation was evaluated by studying various parameters such as solubility, M.P, ph, appearance, thicknesses, hardness, friability, weight variation, wetting time, water absorption, dissolution, disintegration & *in-vitro* drug release. Micromeritics properties of API & other excipients were studied & determined by various parameters such as bulk density, tapped density, angle of repose, Carr's index and Hausner's ratio. Optimized batch F5 containing a quantity of crospovidone 10mg & MCC 30mg was found to be the most stable formulation.

INTRODUCTION: Hypertension is a chronic disorder, where the blood pressure is high and it puts pressure on the heart, leads to hypertensive heart disease and coronary artery disease if not treated at primary stage. To reduce hypertension Selective Beta-1 blockers used. It makes heartbeat more slowly and hence it reduces force, leading to reducing in blood pressure [1]. Tablet is most convenient dosage forms, because of easy administration, small pellet in nature, easy to formulate & prepare which can be delivered in accurate dose.

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One major disadvantage of solid dosage forms is swallowing difficulties, chewing problems for childrens, this might be due to fear of choking, hand tremors and in young age individuals due to poor developed muscular and nervous systems which leads to poor patient compliance. Difficulties in swallowing of tablet and capsule also occur when water is not available, in diarrhea, coughing during the common cold, allergic condition and bronchial infection.

For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have great impact nowadays [2]. If easy swallowing, and thus it is free of risk of choking [3]. United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of

seconds when placed upon the tongue [4]. Fast dissolving tablets are also known as mouth-dissolving tablets, Orodispersible, rapimelts. Most fast-dissolving tablets must include substances to mask the bitter taste of API. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. The fast-dissolving solid dosage form turns into a soft paste or liquid form Fast dissolving tablet have major advantages that there is rapid onset of action, reduce risk of suffocation & avoid hepatic first pass metabolism [5]. The advantage of Fast dissolving tablets over other solid dosage forms is to improve patients' compliance, increased bioavailability and good stability which make them dosage form of choice in the current market [6]. The distribution of dosage includes a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates and adheres onto the site of application, which then rapidly disintegrates and dissolves to release the medication for oral cavity absorption, which will maintain the quick-dissolving characteristic & allow for gastrointestinal absorption to be achieved when swallowed [7]. So, the sublingual drug delivery is most acceptable. Angina pectoris is acute disorder characterized by chest pain or discomfort caused by reduced blood flow to heart [8]. Metoprolol succinate is a cardio selective beta-1 adrenoreceptor used to treat acute disorders such as angina pectoris, CHF, & hypertension. It is a BCS class-1 drug. It has high solubility and high permeability. Metoprolol succinate is freely soluble in water and methanol. The half-life of Metoprolol succinate is approximately 3 to 4 hours. It undergoes extensive first pass hepatic metabolism resulting in 40% oral bioavailability [9]. This review presents the detailed information about FDTs of metoprolol succinate.

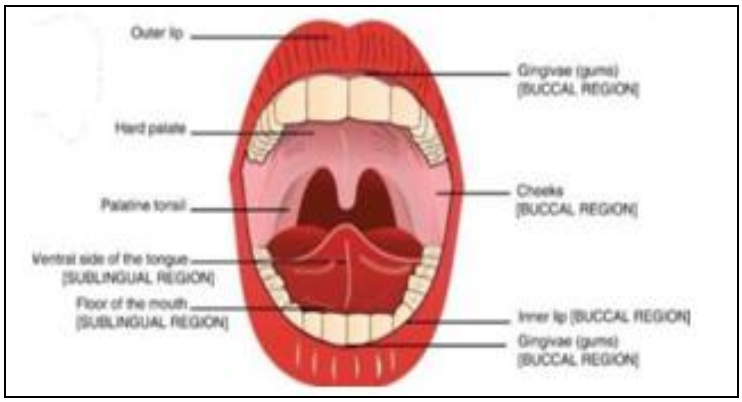


FIG. 1: SCHEMATIC REPRESENTATION OF SUBLINGUAL ROUTE

Need for Development for Metoprolol Sublingual Formulation:

- Patients who have swallowing and chewing difficulties.
- Patients' incompliance due to fear of choking
- Elderly patients of depression who may not be able to swallow the solid dosage forms.
- A patient who travels frequently, or has little or no access to water [10].

