ABSTRACT

Lansoprazole is a proton pump inhibitor used as anti ulcer drug. In the present work, fast dissolving tablet of Lansoprazole was design with a view to and provide a quick onset of action. The main objective of the study was to formulate fast dissolving tablets of Lansoprazole to achieve a better dissolution rate and further improving the bioavailability of the drug. Fast dissolving tablets prepared by direct compression and using super disintegrates in different concentration and evaluation parameters. The prepared tablets were evaluated. Among all, the formulation F5 containing super disintegrate cross povidine and sodium starch glycolate was considered to be best formulation, which release up to 85% in 5 minutes.

KEYWORDS: Lansoprazole, super disintegrates, In-vitro tests.

INTRODUCTION[1-15]

The need for delivering drugs to patients efficiently with minimum side effects has prompted pharmaceutical industries to be engaged in development of new drug delivery systems. Pediatric and geriatric patients find it difficult to swallow solid dosage forms like tablets. Fast
dissolving tablet$^{[1]}$ that dissolve or disintegrate rapidly in oral cavity result in solution, is an ultimate remedy for this problem. In addition they give pleasing mouth feeling.

Fast dissolving is also called as oro dispersible tablets, melt-in-mouth, mouth dissolving tablet, rapid melts, porous tablets, quick dissolving, etc. Their growing importance was underlined recently when European Pharmacopoeia$^{[2]}$ adopted the term “Orodispersible Tablets” as a tablet that to be placed in the mouth where it disperses rapidly before swallowing. It is one of the fastest growing segment in the pharmaceutical market.

In recent past, several manufacturing technologies such as sublimation technique, spray drying technique direct compression… etc. are employed to overcome the limitations of conventional tablet dosage forms. Once the mouth dissolving tablets$^{[1]}$ are prepared they are required to be evaluated for various parameters so as to have long term stability and better therapeutic efficacy.

Oral drug administration has been one of the most suitable and widely accepted by the patients for the delivery of most therapeutically active drugs. Various dosage forms like tablets, capsules and liquid preparations have been administered by oral route. But, due to some unsuitable physiological conditions of the gastro-intestinal tract like relatively poor absorption, presence of various digestive enzymes of the gastro-intestinal lumen and epithelium, poor absorption efflux (i.e. by P-glycoprotein, etc.) and first pass metabolism by hepatic enzymes, the administration of some drugs is affected. Also, it limits many drugs to reach into the therapeutic level. Hence, to minimize the problems associated with drug-absorption through gastro-intestinal membrane, researchers have been developing intraoral drug delivery systems that will enhance the therapeutic drug level, avoids first-pass and gut-wall metabolism, increases the bioavailability of active medicament or improve convenience of dosing. The target sites for local drug delivery in the oral cavity include the following: buccal, sublingual, periodontal region, tongue and gum. Other desirable targeting sites adjacent to oral cavity include pharynx, larynx, adenoids and tonsils.

Within the oral cavity, delivery of drugs via the membranes of the oral cavity is classified into three categories.

1) Sublingual delivery, which is systemic delivery of drugs through the mucosal membranes lining the floor of the mouth to the systemic circulation;
2) Buccal delivery, which is drug administration through the mucosal membranes lining the cheeks and the area between the gums and upper and lower lips to the systemic circulation;

3) Local delivery, which is drug delivery to periodontal, gingival, and odontal delivery for the local treatment of aphthous ulcers, bacterial and fungal and periodontal diseases.

The oral route of administration still continue to be the most preferred route due to its manifold advantages including ease of ingestion, pain avoidance, versatility and most importantly patient compliance. The most popular dosage form being tablets and capsules. Even few of the drawbacks of these dosage forms like swallowing and some drugs resist comparison in dense compacts, owing to their amorphous nature or flocculent, low-density characteristics. Drugs with poor wetting, slow dissolution properties, intermediate to large dosage, and optimum absorption in the gastrointestinal tract or any combination of these features may be difficult or impossible to formulate and manufacture as a tablet that will still provide adequate or full drug bioavailability. Bitter tasting drugs, drugs with an objectionable odor, or drugs that are sensitive to oxygen or atmospheric moisture may require encapsulation or entrapment prior to compression. The target population of these dosage forms is pediatric, geriatric, bedridden, developmentally disabled and the patients with persistent nausea or who are in traveling or who have little access to water. Even many patients find it difficult to swallow tablets and hard gelatin capsules and thus do not comply with prescription, which results in high Incidence of non-compliance and ineffective therapy.
Recent advances in novel drug delivery systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulation and to achieve better patient compliance. One such approach is ‘mouth dissolving tablets, which disintegrate or dissolve in saliva and are swallowed without water as tablet disintegrate in mouth, this could enhance the clinical effect of drug through pre-gastric absorption from the mouth, pharynx, esophagus. This leads to an increase in the bioavailability by avoiding first pass liver metabolism.

