

# Screening, Development and Optimization of an herbal film former for the purpose of film coating of losartan potassium tablets

Mr. Ayan Kumar Kar<sup>1</sup>, Miss Banhishikha Kar<sup>2</sup>, Dr. Amitava Roy<sup>3</sup>, Mr. Hiranmoy Parya<sup>5</sup>, Dr. Jyotirmoy Dev<sup>4</sup>

<sup>1,2,5</sup>Department of Pharmaceutics, Calcutta Institute of Pharmaceutical Technology & AHS, Banitabla, Uluberia-721636, Howrah, West Bengal, India.

<sup>3</sup>Department of Pharmaceutics, Himalayan Pharmacy Institute, Majitar, Rangpo, East Sikkim, West Bengal, India.

<sup>4</sup>Department of Pharmacy, HUDA Group of Institutions, Nagaon, Assam.

Email : ayancipt@gmail.com<sup>1</sup>

**Abstract:** Film coated Losartan potassium tablet was prepared by the wet granulation method with a coat consisting of different proportion of the respective synthetic polymer hydroxypropyl methyl cellulose and the natural herbal polymer *Moringa Oleifera* which is the main objective of my project work for its gum, exudates and adhesive yielding properties. *Moringa Oleifera* belongs to a monogeneric family, the *Moringaceae*. Water based extraction procedure was used to extract the gum that is used for the purpose of film coating on a model drug, namely losartan potassium tablets to retard its release. Primary development of the coating formulation has done on the basis of optimization of different in-process physical parameters. Hence, there is no interaction between drug and polymers used in the study. After coating with different proportion of synthetic and extracted natural polymer, primarily visual observation was done to show the normal defect during the preliminary coating procedure like chipping, cracking etc. Simultaneous evaluation of the uncoated and coated tablets for its physical performances like disintegration, hardness etc was satisfactory. The release data was analyzed according to different kinetic equations where it is normally said to follow non-fickian anomalous release. The stability study was carried based on the best formulation.

**Keywords:** Moringa Oleifera1; Losartan Potassium2; Hydroxypropyl methyl cellulose3; Wet granulation method4.

## 1. INTRODUCTION

The oral route of drug administration is the most important method of administering the drugs to the systemic effects. Solid dosage forms represent the preferred class of the product. Among the drugs administered orally, solid dosage forms represent the preferred choice of class of product. Most common solid oral dosage forms are tablets and capsules. Tablets and capsules account for well over half the total number and cost of all prescription issued. In December 1843, a patent was granted to the Englishman, William Brockedon, for a machine to compress powders to form compacts. The invention was first used to produce compacts of potassium bicarbonate and caught the imagination of a number of pharmaceutical companies. Later, in Britain the first company was to use the term tablets to describe the compressed dosage forms. Generally, tablets are oral, solid, unit dosage form containing one or more than one medicaments. It is normally swallowed with

water but some tablets may be chewed, dissolved or dispersed in water before administration or some are retained in the buccal cavity of the mouth<sup>[1]</sup>. The granulation process combines one or more powders and forms a granule that will allow the tableting process to be predictable and will produce quality tablets within the required tablet-press speed range. A tablet formulation contains several ingredients, and the active ingredient is the most important among them. The remaining ingredients are necessary because a suitable tablet cannot be composed of active ingredients alone. The tablet may require variations such as additional bulk, improved flow, better compressibility, flavoring, improved disintegration characteristics, or enhanced appearance<sup>[2]</sup>. Losartan Potassium is the first of a new class of drugs to be introduced for clinical use in hypertension. It is an orally active, non-peptide angiotensin II receptor (type AT1) antagonist. Angiotensin receptor blockers (ARBs) represent an

important therapeutic advance in the blockade of the rennin-Angiotensin pathways. Losartan is an orally active agent that undergoes substantial first pass metabolism by cytochrome P450 enzymes. It is converted, in part, to an active carboxylic acid metabolite which is also responsible for Angiotensin-II receptor antagonism that follows Losartan treatment. In vitro studies indicate that cytochrome P450, 2C9 and 3A4 are involved in the biotransformation of Losartan to its metabolite. Oral absorption of Losartan is not affected by food, but bioavailability is only 33% due to first pass metabolism. It is partially carboxylated in liver to an active metabolite E3174 which is a 10-30 times more potent noncompetitive AT<sub>1</sub> antagonist<sup>[3]</sup>.

The Miracle Tree<sup>[4]</sup>, *Moringa Oleifera* is the most widely cultivated species of a monogeneric family, the *Moringaceae* that is native to the sub-Himalayan tracts of India, Pakistan, Bangladesh and Afghanistan. This tree has in recent times been advocated as an outstanding indigenous source of highly digestible protein, Ca, Fe, Vitamin C, and carotenoids suitable for utilization in many of the so-called “developing” regions of the world where undernourishment is a major concern. All parts of the tree are considered to possess medicinal properties and used in the treatment of ascites, rheumatism, venomous bites and as cardiac, circulatory stimulant and others<sup>3</sup> which is shown in Figure 1<sup>[5]</sup>.

