COMPARATIVE EVALUATION OF NATURAL AND SEMI-SYNTHETIC SUPERDISINTEGRANTS IN THE FORMULATION OF ORO-DISPERSIBLE TABLETS OF NORFLOXACIN

SHASHANK CHATURVEDI1, VIPI KUMAR AGARWAL1, ANURAG VERMA2, NAVNEET VERMA2, SUNIL SINGH1

1Department of Pharmaceutics, Invertis Institute of Pharmacy, Invertis University, Bareilly, U.P, 2Department of Pharmaceutics, School of Pharmaceutical Sciences, IFTM University, Moradabad, U.P. India. Email: shashank.c@invertis.org

ABSTRACT

The purpose of the present study was to develop Oro-Dispersible Tablet containing Norfloxacin using Natural and Semi-synthetic Superdisintegrants. To prevent the bitter taste of Norfloxacin it was coated with Sucralose (Sweetener). Coated drug particles were mixed with Sucralose, Avicel PH 101, Starch 1500 X, Superdisintegrant, Stearic acid, and other ingredients & compacted under single punch tabletting machine into 12mm round beveled tablets. Seven lots of tablets were assessed if suitable as Oro-Dispersible tablets by determination of range of technological parameters. Dissolution profile suggested that tablet prepared with Croscarmellose sodium and Plantago ovata husk were capable of releasing up to 90 % drug within 15 minutes in phosphate buffer 6.8 pH, by an appropriate combination of excipients it is thus possible to obtain Oro-Dispersible Tablets using simple and conventional technique.

Keywords: Oro-Dispersible Tablet, Plantago ovata Husk, Croscarmellose sodium, Starch 1500X, Sucralose.

INTRODUCTION

Many patients have difficulty swallowing tablets and hard gelatin capsules and consequently do not take medications as prescribed. It is estimated that 50% of the population is affected by this problem, which results in a high incidence of noncompliance and ineffective therapy. Swallowing problems are also common in young individuals because of their under developed muscular and nervous system. Other groups, who may experience problems in swallowing solid dosage forms, are the mentally ill, the developmentally disabled, uncooperative patient and reduced liquid intake plans or nausea. Swelling is also associated with number of medical conditions including Stroke, Parkinson’s disease, AIDS, head and neck radiation therapy and other neurological disorders including cerebral palsy. The demand for solid dosage forms that can be chewed, or rapidly dissolved or dispersed or dissolved/suspended in water prior to administration, particularly strong in the pediatric and geriatric markets, with further application to other patients who prefer the convenience of a readily administered dosage form. Oral fast-disintegrating dosage forms (tablet or a capsule) are a relatively novel dosage technology that involves the rapid disintegration or dissolution of the dosage form into a solution or suspension in the mouth without the need for water. The United States Food and Drug Administration define ODT as “a solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue.” The disintegration time for ODTs generally ranges from several seconds to about a minute. The active agent can thus be rapidly dissolve in saliva and be absorbed through whatever membrane it encounters, during deglutination, unless it is protected from pregastric absorption. To fulfill these requirements tablet must be highly porous, incorporating highly hydrophilic excipients, able to rapidly absorb water for a rapid deagregation of matrix. Muclage and gums have been used since ancient times for their medicinal uses. In the modern era also they are widely used in the pharmaceutical industries as thickeners, water retention agents, and emulsion stabilizers, suspending agents, binders and film formers. Apart from its use in finished medicines, newer uses have been found in the preparation of cosmetics, textiles, and paint paper.

Norfloxacin is a synthetic, broad-spectrum antibacterial agent for oral administration. Norfloxacin is a second generation synthetic fluoroquinolone (quinolone). It is a synthetic chemotherapeutic agent, occasionally used to treat common as well as complicated urinary tract infections and it differs from non-fluorinated quinolones by having a fluorine atom at the 6 position and a piperazine moiety at the 7 position, falls under BCS class IV is selected as model drug.

MATERIALS

Norfloxacin (1-ethyl-6-fluoro-4-oxo-7-piperazin-1-yl-1H-quinoline-3-carboxylic acid,) was gifted by Simpex Pharma Pvt. Ltd Kotdwra, (Uttarakhand). Croscarmellose sodium was procured from S.D. Fine Chemicals. Plantago ovata husk was procured form local market. Norfloxacin was gifted by JK Suclarose; Starch 1500 X was gifted by Colorcon Asia Pvt.Ltd, Avicel PH101 was gifted by Vjalak Pharma ltd, India. All other ingredients used were of analytical grade.