**Salient features of fast dissolving tablets.**

a) Ease of administration to patient who refuses to swallow tablets, such as pediatric, geriatric and psychiatric patients.
b) No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
c) Rapid dissolution and absorption of drug, which will produce quick onset of action.
d) Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach; in such cases bioavailability of drugs\(^{12}\) is increased.
e) Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.

**Desired criteria for FDDS**

The tablets should

a) Not require water to swallow, but is should dissolve or disintegrate in the mouth in matter of seconds.
b) Be compatible with taste masking.
c) Be portable with taste masking.
d) Have a pleasing mouth feel.
e) Leave minimal or no residue in the mouth after oral administration.
f) Exhibit low sensitivity to environmental conditions as humidity equipment at low cost and temperature.
g) Allow the manufacture of tablet\(^{3}\) using conventional processing and packaging.

**MATERIALS AND METHODS\(^{16-32}\)**

**Materials**

Lansoprazole, Microcrystalline cellulose, citric acid, magnesium stearate, HPMC, lactose.
Methods

Preparation of fast dissolving tablets of lansoprazole

The critical parameters to formulate a fast dissolving tablet are choice of superdisintegrant and optimization of concentration of superdisintegrant. The main criteria for fast dissolving tablets is to disintegrate or dissolve rapidly in oral cavity in 15-60 seconds, without need of water and should have pleasant mouth feel. The super disintegrant, direct compression tablets were used to formulate the tablets. All the ingredients were co-ground in a pestle and motor and then talc and magnesium stearate were added and mixed for 10 minutes. Then mixed blend of drug-excipient was compressed using a single punch tablet machine to produce tablets with 2.75 mm thickness and 9.28 mm in diameter.

![Figure 3: Tablet compression mechanism.](image)

METHOD OF PREPARATION

Methods of preparation of fast dissolving tablets by direct compression technique.

Fast dissolving tablets of lansoprazole were prepared by direct compression method according to the formula. All the ingredients were passed through 40 mesh sieve separately. The drug and microcrystalline cellulose was mixed by small portion of both each time and blending it to get a uniform mixture kept aside. Then the ingredients were weighed and mixed in geometrical order and tablets were compressed at 6mm sizes flat round punch to get tablet using Cadmach Compression Machine.
Figure 4: Tablet punching machine.

Table 1: List of different formulations by using different super disintegrates.

<table>
<thead>
<tr>
<th>Ingredients (mg)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross carmellose</td>
<td>30 mg</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sod. starch glycolate</td>
<td>-</td>
<td>-</td>
<td>35 mg</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cross providone</td>
<td>-</td>
<td>40 mg</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>C. carmellose &amp; cross providone</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>15 mg + 15 mg</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>c. Providone &amp; s.s.g</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>20 mg + 25 mg</td>
<td>-</td>
</tr>
<tr>
<td>c.c &amp; s.s.g</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>20 mg + 30 mg</td>
</tr>
<tr>
<td>Mg stearate</td>
<td>35 mg</td>
<td>22 mg</td>
<td>25 mg</td>
<td>30 mg</td>
<td>20 mg</td>
<td>30 mg</td>
</tr>
<tr>
<td>HPMC</td>
<td>10 mg</td>
<td>25 mg</td>
<td>20 mg</td>
<td>20 mg</td>
<td>22 mg</td>
<td>20 mg</td>
</tr>
<tr>
<td>API</td>
<td>15 mg</td>
<td>15 mg</td>
<td>15 mg</td>
<td>15 mg</td>
<td>15 mg</td>
<td>15 mg</td>
</tr>
<tr>
<td>Lactose</td>
<td>70 mg</td>
<td>43 mg</td>
<td>60 mg</td>
<td>60 mg</td>
<td>43 mg</td>
<td>60 mg</td>
</tr>
<tr>
<td>MCC</td>
<td>40 mg</td>
<td>55 mg</td>
<td>50 mg</td>
<td>15 mg</td>
<td>55 mg</td>
<td>25 mg</td>
</tr>
</tbody>
</table>