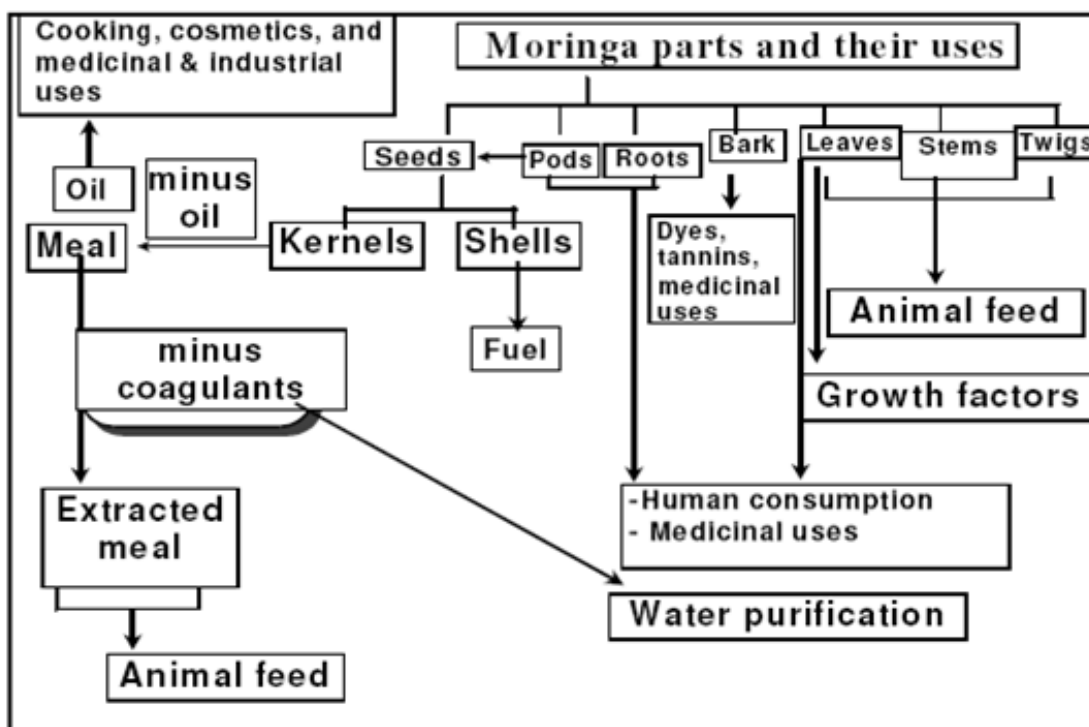


Figure 1: Use of different parts of *Moringa Oleifera* tree.

## 2. MATERIAL AND METHODS

Losartan Potassium was obtained as a gift sample from Orchid Pharmaceuticals Ltd, Chennai. Hydroxy propylmethyl cellulose was obtained from Loba Chemie Pvt. Ltd., Mumbai. Other chemicals like lactose, PVP, starch and talc was obtained from S.D. Fine Chem. Limited, Mumbai. The *Moringa Oleifera* exudates were collected from the local areas of the

Himalayan region and PEG- 4000, Propylene Glycol, Glycerine were purchased from S.D Fines Chemical, Mumbai. All other chemicals were used as analytical grade.

### Preparation of *Moringa Oleifera* Extract<sup>[6]</sup>:-

Collection of the exudates:-

The fresh exudates were collected from the fully grown *Moringa Oleifera* trees growing local areas of the Himalayan region. The bark of the trees were scrapped off and left undisturbed for 7-10 days. The scrapped portions were covered with a cotton membrane to prevent exposure to direct sunlight. The exudates in the form of the hard lumps were collected by using a hard knife after 10<sup>th</sup> days.

*Preparation of the Moringa oleifera powder (polymer):-*

Purified water was found to be the best solubility's medium for *Moringa oleifera*. This was done by addition of the powder extracts with water on a glass beaker and was heated up to 60-70<sup>o</sup>C with continuous stirring. Once the powder gets dissolved within the aqueous phase, the whole content was poured on a Maslin cloth for filtration and the filtrate was collected in another glass beaker. The filtrate was mixed with an antioxidant, ascorbic acid to prevent any further oxidative damages and a edible preservative, methyl paraben to prevent the further microbial degradation. The filtrate was sprayed on a previously clean tray dries and subjected to dry on an hot air oven(lab instruments, siliguri) at 40<sup>o</sup>±2<sup>o</sup>C, After 2 days of drying the flakes obtained at the bottom were collected and was crushed in the mill (Shakti engineering, India). The powders were collected and were stored in a completely air-tight zipper pack for further use.

*Determination of λ<sub>max</sub> by scanning and Preparation of Standard Graph of losartan potassium:-*

About 100mg Losartan potassium powder were weighed out accurately and taken in respective 100 ml volumetric flask and Kept 10 min with some amount of water for complete reaction. Finally the

volume was made up to mark with the water. The absorbance was measured at 205.5 nm in UV visible Spectrophotometer (UV-1700, Shimadzu, Japan) against a blank. A graph was plotted by taking concentration vs. absorbance. The slope and regression value was calculated from the graph which is given in Figure 2.

*Fourier Transform Infrared Radiation measurement (FTIR)<sup>[7]</sup>:-*

To determine any interaction between drug and polymer, Fourier Transform Infrared (FTIR-840, Shimadzu, Japan) study was carried out. FTIR was recorded on FTIR-840, Shimadzu, Japan. Samples were triturated with potassium bromide and transform into the disk. Disk was applied to the centre of the sample holding device and scanned between 4000-400 cm<sup>-1</sup> at a resolution of 2 cm<sup>-1</sup>. The IR scans were processed using IR solution and represented as percentage transmittance (% T) on a common scale. The FTIR study of pure drug, Losartan Potassium and the extracted herbal polymer, *Moringa Oleifera* was given in Figure 3 and Figure 4 and the interaction study of drug with polymers was also given in Figure 5 and Figure 6.

*Preparation of coating solution<sup>[7],[8]</sup>:-*

In a 200 ml clean beaker about 100 ml of purified water was measured and the weighed amount of natural polymer *Moringa Oleifera* was added and allowed to soak overnight. Next morning, it was stirred using a magnetic stirrer (Remi motors, Mumbai) for 10-20 minutes to get a uniform dispersion of the polymer solution. Other ingredients such as plasticizer, opacifier, colouring agent were added gradually in required qualities which is given in Table 1.

Table 1: Different ratio of the coating solution.

Formulations	Moringa Oleifera	HPMC	Plasticizer (Glycerine)	Colourants	Opacifier (T <sub>2</sub> O)	Distilled Water
F1 (%)W/W	-----	2	2	0.6	1.5	q.s.
F2 (%)W/W	-----	4	2	0.6	1.5	q.s.
F3 (%)W/W	-----	6	2	0.6	1.5	q.s.

F4 (%)W/W	-----	8	2	0.6	1.5	q.s.
F5 (%)W/W	2	----	2	0.6	1.5	q.s.
F6 (%)W/W	4	----	2	0.6	1.5	q.s.
F7 (%)W/W	6	----	2	0.6	1.5	q.s.
F8 (%)W/W	8	----	2	0.6	1.5	q.s.