MATERIAL & METHOD:

Material: Metoprolol succinate an API was purchased from Balaji chemicals, mannitol used as Directly compressible material, microcrystalline cellulose act as diluent and disintegrating agent, and crosspovidone plays major role of super disintegrating agent whereas starch used as binder and sodium saccharine as sweeting agent to mask bitter taste and talc for lubrication purpose. Using this above-mentioned material sublingual formulation was prepared by direct compression method as follows [11].

Method: Metoprolol succinate or dispersible tablets were prepared by direct compression method. The drug 20 mg was blended, triturated homogeneously until it was found to be homogenous mixture. The resultant mixture was compressed into tablets in 8 mm die cavities using tablet punching machine. Fifteen formulations were prepared by five different formulas, table and quantity as mentioned below [12].

TABLE 1: FORMULATION OF BATCH F1 TO F5 BY DIRECT COMPRESSION TECHNIQUE

Sr. no.	Ingredients	Formulation code in (qty. in mg)				
		F1	F2	F3	F4	F5
1.	Metoprolol succinate	25mg	25mg	25mg	25mg	25mg
2.	Mannitol	128mg	128mg	128mg	128mg	128mg
3.	MCC	36mg	32mg	30mg	28mg	30mg
4.	Crosspovidone	4mg	8mg	10mg	12mg	10mg
5.	Starch	3mg	3mg	3mg	3mg	3mg
6.	Sod. Saccharin	2mg	2mg	2mg	2mg	2mg
7.	Talc	2mg	2mg	2mg	2mg	2mg

Evaluation Parameter: Micromeretic properties of triturated or homogenous blend formulation.

Preformulation Study of Homogenous Powder:

FTIR: An admixture of metoprolol succinate & other excipients which used in preparation their FTIR study was carried out to determine the chemical reactions between the API & the other excipients [13]. The spectrum of pure API drug show characteristic peaks between 2500 to 3000 (OH stretching) 3600 (NH stretching) 1800 (C=C group) 1600-1400 (Aliphatic group) around 3100 & (Aromatic group) around 3000-3900 and (carbonyl group) 1700-1800. All these characteristic peaks of pure drug were found in FTIR spectrum. It reveals that there was no predominant chemical interaction between API & other excipients used. (Scanning from 4,000 to 400cm) [14].