Preformulation studies

The following preformulation studies were carried out for lansoprozole

1) Determination of melting point of lansoprozole.
2) Drug-excipient compatibility studies.
3) Micromeretic properties.
4) Angle of repose.
5) Bulk density and tapped density.
6) Carr’s consolidation index.
Angle of repose (θ)
The frictional force in a loose powder and granules can be measured by angle of repose. Angle of repose\textsuperscript{22} is defined as maximum angle possible between the surface of a pile of the powder and horizontal plane
\[
\tan \theta = \frac{h}{r}
\]
\[
\theta = \tan^{-1}\left(\frac{h}{r}\right)
\]
Where
\[
\theta = \text{angle of repose}
\]
\[
h = \text{height of pile}
\]
\[
r = \text{radius of the base of pile}
\]

Bulk density
It is defined as a mass of powder divided by the bulk volume. The bulk density\textsuperscript{23} of a powder depends on the particle size distribution, particle shape and tendency of particles to adhere to one another.

Method
Both loose bulk density and tapped bulk density were determined. A quantity of accurately weighed powder from each formula, previously shaken to break any agglomerates, formed, was introduced into a 25ml measuring cylinder. After the initial volume was observed the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5cm at 2sec interval. The tapping was continued until no further change in volume was noted. LBD and TBD was calculated using following formulae.
\[
\text{LBD} = \frac{\text{weight of the powder}}{\text{Volume of the packing}}
\]
\[
\text{TBD} = \frac{\text{weight of the powder}}{\text{Tapped volume of packing}}
\]

Carr’s compressibility index
Compressibility index of the granules\textsuperscript{27} was determined by Carr’s compressibility index.
\[
\text{Carr’s index (\%)} = \left(\frac{\text{TBD} - \text{LBD}}{\text{TBD}}\right) \times 100
\]
Hausner ratio

Method

The tapped density and bulk density were measured and the Hausner ratio was calculated using the formula.

Hausner ratio = $D_t / D_b$

Where, $D_t$ = Tapped density

$D_b$ = Bulk density

Table 2: Physical parameters of drug and polymer.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Angle of repose</th>
<th>Bulk density (gm/cm$^3$)</th>
<th>Tap density (gm/cm$^3$)</th>
<th>Carr’s index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprozole</td>
<td>32° 10’</td>
<td>0.4</td>
<td>0.57</td>
<td>24.83</td>
</tr>
<tr>
<td>HPMC</td>
<td>26° 10’</td>
<td>0.30</td>
<td>0.39</td>
<td>26.83</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>32° 87’</td>
<td>0.30</td>
<td>0.40</td>
<td>28.91</td>
</tr>
<tr>
<td>MCC</td>
<td>30° 01’</td>
<td>0.43</td>
<td>0.51</td>
<td>21.28</td>
</tr>
<tr>
<td>DCL</td>
<td>34° 16’</td>
<td>0.54</td>
<td>0.50</td>
<td>22.10</td>
</tr>
</tbody>
</table>

EVALUATIONS TEST PROCEDURES FOR FAST DISSOLVING TABLETS

Hardness

The tablet hardness, which is the force required to break a tablet in a diametric compression force. The hardness tester used in the study was Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring.

Friability

The friability of a sample of 20 tablets was measured using Roche friabilator. Twenty tablets were weighed, rotated at 25 rpm for 4 minutes. Tablets were reweighed after removal of fines (dedusted) and the percentage of weight loss was calculated. Friability below 1% was considered acceptable.

$\%F = \left\{(W - W_0)/W_0\right\} \times 100$

Where, $\%F$ = Friability in percent,

$W$ = Initial weight of tablet.

$W_0$ = Weight of tablet after test

Weight variation Test.