Table 2:-The different adjusted process variables

Process variables	Adjusted specifications
Pan design/Baffling	1 feet diameter with no baffles.
Rotational speed of the pan	40 rpm
Spray pressure (operational)	60-70 pound per square inch (p.s.i.)
Bed to Gun distance	1-1.5 feet
Bed temperature	40±5 <sup>0</sup> c
Spray pattern type	Circular
Heating Source	IR-Lamp (150 watt, 250 volt)

***Preliminary coating procedure<sup>[8]</sup>:-***

Two hundred tablets of Losartan Potassium were loaded on a lab-scale pan coater previously cleaned, dedusted. The coating liquid was filled into the spray gun with pneumatic pump attachment. The pan was rotated at 40 rpm for obtaining a cascading fall of tablets. All the parameters were previously adjusted with dummy tablets as shown below. As the tablets rolled, the film forming liquid was sprayed intermittently allowing the solvent to evaporate. The process was continued until all the coating solution was used up. The different specification of coating procedure was shown in Table 2.

***Formulation of losartan potassium tablets<sup>[9]</sup>:-***

Granules were prepared using the conventional wet granulation technique. According to the ratio given in the Table 3, appropriate amounts of excipients and drug for each batch were weighed and added into a mortar. The drug powder was properly mixed with PVP, Talc for 20 min. Starch paste was prepared and added to moisten the granules. The coherent mass was passed through a 12 mesh screen sieve and dried in an oven (Lab instruments and Chemical works, Siliguri.) at 60 °C for 50 min. Dried granules were forced through a 8/12 mesh, lubricated with magnesium stearate and purified talc and then compressed on a single punch tablet machine (Shakti engineering, Siliguri). The tablets were round and flat with an average diameter 0.603± 0.065 cms.

Table 3: Formulation ratio of Losartan potassium tablet.

<b>Drug</b>	10 gm
<b>Drug : Diluent(Lactose)</b>	1:3
<b>Drug : Binder(Polyvinyl Pyrollidone)</b>	1:0.25
<b>Drug : Disintegrant(Starch)</b>	1:0.5
<b>Drug : Glidant(Talc)</b>	1:0.25

### 3. EVALUATION STUDY

#### *Evaluation of Physical parameters*<sup>[10], [11]</sup>:-

Pre formulation testing is the first step in the rational development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance combined with excipients. The overall objective of pre-formulation testing is to generate information useful to the formulator in developing stable and bio available dosage forms that can be developed to an industrial scale. Before compression process, the prepared granules were evaluated for flow properties such as angle of repose and bulk density and tapped density shown in Table 4. From the data obtained, compressibility index, Hausner ratio was calculated shown in Table 4. After compression of prepared tablets, the prepared tablets are further evaluated for the physical parameters like weight variation, thickness, hardness, moisture content and friability. The weights and thickness of twenty tablets of losartan potassium were measured using digital balance and a digital screw gauge, respectively given in Table 7. The hardness of core tablets which is given in Table 8 was measured by Monsanto hardness tester (Testing Instrument, Kolkata, India) and results were expressed in kg/cm<sup>2</sup>. Friability is a measure of mechanical strength of tablets. Roche friabilator (Testing Instrument, Kolkata, India) was used to determine the friability which is given in Table 7. Losartan potassium loaded coated tablet were evaluated for percentage of moisture loss which sharing an idea about its hydrophilic nature given in Table 8. The average values, standard deviation, and relative standard deviation were calculated.

#### *Drug Content*<sup>[11]</sup>:-

Prepared coated and uncoated tablet of Losartan Potassium from a batch was taken at random and was crushed to a fine powder. The powdered material was transferred into a 100 ml volumetric flask and 70 ml of distilled water was added to it. It was shaken occasionally for about 30 minutes and the volume was made up to 100 ml by adding distilled water. About 10 ml of the solution from the volumetric flask was taken and centrifuged. The supernatant solution from the centrifuge tube was collected and again filtered by using Millipore filter. Then the filtrate was subsequently diluted and the absorbance was measured at 205.5 nm by UV spectrophotometer (Shimadzu Spect-1700, Japan). This test was repeated three times (N=3) for each batch of tablets. The amounts of Losartan Potassium estimated from different batches were given in Table 8.

#### *Disintegration Test*<sup>[12]</sup>:-

Disintegration tester (Excel enterprise, Kolkata, India) was used to determine the resistance or breaking time of the selected aqueous film coated tablets. Three tablets were randomly selected from each batch and one tablet was placed in each of the five tubes. The basket rack was positioned in a one-liter beaker of water at 37±5<sup>0</sup>c. Perforated auxiliary disc were placed on the bottom. The instrument was operated and the time taken for a tablet to disintegrate and all the particles to pass through the No. 10 USP mesh apertures was noted according to USP/IP. The average time is reported. All methods of this experiment were performed in triplicate manner and average value is taken. The disintegration time of Losartan Potassium tablet estimated from different batches were given in Table 7.

#### *In-Vitro drug release studies*<sup>[11]</sup>:-

The release measurements were performed using 8 stage USP dissolution apparatus (VDR-8DR, Veego). The dissolution rates of manufactured film coated Losartan Potassium tablets with HPMC (F1, F2, F3, F4) and with herbal polymer Moringa Oleifera (F5, F6, F7, F8) and were studied using Veego dissolution test apparatus (USP II) rotating paddle method under sink conditions at 37±0.5<sup>0</sup> c and 50 rpm. The tablets were placed in the basket and tested for drug release for 5 hours in the water. The samples each of 5ml were taken at appropriate time intervals, filtered and assayed using UV-1700 Shimadzu spectrophotometer

at 205.5nm wavelength respectively. The data for percent drug release was fitted for zero order equation. The percent of drug release was determined as a function of time. All methods of this experiment were performed in triplicate manner for each batch and average value is taken.