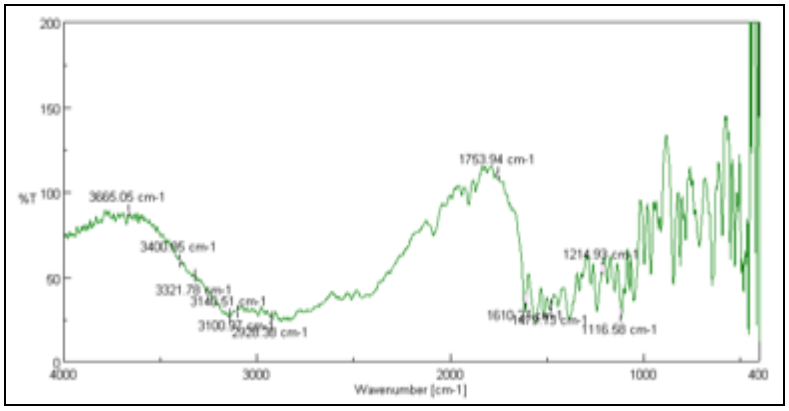


FIG. 2: DISPLAYS FTIR OF PURE METOPROLOLDRUG

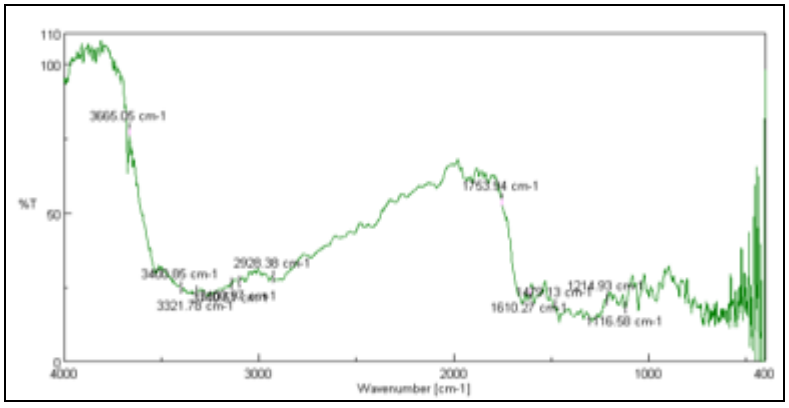


FIG. 3: DISPLAYS FTIR OF API & ADMIXTURE OF ALL EXCIPIENTS USED IN THE FORMULATION

Flow Parameter of Powder: Flow properties were determined by various parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio.

Bulk Density: A quantity of 5gm of metoprolol succinate & admixture of excipients was introduced into a 10 ml measuring cylinder. The weight and volume of the sample was calculated. The bulk volume & weight of powder was determined by following formula [15] **Table 2.**

$$\rho b = W / Vb$$

Where, ρb = Bulk density, Vb = Bulk volume of blend (cm^3) W = Weight of power (gm).

Tapped Density: A quantity of 5gm of metoprolol succinate & admixture of exicipents was introduced into a 10 ml measuring cylinder. That was tapped for 100 times and change in volume & weight was calculated by following the formula [16] **Table 2.**

$$\rho t = W / Vt$$

Where, ρt = Tapped density, Vt= Final volume of blend after tapping (cm^3).

Angle of Repose: It was determined by the funnel method. An accurately weighed 5gm powder of metoprolol succinate & other excipients were poured into the funnel with its tips about 2 cm height (h) from the surface. The blend was discharged from the funnel until the tip of pile of powder touches the lower end of funnel. The mean diameter ® and height were calculated and the angle of repose (°) was calculated using the formula [17, 18] **Table 2.**

$$\text{Angle of repose } (°) = \tan{-1}h/r$$

Carr's Compressibility Index: Carr's compressibility index is determined by following equation [19, 20] **Table 2.**

$$C = (\rho t - \rho b) / \rho t \times 100$$

Where, C = % compressibility, ρb = Bulk density, ρt = Tapped density.

Hausner's Ratio: This is an indirect index of ease of powder flow[21] **Table 2.**

It is calculated by following formula;

$$H = \rho t / \rho b$$

Physical Evaluation Tests: The tablets were tested for post-compression quality control tests such as solubility, ph, appearance, thickness & diameter, hardness, friability, weight variation, wetting time, water absorption ratio, drug content uniformity, dissolution & disintegration, and DSC.

Solubility: Soluble in water, Ethanol (organic & inorganic solvents).

Appearance: Tablets were determined for shape, colour & odor [22].

Thickness and Diameter: The size of tablets was examined by Vernier calipers [23] **Table 3.**

Hardness: The tablet strength was studied by applying pressure required for breaking a tablet into two half. This was determined using Monsanto hardness tester. Five tablets were randomly selected from different formulation and the average hardness was noted [24] **Table 3.**

Friability: This test was performed by placing five different formulation in friabilator, these tablets were Pre-weighed and placed. (Roche friabilator) and rotated at 25 rpmfor 4 minutes. The tablets size was reduced reweighed, and the percentage friability was calculated [25, 26, 27] **Table 3.**

$$\% \text{ Friability} = (W_{initial} - W_{Final} / W_{initial}) \times 100$$

Where, $W_{initial}$ = Initial weight of tablet, W^{Final} = Final weight of tablet

Weight Variation: Twenty tablets were selected randomly from each formulation, weighed individually and the average weight and was calculated [28] **Table 3.**

Wetting Time: The wetting time was determined by using piece of tissue paper that was cut circularly and placed on a petridish containing 6 ml of water at room temperature [29, 30, 31] **Table 4.** A tablet was placed on the flat cutted circular tissue paper and the time required for the complete wetting of the tablet was noted.