Weight variation test was done by weighing 20 tablets individually, calculating the average weight and comparing the individual tablet weight to the average weight.

PD= (Wavg) – (W initial) / (W avg) x 100
Where PD = Percentage deviation,
Avg wt = Average weight of tablet,
W_initial = Individual weight of tablet.

**In vitro disintegration time**
The disintegration time of the tablet was measured in water (37±2°C) according to disintegration test apparatus with disk. The time in seconds taken for the complete disintegration of the tablet with no palpable mass in the apparatus \(^{38}\) was measured in seconds. Three tablets from each batch (formulation) were tested for the disintegration time calculations.

**Wetting time**
A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of simulated saliva pH 6.8, a tablet was put on the paper, and the time for complete wetting was measured.

\[ R = 100 \left( \frac{W_a - W_b}{W_b} \right) \]

Where, Wb and Wa were the weights of the tablet before and after study.

**In vitro dissolution profile**
Dissolution studies were carried out by USP paddle method at 37± 0.50 c, taking 900ml of phosphate buffer pH 6.8 as a dissolution medium. Speed of rotation of paddle \(^{42}\) was set at 50 rpm. Absorbance of sample was measured at 310 nm by spectrometrically.

**Stability studies**
Stability studies were carried out at 250c/60% RH and 400c/75% RH for 60 days for optimized formulation.

**Drug-Excipient Interaction Study**
There is always a possibility of drug-excipient interaction in any formulation due to their intimate contact. The technique employed in this study is IR spectroscopy. IR spectroscopy is one of the most powerful analytical technique \(^{48}\) which offers the possibility of chemical identification.
Drug Content Uniformity Study
Five tablets were weighed individually and powdered. The powder equivalent to 2 mg of lansoprazole was weighed and extracted in phosphate buffer pH 6.8 (100 ml) and the concentration of drug was determined by measuring absorbance at 310nm by spectrophotometer.

In Vitro Drug Release Study
Dissolution rate was studied by using USP type-II apparatus at 50 rpm (USP XXIII Dissolution Test Apparatus) using 500 ml of phosphate buffer PH 6.8 as dissolution medium. Temperature of the dissolution medium[33] was maintained at 37±0.5ºC, aliquot of dissolution medium was withdrawn at every 1 minute interval and filtered. The absorbance of filtered solution was checked by UV spectrophotometric method[54] at 310 nm and concentration of the drug was determined from standard calibration curve.

In vitro drug release studies details
Apparatus used: USP XXIII dissolution test apparatus[55]
Dissolution medium: 6.8 pH phosphate buffer solution
Dissolution medium volume: 500 ml
Temperature: 37±0.5ºC
Speed of basket paddle: 50 rpm
Sampling intervals: 1 min
Sample with drawn: 5 ml
Absorbance measured: 310 nm

RESULTS AND DISCUSSION
Analytical method for fast dissolving drug delivery system
Preparation of Phosphate buffer solution: 50ml of 0.2M potassium dihydrogen phosphate was taken in 200ml volumetric flask to which 22.4ml of 0.2M sodium hydroxide was added and made up to the mark with distilled water.

Preparation of lansoprazole standard stock solution in phosphate buffer solution pH 6.8: Standard stock solution of lansoprazole was prepared by dissolving accurately weighed 10mg of lansoprazole in phosphate buffer solution pH 6.8 in 100ml volumetric flask. The volume was then made up to 100ml by using phosphate buffer solution, pH 6.8 to obtain the solution of 100µg/ml.
Standard calibration curve of lansoprazole: Solutions ranging from 5 to 25 µg/ml were prepared using phosphate buffer (pH 6.8) separately and absorbance was measured for each solution at $\lambda_{\text{max}}$ of 310nm using UV/visible spectrophotometer. Graph was plotted for absorbance versus concentration of Lansoprazole was shown in the following graph.

Table 3: Standard calibration graph of Lansoprazole in 6.8 Buffer Solution at $\lambda_{\text{max}}$ 310 nm.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Concentration (mcg/ml)</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>00</td>
<td>0.00</td>
</tr>
<tr>
<td>2</td>
<td>05</td>
<td>0.040</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>0.070</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
<td>0.105</td>
</tr>
<tr>
<td>5</td>
<td>20</td>
<td>0.138</td>
</tr>
<tr>
<td>6</td>
<td>25</td>
<td>0.170</td>
</tr>
</tbody>
</table>

Fig 5: Standard graph of lansoprazole.