To elucidate kinetics of drug release from the prepared coated & uncoated losartan potassium tablets, cumulative release and cumulative percentage of drug remained was plotted as the function of time (t) in the following equations<sup>[14]</sup>.

$$Q = K_0t \quad \text{Zero order equation. Eq. (1)}$$

$$Q = 100 (1 - e^{-kt}) \quad \text{First orders equation. Eq. (2)}$$

$$Q = K_H t^{1/2} \quad \text{Higuchi equation. Eq. (3)}$$

$$\text{Log } Mt/M_\infty = n \text{ Log } t + \text{log } K_p \quad \text{Peppas \& Korsmeyer equation. Eq. (4)}$$

Q for Eq. (1) and (3) is cumulative percent drug release. While Q for Eq. (2) is cumulative percent drug remaining. K is the rate constant, and  $Mt/M_\infty$  is the fraction of drug released. Value of K and n were calculated from the intercept and the slope of plot of  $\text{log } Mt/M_\infty$  vs  $\text{log } t$  for Eq. (4). n-value from Eq. (4) considered as release exponent indicating the mechanism of drug release was chosen as a response variable to help characterize the shape of dissolution release curve and to determine the under lying release mechanism governing release of drug from the

dosage form. The In-Vitro release data of different batches to various kinetics models was given in Table 9.

#### Accelerated Stability Studies<sup>[11], [13]</sup>:-

The formulation which showed good in vitro performance was subjected to accelerated stability studies which carried out by investigating the effect of temperature on the physical properties of tablets and drug release from compressed tablets containing Losartan potassium. The formulations were stored in room temperature at  $25 \pm 1^\circ\text{C}$ , and in refrigeration condition at  $4 \pm 1^\circ\text{C}$  for a period of 3 weeks. The samples were analyzed for drug content every week by spectrophotometer at 205.5 nm and compatibility of drug with excipients was determined by IR spectroscopy using shimadzu FTIR-840 model IR spectrophotometer. Percent of potency data of the formulation was given in Table 10.

#### 4. RESULT AND DISCUSSION

Film coated Losartan potassium tablet was prepared by the direct compression method with a coat consisting of different proportion of the respective synthetic polymer hydroxypropyl methyl cellulose and the natural herbal polymer *Moringa Oleifera* which is the main objective of my project work for its gum, exudates and adhesive yielding properties. Micromeritic study of pure drug powder to determine the flow ability (angle of repose, bulk density, tapped density etc) was done & given in the table 4. Standard graph of losartan potassium drug powder was also prepared and the correlation coefficient (r) was found to be 0.999 respectively. The standard graph of the pure drug is shown in Figure 2.

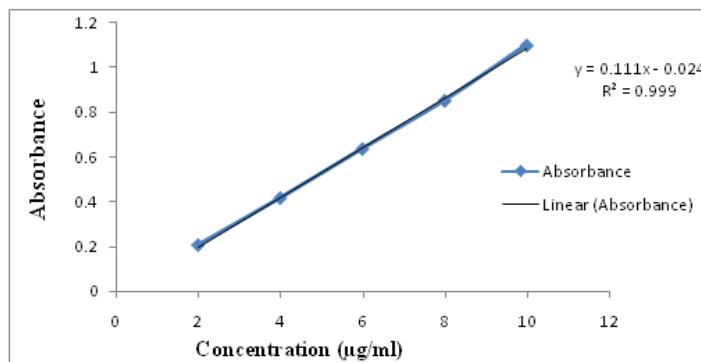


Figure 2: Calibration Curve of Pure Drug, Losartan Potassium.

Table 4:- Micromeritic analysis of Losartan potassium granules.

<b>Granules</b>	Losartan Potassium granules
<b>Colour</b>	White/ Off-white powder
<b>Angle of Repose (<math>\theta</math>)</b>	27.389 $\pm$ 0.6740
<b>Tapped Density</b>	0.692 $\pm$ 0.075
<b>Bulk Density</b>	0.593 $\pm$ 0.053
<b>Hausner Ratio</b>	1.167
<b>Car's Index</b>	0.130
<b>% of Compressibility</b>	13.00
<b>Ph</b>	5
<b>Melting Point</b>	275-280 <sup>0</sup> c
<b>Solubility</b>	Freely Soluble – Water & methanol. Soluble – 0.1 N HCL Slightly Soluble – Chloroform, Toluene, Isopropyl alcohol.

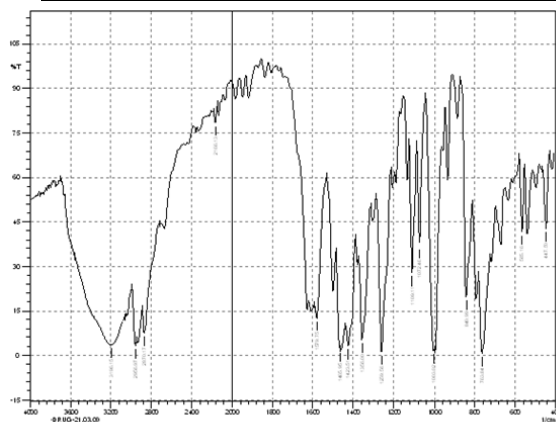


Figure 3: FTIR Study of Pure Drug, Losartan Potassium.

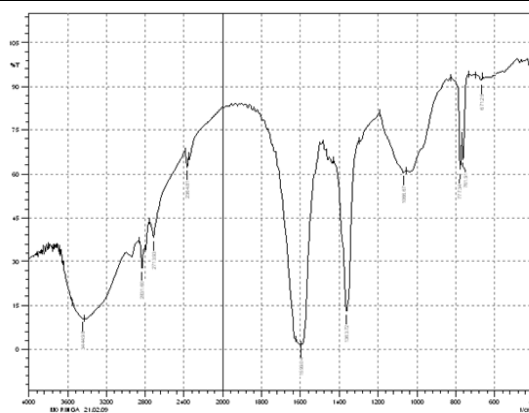


Figure 4: FTIR Study of Herbal Polymer, *Moringa Oleifera*.