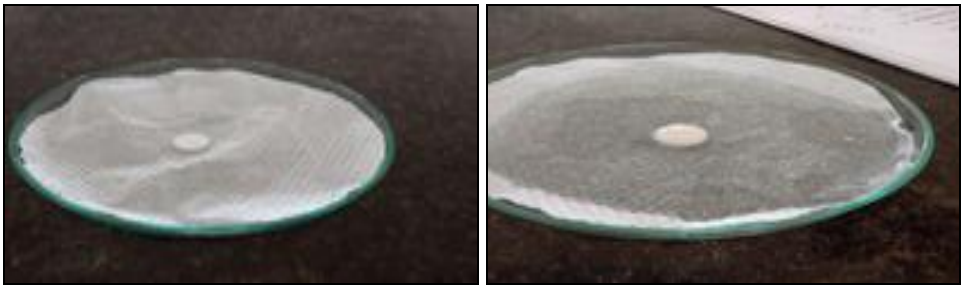


FIG. 4 & FIG. 5: REPRESENTS THE WETTING TIME AT 0 SEC AND 10SEC RESPECTIVELY

Water Absorption Ratio: Tissue paper folded twice was kept in a petridish containing 6 ml of purified water. The formulation was then placed on the tissue paper and allowed to wet completely. The wetted tablet was removed and reweighted [32] **Table 4.** Water absorption ratio (R) is determined by following equation:

$$R = 100 (Wa - Wb) / Wb$$

Where, Wb =Weight of tablet before absorption, Wa =Weight of tablet after absorption.

Disintegration Time: The formulation was disintegrated by various disintegration methods mentioned as below:

Modify Disintegration Test I (Petri Plate Method): In this method, a petridish (10 cm diameter) was filled with 10 ml of purified water. [33, 34, 35, 36].

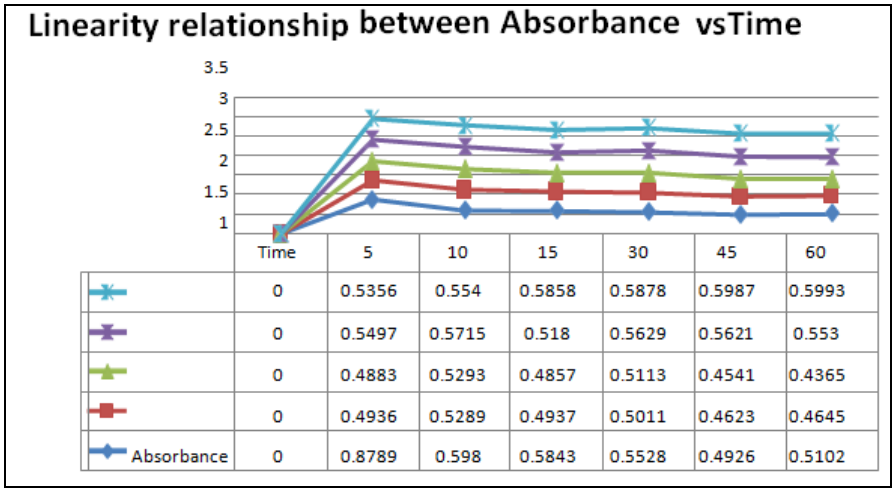
The tablet was carefully placed at the centre of Petri dish and the time required by the tablet to disintegrate completely into fine particles was noted down **Table 4.**

Modified Disintegration Test Method III (Measuring Cylinder Method): It is one of the simplest method in which 6 ml of purified water was taken in a 25 ml measuring cylinder. With the help of a thermometer Temperature was maintained at 37±2°C [37, 38, 39].