Evaluation parameters of fast dissolving tablets

Hardness
The tablet hardness, which is the force required to break a tablet in a diametric compression force. The hardness tester used in the study was Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring.

Friability
The friability of a sample of 20 tablets was measured using Roche friabilator Twenty tablets were weighed, rotated at 25 rpm for 4 minutes. Tablets were reweighed after removal of fines (dedusted) and the percentage of weight loss was calculated. Friability below 1% was considered acceptable.
%F = \{(W – W_0)/W_0\} \times 100

Where,

%F = Friability in percent,

W = Initial weight of tablet.

W_0 = Weight of tablet after test.

**Weight variation test**

Weight variation test was done by weighing 20 tablets individually, calculating the average weight and comparing the individual tablet weight to the average weight.

**In vitro disintegration time**

The disintegration time of the tablet was measured in water (37±2°C) according to disintegration test apparatus with disk. The time in seconds taken for the complete disintegration of the tablet with no palpable mass in the apparatus was measured in seconds. Three tablets from each batch (formulation) were tested for the disintegration time calculations.

**Wetting time**

A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of simulated saliva pH 6.8, a tablet was put on the paper, and the time for complete wetting was measured.

**In vitro dissolution profile**

Dissolution studies were carried out by USP paddle method at 37± 0.50 c, taking 900 ml of phosphate buffer pH 6.8 as a dissolution medium. Speed of rotation of paddle was set at 50 rpm. Absorbance of sample was measured at wavelength of 310 nm by spectrometrically.

**Stability studies**

Stability studies were carried out at 250c/60% RH and 400c/75% RH for 60 days for optimized formulation.

**Drug Content Uniformity Study**

Five tablets were weighed individually and powdered. The powder equivalent to 2 mg of lansoprazole was weighed and extracted in phosphate buffer pH 6.8 (100 ml) and the concentration of drug was determined by measuring absorbance at 310 nm by spectrophotometer.
**In Vitro Drug Release Study**

Dissolution rate was studied by using USP type-II apparatus at 50 rpm (USP XXIII Dissolution Test Apparatus) using 500 ml of phosphate buffer PH 6.8 as dissolution medium. Temperature of the dissolution medium was maintained at 37±0.5°C, aliquot of dissolution medium was withdrawn at every 1 minute interval and filtered. The absorbance of filtered solution was checked by UV spectrophotometric method at 310 nm and concentration of the drug was determined from standard calibration curve.

**In vitro drug release studies details**

![Dissolution apparatus](image)

**Fig 6: Dissolution apparatus.**

Apparatus used: USP XXIII dissolution test apparatus.
Dissolution medium: 6.8 pH phosphate buffer solution.
Dissolution medium volume: 500 ml.
Temperature: 37±0.5°C
Speed of basket paddle: 50 rpm
Sampling intervals: 1 min
Sample withdrawn: 5 ml
Absorbance measured: 310 nm
Evaluation tests i.e; friability, hardness\[46\], weight variation, etc….of fast dissolving lansoprazole tablet results was shown in following table.
Table 4: Evaluation tests for lansoprazole tablets.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Hardness (kg/cm$^2$)</th>
<th>Friability (%)</th>
<th>Weight variation (%)</th>
<th>w.t in sec</th>
<th>D.t in sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>2.2</td>
<td>0.40</td>
<td>4.5</td>
<td>38.00</td>
<td>35</td>
</tr>
<tr>
<td>F2</td>
<td>3.0</td>
<td>0.42</td>
<td>4.8</td>
<td>36.46</td>
<td>38</td>
</tr>
<tr>
<td>F3</td>
<td>2.5</td>
<td>0.48</td>
<td>5.6</td>
<td>41.11</td>
<td>40</td>
</tr>
<tr>
<td>F4</td>
<td>3.1</td>
<td>0.43</td>
<td>5.9</td>
<td>34.50</td>
<td>45</td>
</tr>
<tr>
<td>F5</td>
<td>2.8</td>
<td>0.44</td>
<td>6.0</td>
<td>37.30</td>
<td>30</td>
</tr>
<tr>
<td>F6</td>
<td>2.7</td>
<td>0.47</td>
<td>4.6</td>
<td>42.07</td>
<td>60</td>
</tr>
</tbody>
</table>

Preformulation study of lansoprazole with excipients

Inter-particulate interactions influence the bulking properties of powder. A comparison of the bulk density and tapped density can give a measure of the relative importance of this interaction in a given powder result shown in following table.