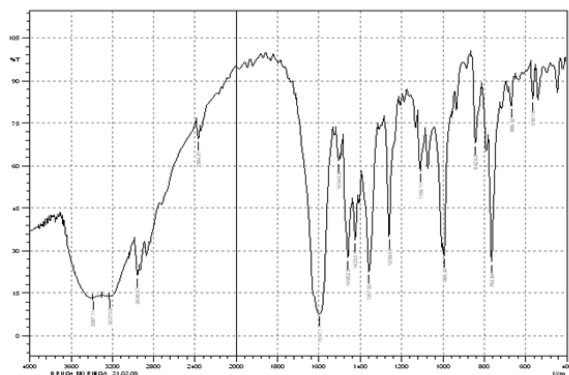


Figure 5: FTIR Study of Drug, Losartan Potassium with Herbal Polymer, *Moringa Oleifera*.

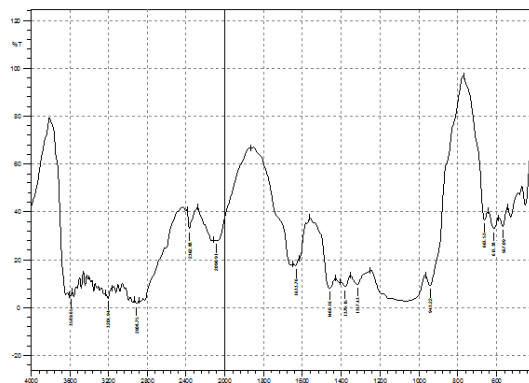


Figure 6: FTIR Study of Drug, Losartan Potassium with Synthetic Polymer, HPMC

Uncoated losartan potassium tablets were coated with different proportion of hydroxypropyl methyl cellulose and the herbal polymer, *Moringa Oleifera*. After coating, primarily visual observation was done to show the normal defect during the preliminary coating procedure like chipping, cracking etc. which is shown in Table 5 and table 6. The photograph of uncoated and coated tablet with different proportion of synthetic polymer as well as extracted herbal

polymer was shown in Figure 7. The films formed with 4% Hydroxypropyl methyl cellulose (F2) were free from major defects like blistering, blooming, cracking, chipping, orange peel, roughness, having good gloss with very slight sticking than other formulations and the films formed with 6% *Moringa oleifera* (F7) were free from major defects with having good gloss than other formulations.

Table 5:- Visual observation for defects in the formulations containing HPMC coat.

Defects	F1	F2	F3	F4
Blistering	++	--	+	+++
Blooming	++	--	+	+++
Chipping	+	--	+	+++
Cracking	+	--	+	+++
Orange Peel	+	--	--	++
Roughness	++	+	+	+++
Sticking	++	+	++	+++
Edge erosion	+	--	--	++

Values expressed in mean± Standard Deviation (n=5). Yes- (+++), No- (--), Slight- (++) , Very slight- (+)



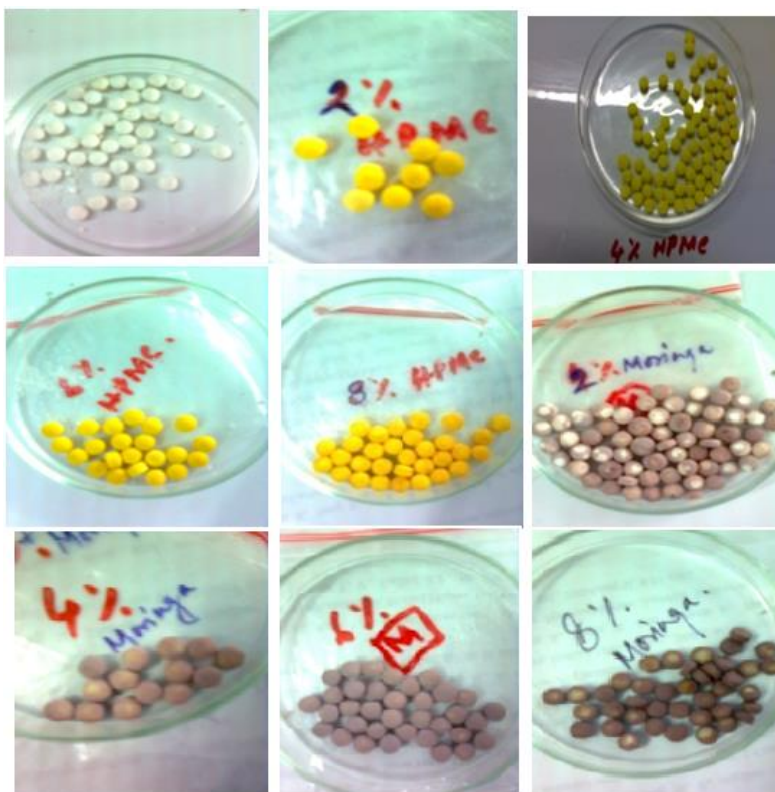


Figure 7: Photograph of uncoated and coated Losartan Potassium tablets.

Table 6:- Visual observation for defects in the formulations containing Moringa Oleifera coat.

Defects	F5	F6	F7	F8
Blistering	++	++	--	+++
Blooming	+	+	--	++
Chipping	++	+	--	+++
Cracking	+	--	--	++
Orange Peel	+	+	--	++
Roughness	++	+	+	+++
Sticking	++	+	+	+++
Edge erosion	+	--	--	++

Values expressed in mean± Standard Deviation (n=5). Yes- (+++), No- (--), Slight- (++) , Very slight- (+)

Primary evaluator parameters of Uncoated & coated losartan potassium tablets like thickness & diameter, weight gain, drug content etc were summarized in Table 7 and Table 8. The thickness of the tablets prepared with different ratio of HPMC and Moringa Oleifera were found to be in between 3.3 to 3.9 cm. A low standard deviation value in the coated tablets thickness measurement confirms uniformity of films prepared by the film coating procedure. The percent of moisture content (% W/W) of the prepared coated formulation with Synthetic polymers, HPMC were found in between 0.54 to 0.58 (% W/W) and the percent of moisture content with the herbal polymer, Moringa Oleifera were found in between 0.65 to 0.68

(% W/W). It was observed that with increase in hydrophilic polymer concentration the moisture content was also increasing, for different formulations containing the synthetic polymer, HPMC and the herbal polymer, Moringa Oleifera. The percent drug content of different formulations prepared was found in between 90 to 91 %. Hardness of the tablets was satisfactory and the weight loss in friability test was significant in all the batches with respect to the uncoated formulation. Overall the prepared batches were of good quality with regard to hardness, friability, weight uniformity and drug content.