The tablets were placed down into it and t required time to complete disintegrate was noted down **Table 4.**

FIG. 6, 7: REPRESENTS DIFFERENT KIND OF DISINTEGRATING TYPES DEPENDING ON THE APPARATUS SUCH AS PETRI PLATE METHOD SEEN IN FIG. 7 AND MEASURING CYLINDER METHOD SEEN IN FIG. 6

***In-vitro* Dissolution:** The dissolution study was determined using USP Type I (Basket type) dissolution apparatus. This was conducted in 900 ml at ph 7.2 which is of saliva and temperature was maintained at 37 °C and 50 rpm (rotation per minute). 5ml of sample was pipette out and make upto 10ml with buffer solution respectively at various time intervals (5min, 10min, 15min, 30min, 45min, 60 min). The pipette out sample was then again replaced with same volume of fresh pH that is pH 7.2 of saliva and temperature maintained at 37°C and 50 rpm. The API in the sample was then determined using spectrophotometrically at λmax of 222 nm. The results were expressed in the form of graph as given below [40].



Time	5	10	15	30	45	60
0	0.5356	0.554	0.5858	0.5878	0.5987	0.5993
0	0.5497	0.5715	0.518	0.5629	0.5621	0.553
0	0.4883	0.5293	0.4857	0.5113	0.4541	0.4365
0	0.4936	0.5289	0.4937	0.5011	0.4623	0.4645
Absorbance 0	0.8789	0.598	0.5843	0.5528	0.4926	0.5102

According to the above-mentioned readings, we can conclude that the batch of F5 is the most stable from this different formulation batch.

OBSERVATION AND RESULTS:

Determination of λmax of Metoprolol succinate in phosphate buffer pH 6.8 shown in Fig. 8:

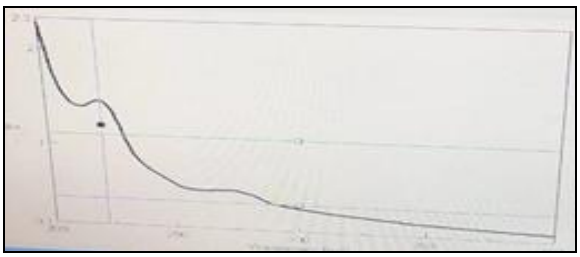
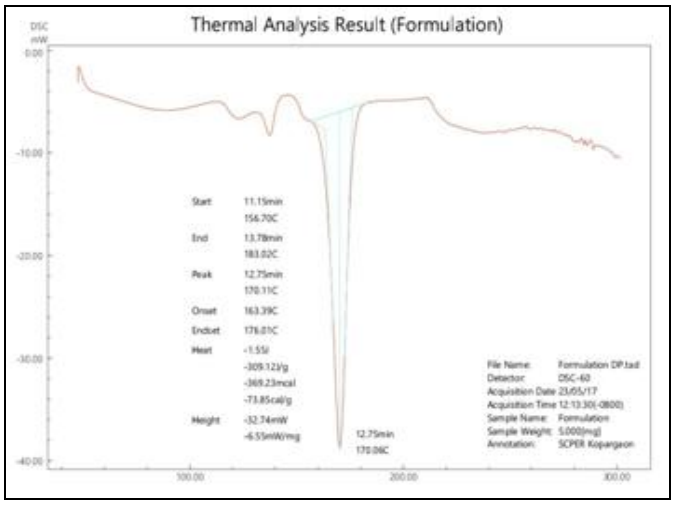


FIG. 8: ΛMAX OF METOPROLOL SUCCINATE IN PHOSPHATE BUFFER PH 6.8

Compatibility Study: It is carried out by two methods-FTIR and DSC.

DSC (Differential scanning Calorimetry): It provides information on melting, crystallization, decomposition or change in heat capacity & it is useful to assess the physicochemical status of entrapped drug as well as interaction among different excipients.