Table 5: Physical properties of powder blends.

<table>
<thead>
<tr>
<th>Sl.no</th>
<th>Parameters</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LBD (gm/cc)</td>
<td>0.430</td>
<td>0.360</td>
<td>0.338</td>
<td>0.514</td>
<td>0.520</td>
<td>0.516</td>
</tr>
<tr>
<td>2</td>
<td>TBD (gm/cc)</td>
<td>0.574</td>
<td>0.543</td>
<td>0.513</td>
<td>0.666</td>
<td>0.666</td>
<td>0.653</td>
</tr>
<tr>
<td>3</td>
<td>Angle of repose</td>
<td>26°56'</td>
<td>27°24'</td>
<td>25°18'</td>
<td>29°16'</td>
<td>24°01'</td>
<td>22°08'</td>
</tr>
<tr>
<td>4</td>
<td>Carr’s index</td>
<td>25.00</td>
<td>33.70</td>
<td>34.11</td>
<td>22.22</td>
<td>21.21</td>
<td>20.2</td>
</tr>
</tbody>
</table>

Disintegration is defined as the disaggregation of a solid dosage form into its primary particles the dissolution of a drug substance may depend on the drug dosage form, on the rate of disintegration and on the properties of the drug itself, such as high or low solubility, which determines the dissolution rate. Dissolution test was performed using 900ml phosphate buffer pH 6.8 with USP dissolution apparatus-2 at 50 rpm and 37±0.5°C. The result of drug release are shown in following table and graph.

Table 6: Percentage of drug release for F1.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Time</th>
<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>4.23</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>10.63</td>
</tr>
<tr>
<td>3</td>
<td>15</td>
<td>23.43</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
<td>32.65</td>
</tr>
<tr>
<td>5</td>
<td>25</td>
<td>49.82</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>58.23</td>
</tr>
</tbody>
</table>
Results and Discussion 1
In this F₁ formulation by using cross carmellose as super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 58% with in 30sec.

Table 7: content of drug release for F₂.

<table>
<thead>
<tr>
<th>S.no</th>
<th>Time</th>
<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5</td>
<td>5.63</td>
</tr>
<tr>
<td>2.</td>
<td>10</td>
<td>11.32</td>
</tr>
<tr>
<td>3.</td>
<td>15</td>
<td>29.38</td>
</tr>
<tr>
<td>4.</td>
<td>20</td>
<td>48.23</td>
</tr>
<tr>
<td>5.</td>
<td>25</td>
<td>50.76</td>
</tr>
<tr>
<td>6.</td>
<td>30</td>
<td>60.73</td>
</tr>
</tbody>
</table>

Fig 7: content of drug release for F1.

Fig 8: content of drug release for F2
Results and Discussion 2.
In this F₂ formulation by using sodium starch glycolate as super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 60% with in 30sec.

Table 8: content of drug release for F3.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Time</th>
<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5</td>
<td>6.82</td>
</tr>
<tr>
<td>2.</td>
<td>10</td>
<td>12.62</td>
</tr>
<tr>
<td>3.</td>
<td>15</td>
<td>28.32</td>
</tr>
<tr>
<td>4.</td>
<td>20</td>
<td>49.72</td>
</tr>
<tr>
<td>5.</td>
<td>25</td>
<td>59.61</td>
</tr>
<tr>
<td>6.</td>
<td>30</td>
<td>68.96</td>
</tr>
</tbody>
</table>

Fig 9: content of drug release for F₃.

Results and Discussion 3.
In this F₃ formulation by using cross providone as super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 68% with in 30sec.

Table 9: Percentage of Drug Release for F4.