Table 7:- Primary evaluation parameters for uncoated and coated tablets of Losartan potassium tablets.

<b>Formulation</b>	<b>Thickness (mm)</b>	<b>Diameter (mm)</b>	<b>Weight Gain</b>	<b>Friability (%)</b>	<b>Disintegration Time</b>
Uncoated	3.3 ±0.02	6.0±0	Nil	0.42±0.01	14 min 18 sec ± 3 sec
F1	3.4±0.02	6.3±0.02	0.6±0.02	0.44±0.02	15 min 21 sec ± 7 sec
F2	3.44±0.01	6.3±0.02	0.7±0.01	0.35±00.01	15 min 57 sec ± 3 sec
F3	3.53±0.02	6.4±0.01	1.00±.02	0.39±0.02	16 min 42 sec ± 5 sec
F4	3.71±0.04	6.6±0.02	1.6±0.04	0.46±0.02	18 min 54 sec ± 5 sec
F5	3.5±0.02	6.4±0.02	2.1±0.02	0.5±0.03	15 min 38 sec ± 4 sec
F6	3.62±0.02	6.5±0.01	3.2±0.01	0.47±0.01	16 min 22 sec ± 4 sec
F7	3.67±0.02	6.4±0.02	3.5±0.01	0.43±0.01	17 min 50 sec ± 3 sec
F8	3.93±0.02	6.7±0.03	5.1±0.04	0.51±0.03	19 min 56 sec ± 6 sec

Table 8:- Primary evaluation parameters for uncoated and coated tablets of Losartan potassium tablets.

Formulation	Moisture Loss (%)	Drug Content (%)	Hardness (kg)
Uncoated	0.54±0	90±1	5.2±0.1
F1	0.57±0.01	90±1	5.2±0.1
F2	0.56±0.01	90±1	5.2±0.1
F3	0.56±0.02	90±0.98	5.2±0
F4	0.58±0.01	90±0.98	5.2±0.1
F5	0.65±0.02	90±1	5.2±0.2
F6	0.64±0.01	90±1	5.2±0.1
F7	0.68±0.01	90±1	5.2±0.01
F8	0.68±0.01	90±0.99	5.2±0

Values expressed in mean ± Standard Deviation (n=3)

From the above *in-vitro* release profile of all four formulations of HPMC (F1, F2, F3, F4), it can be seen that F2 shows 88.173% cumulative drug release over the period of 5 hr and that formulation gives the better result than other formulation. Similarly, from all four formulations of *Moringa oleifera* coated losartan potassium tablets, it can be shown that F7 showed 88.873% cumulative drug release over the period of 5 hr and that formulation gives the better release than other formulations. To describe the kinetic of drug release from coated Losartan

potassium tablets, release data was analyzed according to different kinetic equations described in text. The zero order, first order, Higuchi model and Peppas-Korsmeyer equation represent diffusion exponent, in all formulation it is in between 0.45 to 0.89, so it is normally said to follow non-Fickian anomalous release shown in the Table 9. Comparative studies were also done in-between the uncoated and coated losartan potassium tablets with HPMC and *Moringa Oleifera* which was carried out on the Figure 8 and Figure 9.