The compatibility study was performed by Differential Scanning Calorimetry (DSC) and found that there was no any interaction between Metoprolol succinate and excipients. As shown in **Fig. 8 and Fig. 9** [41]**.**



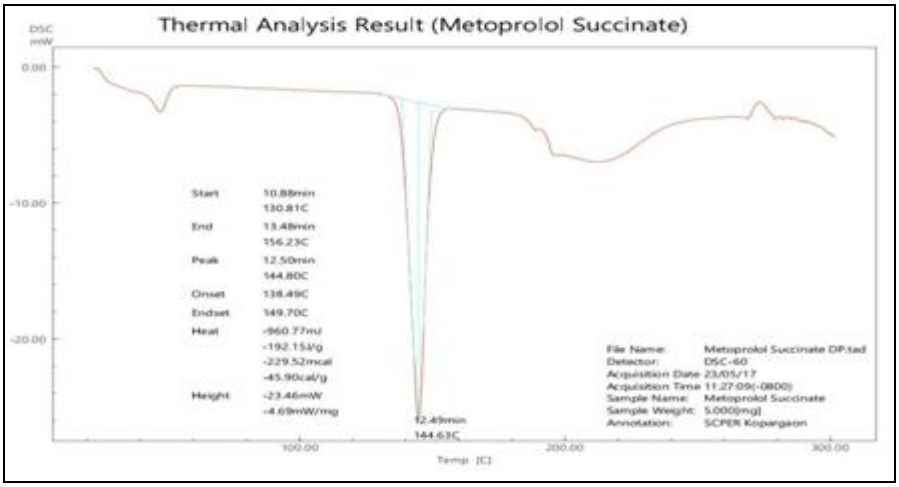


TABLE 2: EVALUATION OF MICROMERITICS PROPERTIES OF ADMIXTURE

Sr. no.	Formulation code	Bulk density	Tapped density	Angleof repose	Carr's Index	Hausner Ratio
1.	F1	0.479	0.529	19.3	5	1.10
2.	F2	0.476	0.501	19.0	2.5	1.05
3.	F3	0.472	0.530	18.9	5.8	1.12
4.	F4	0.483	0.526	20.4	4.3	1.08
5.	F5	0.470	0.500	19.6	3	1.06

TABLE 3: EVALUATION OF TABLETS

Sr. no.	Formulation code	Hardness	Thickness (mm)	Diameter (mm)	% Friability	Weight variation
1.	F1	3.1±0.18	1.1±0.05	9.4±0.01	±0.01	0.18±0.02
2.	F2	3.0±0.15	1±0.03	8.9±0.06	±0.02	0.16±0.05
3.	F3	3.1±0.19	1.2±0.02	9.2±0.03	±0.1	0.17±0.03
4.	F4	3.3±0.22	1.1±0.01	9.7±0.01	±0.03	0.18±0.02
5.	F5	3.2±0.20	1.0±0.02	9.4±0.04	±0.01	0.20±0.01

TABLE 4: DISINTEGRATION TIME, WETTING TIME, WATER ABSORPTION RATIO AND DRUG CONTENT UNIFORMITY OF FORMULATION F1 TO F8

Sr. no.	Formulation code	Wetting time (sec)	Water absorption ratio	Disintegration time (sec)	In-vitro dispersion time (sec)
1.	F1	22	102	21	88
2.	F2	21	100	20	93
3.	F3	14	90	17	46
4.	F4	12	92	19	61
5.	F5	18	93	19	46

CONCLUSION: The fast-disintegrating sublingual dosage form of Metorolol succinate offers fast release of drug beneath the tounge and it reaches the systemic circulation directly with improved patient compliance particularly for those who have difficulty in swallowing. From the above results we can concluded that 10mg of cross povidone and 30mg of MCC gives immediate release of drug as compare to other formulation batch.

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CONFLICTS OF INTEREST: Nil

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