<table>
<thead>
<tr>
<th>S.No.</th>
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<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5</td>
<td>12.68</td>
</tr>
<tr>
<td>2.</td>
<td>10</td>
<td>23.43</td>
</tr>
<tr>
<td>3.</td>
<td>15</td>
<td>39.63</td>
</tr>
<tr>
<td>4.</td>
<td>20</td>
<td>52.72</td>
</tr>
<tr>
<td>5.</td>
<td>25</td>
<td>60.12</td>
</tr>
<tr>
<td>6.</td>
<td>30</td>
<td>70.93</td>
</tr>
</tbody>
</table>
Results and Discussion 4.

In this F₄ formulation by using cross carmellose and cross providone as combination super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 70% with in 30sec.

Table 10: Content of Drug Release for F₅.

<table>
<thead>
<tr>
<th>Sl.No</th>
<th>Time in sec</th>
<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>14.82</td>
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<tr>
<td>2</td>
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<tr>
<td>5</td>
<td>25</td>
<td>65.72</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>85.25</td>
</tr>
</tbody>
</table>

Fig 10: Content of drug release for F₄

Fig 11: content of drug release for F₅.
Results and Discussion 5.
In this F₁ formulation by using cross providone and sodium starch glycollate as combination super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 85% with in 30sec.

Table 11: percentage of drug release for F₆.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Time</th>
<th>% of Drug Release</th>
</tr>
</thead>
<tbody>
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<td>1</td>
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<td>35.38</td>
</tr>
<tr>
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<td>49.62</td>
</tr>
<tr>
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<td>25</td>
<td>55.19</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>75.96</td>
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</tbody>
</table>

Fig 12: content of drug release for F₆

Results and Discussion 6.
In this F₄ formulation by using cross carmellose and sodium starch glycollate as combination super disintegrate and excipients like m.c.c, mg. sterate, hpmc, citric acid. The % of drug release was found to be 75% with in 30sec.

Content of drug release for F₁-F₆.
Table 12: Invitro release of lansoprazole from ta.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Time</th>
<th>F₁</th>
<th>F₂</th>
<th>F₃</th>
<th>F₄</th>
<th>F₅</th>
<th>F₆</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>4.23</td>
<td>5.63</td>
<td>6.82</td>
<td>12.68</td>
<td>14.82</td>
<td>10.23</td>
</tr>
<tr>
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<td>10</td>
<td>10.63</td>
<td>11.32</td>
<td>12.62</td>
<td>23.43</td>
<td>25.80</td>
<td>21.45</td>
</tr>
<tr>
<td>3</td>
<td>15</td>
<td>23.43</td>
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<td>28.32</td>
<td>39.63</td>
<td>38.92</td>
<td>35.38</td>
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<tr>
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<td>32.65</td>
<td>48.23</td>
<td>49.72</td>
<td>52.72</td>
<td>58.23</td>
<td>49.62</td>
</tr>
</tbody>
</table>
RESULTS AND DISCUSSION

Fast Dissolving Tablet is a new drug delivery system with several advantages and clinical benefits such as ease of administration for patients who are mentally ill, disabled and uncooperative, rapid disintegration and dissolution with increased bioavailability, no necessity of water or chewing and ability to provide advantages of liquid medication in the form of solid preparation. In the present study, attempt was made to prepare such a tablet of various drugs by using addition of super disintegrants technique. The drug was selected for this study from the categories: Anti Migraine Sumatriptan Succinate on the basis of low drug dose and necessity of immediate action.

SUMMARY AND CONCLUSION

In the present investigation, several formulations were prepared by using different polymers like Microcrystalline cellulose, Crospovidone, Croscarmellose sodium, Sodium starch glycolate, Magnesium stearate, Lactose, citric acid and HPMC using aqueous solvent in addition of super disintegrants technique possess all desired parameters in acceptable limits hence chosen for further preparation of FDTs of selected drug candidates lansoprazole for the fast dissolving tablets. Based on the evaluation parameters like friability, dispersion test, wetting time disintegration time in oral cavity, in vitro dissolution study, F5 was found to be
optimized formulation upon its disintegration time i.e., 30 sec and release of the drug for the dosage form was 85% within 10 minutes and in vitro drug release was better than other formulations.

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REFERENCES