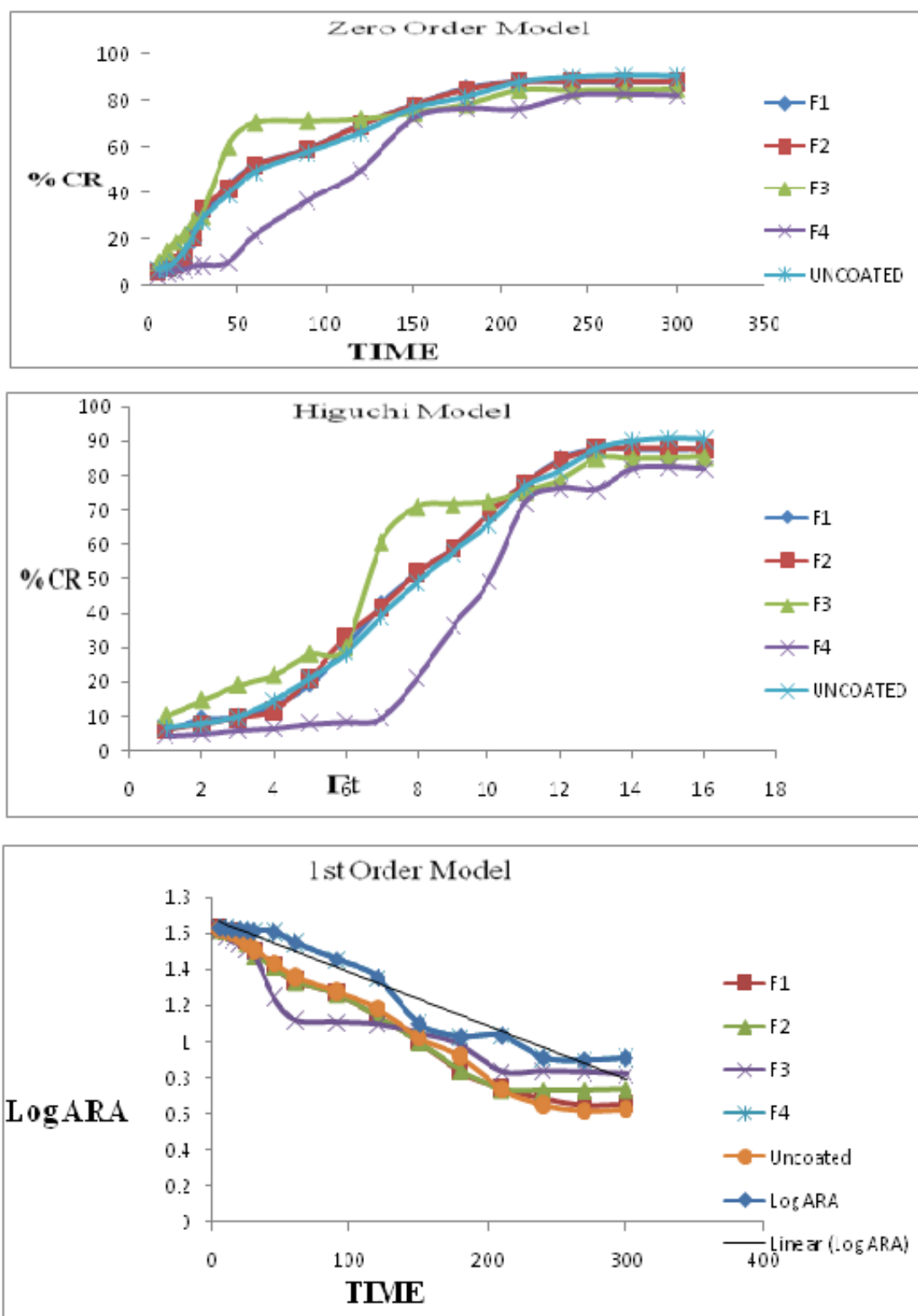
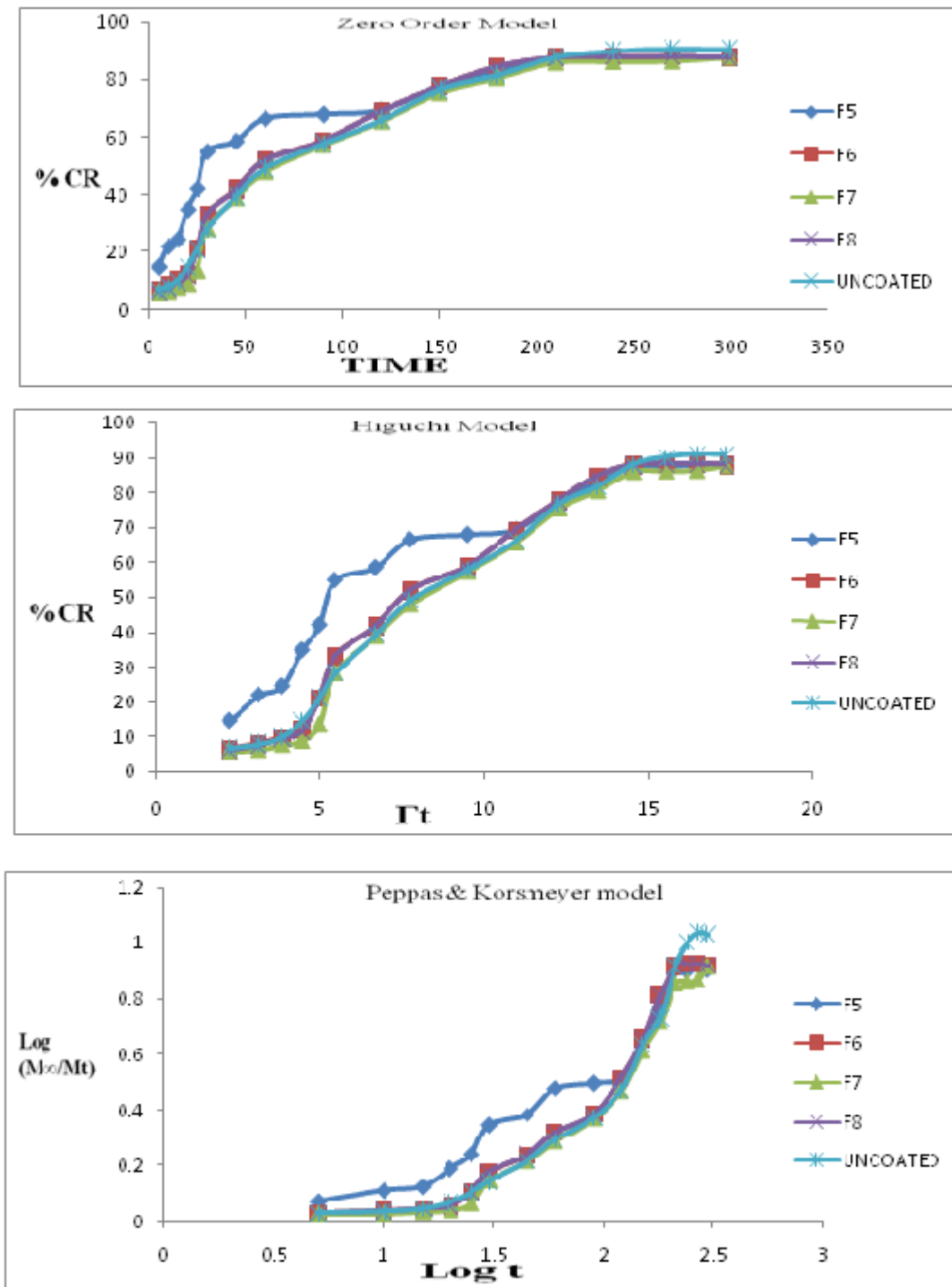


Figure 8: Comparative study of release profile uncoated Losartan Potassium tablet and tablet coated with different proportion of HPMC



**Figure 9: Comparative study of release profile of uncoated Losartan Potassium tablet and coated with different proportion of herbal polymer, Moringa Oleifera (F5, F6, F7, F8)**

Table 9:- In-vitro drug release Data to Various Release Models.

		Zero Order model		1 <sup>st</sup> Order Model		Higuchi model		Peppas- korsmeyer model	
Formulation		R <sup>2</sup>	K <sub>0</sub>	R <sup>2</sup>	K <sub>1</sub>	K <sub>h</sub>	R <sup>2</sup>	R <sup>2</sup>	N
Uncoated		0.888	0.306	0.984	0.003	6.347	0.970	0.860	0.644
H	F1	0.849	0.297	0.959	0.003	6.360	0.956	0.892	0.612
P	F2	0.877	0.297	0.970	0.003	6.834	0.959	0.933	0.527
M	F3	0.732	0.246	0.867	0.002	5.308	0.861	0.892	0.615
C	F4	0.927	0.321	0.956	0.003	6.448	0.949	0.794	0.491
M	F5	0.770	0.221	0.923	0.002	4.739	0.894	0.886	0.585
O	F6	0.848	0.296	0.944	0.003	6.220	0.947	0.892	0.892
R	F7	0.864	0.304	0.955	0.003	6.337	0.953	0.934	0.535
I	F8	0.847	0.297	0.949	0.003	6.241	0.946	0.892	0.615
N									
G									
A									

The accelerated stability studies were performed according to ICH guidelines for a period of 3 weeks and the results met the terms of the ICH guidelines

providing a safety profile of storage of *Moringa oleifera* coated losartan potassium tablets in varying temperature shown in Table 10 respectively.

Table 10: Accelerated stability studies of *Moringa oleifera* coated Losartan potassium tablets.

Percent of potency of the formulation		
Weeks	Atmospheric Condition. (Temperature)	F7
Initial	25 ± 1 <sup>0</sup> c	99.78
3	25 ± 1 <sup>0</sup> c	99.35
	45 ± 1 <sup>0</sup> c	98.55
	4 ± 1 <sup>0</sup> c	98.37
6	25 ± 1 <sup>0</sup> c	99.22
	45 ± 1 <sup>0</sup> c	98.67
	4 ± 1 <sup>0</sup> c	98.13

In conclusion, tablet coating films made of HPMC and Moringa Oleifera with the addition of glycerin at 50% could be considered as an elegant film forming formulation for solving different coating problems generally faced in an industrial scale. The film coating formulations were entirely prepared in an aqueous environment avoiding the environmental unfriendly toxic hazards accompanied with organic solvents, These optimized formulations could be further developed in an industrial scale for the purpose of coating immediate release formulations for those drugs whose integrity needs to be protected from sunlight, oxidations, moisture, thermo liability, and the foreign microbial attack.

## 5. CONCLUSION

The tablets were prepared in an environment free from organic solvent. From the above result, it can conclude that the gum has enormous potential for use in the preparation of the polymeric films as the drug delivery systems. In conclusion, tablet coating films made of HPMC and Moringa Oleifera with the addition of glycerin at 50% could be considered as an elegant film forming formulation for solving different coating problems generally faced in an industrial scale. The film coating formulations were entirely prepared in an aqueous environment avoiding the environmental unfriendly toxic hazards accompanied with organic solvents, These optimized formulations could be further developed in an industrial scale for the purpose of coating immediate release formulations for those drugs whose integrity needs to be protected from sunlight, oxidations, moisture, thermo liability, and the foreign microbial attack.

## REFERENCES:

- [1] Lachman L., Liberman H.A., Kanig J.I., (1991), "The theory and practice of Industrial Pharmacy". Bombay, India : Varghese publishing house.
- [2] Available at : [http://alfresco.ubm-us.net/alfresco\\_images/pharma/2014/08/22/82c5dc49-631c-4a3e-bf66-2cb39f33341f/article-36208.pdf](http://alfresco.ubm-us.net/alfresco_images/pharma/2014/08/22/82c5dc49-631c-4a3e-bf66-2cb39f33341f/article-36208.pdf) [accessed 6 march 2009].
- [3] Pylpchuk G. B., (1998), "ACE inhibitor verses Angiotensin II blocker-induced cough and angioedema". Ann Pharmacother, 32 : pp. 1060-1066.
- [4] Sabale V., Patel V., Paranjape A., Arya C., Sarkanar S. N., Sabale P. M. (2008), "Moringa Oleifera: An overview". Phcog Rev.-supplement, 2: pp. 7-13.
- [5] Dishna. S. (2000), "Water Clarification using Moringa Oleifera". Gate Technical Information, pp. 1-7.
- [6] Karadi R. V., Gadge N. B., Alagawadi K. R., Savadi R. V. (2006), "Effect of Moringa Oleifera Lam. Root-wood on ethylene glycol induced urolithiasis in rats". Journal of ethnopharmacology, 105 (1-2) : pp. 306-311.
- [7] Sandra S., Metz H., Syrowatka F. (2007), "Monitoring of dissolution induced changes in film coat composition by HNMR spectroscopy and SEM". ScienceDirect journal of controlled release, 119 : pp. 190-196.
- [8] Hamashita T., Nakagaya Y., Aketo T., Watano S. (2007), "Granulation of core particles suitable for film coating by agitation fluidized bed optimum formulation for core particles and development of a novel friability test method". Chem. Pharm. Bull. (Tokyo), 55 (8) : pp. 1169-1174.
- [9] Lieberman A. H., Lachmann L., Schwartz J. B. (2005), "Pharmaceutical Dosage forms: Tablet". New York : Marcel Dekker Inc.
- [10] Chakraborty S., Dey B. K., Kar A., Saha S. (2014), "Design and evaluation of floating microspheres of Amoxicilin Trihydrate by Ionotropic gelation method". Journal of Applied Pharm Res., 2(1) : pp. 39-47.
- [11] Vidyadhara S., Lankapalli S. R., Vejella U. M. R., Mupparaju S., Chava S. B. (2014), "Formulation and evaluation of Losartan potassium osmotic controlled matrix tablet". Indian J. Of Pharm Education and Res., 48 : pp. 18-26.
- [12] Begum R., Sultan Z., Rahman A., Hossain A., Amran S. (2014), "The In- Vitro pharmaceutical equivalence studies of Losartan potassium tablets of different manufacturers available in Bangladesh". Int. J. Pharm., 4 (4) : pp. 128-132.
- [13] Kumar M. U., Babu M. K. (2014), "Design and evaluation of fast dissolving tablets containing Diclofenac Sodium using fenugreek gum as a natural superdisintegrant". Asian Pac. J. Trop. Biomed., 4 (1) : pp. S329 – S334.
- [14] Kulkarni G. T., Gowthamarajan K., Suresh B. (2004), "Stability testing of pharmaceutical products: an overview". Indian J. Pharm, 38 : pp. 194-202.