METHODS

Coating of Norfloxacin with sucralose:

Norfloxacin was coated with Sucralose using solvent evaporation technique. An ethanolic solution of Sucralose was added to the pure drug and resultant mixture was kneaded to form a mass of damp ice consistency. The mass so prepared was then dried in an oven at 40 °C overnight. The dried mass was then passed through sieve number 40 to obtain uniform size powder. The coated drug was then triturated with Menthol which serves as sensitizing agent and blended with other excipients to formulate ODT of Norfloxacin.

Preparation of ODT

Tablets of Norfloxacin were prepared by direct compression method. Starch 1500 and Fumed silica were passed through 40 mesh screen, thereafter coated Norfloxacin with Sucralose, Avicel PH 101, Stearic acid, Croscarmellose sodium / Plantago ovata husk were blended for 15 minutes with pestle and mortar. Magnesium stearate was further added and blended for additional 5 mins. Finally, each mixture were weighed and fed manually into the die of a single punch tabletting machine, equipped with round beveled punches (12.0 mm), to produce the desired tablets. Composition of Norfloxacin ODT has been shown in the Table 1.
Table 1: Composition of Norfloxacin ODT

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>C0</th>
<th>C1</th>
<th>C2</th>
<th>C3</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norfloxacin</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>Starch 1500 X</td>
<td>37.85</td>
<td>32.7</td>
<td>27.55</td>
<td>22.4</td>
<td>22.4</td>
<td>17.25</td>
<td>12.1</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>-</td>
<td>5.15</td>
<td>10.30</td>
<td>15.45</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Husk</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>15.45</td>
<td>20.6</td>
<td>25.75</td>
</tr>
<tr>
<td>Saturated silica</td>
<td>1.29</td>
<td>1.29</td>
<td>1.29</td>
<td>1.29</td>
<td>1.29</td>
<td>1.29</td>
<td>1.29</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.645</td>
<td>0.645</td>
<td>0.645</td>
<td>0.645</td>
<td>0.645</td>
<td>0.645</td>
<td>0.645</td>
</tr>
<tr>
<td>Sucrose</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Menthol</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**In Vitro evaluation of powder blends**

**Bulk density**
A known quantity of each sample (25 g) was poured through a funnel into a 100-mL tarred graduated cylinder. The cylinder was then lightly tapped twice to collect all the powder sticking on the wall of the cylinder. The volume was then read directly from the cylinder and used to calculate the bulk density; results are expressed in (gm/ml) 13.

**Bulk Density (BD) = Weight of the powder sample / Volume of the powder sample**

**Tapped density**
The cylinder was tapped from a height of 2.5 cm 50 times on a wooden bench to attain a constant volume reading from the cylinder, results are expressed in (gm/ml) 13.

**Tapped density (TD) = Weight of the powder sample / Volume of the tapped powder sample**

**Carr's index**
An accurate weight of formula blend was poured into a volumetric cylinder to occupy a volume (Vf) and then subjected to a standard tapping procedure onto a solid surface until a constant volume was achieved (Vf). Carr’s “per cent compressibility” was calculated using the equation 11.

\[
\text{Compressibility Index (CI)} = \frac{V_f - V_o}{V_o} \times 100
\]

**Angle of repose**
The angle of repose was measured by passing the prepared blend through a sintered glass funnel of internal diameter 27 mm on the horizontal surface. The height (h) of the heap formed was measured with a cathetometer, and the radius (r) of the cone base was also determined. The angle of repose (θ) was calculated from 12.

\[
\theta = \tan^{-1} \left( \frac{h}{r} \right)
\]

Where θ is angle of repose.

**Hausner's ratio**
Hausner’s ratio is an index of ease of powder flow, it is calculated by the formula 13.

\[
\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}
\]

**Swelling index**
The study was carried out using a 100 ml stoppered graduated cylinder. The initial bulk volume of 1 gm of dried mucilage was recorded. Water was added in sufficient quantity to yield 100 ml of a uniform dispersion. The sediment volume of the swollen mass was measured after 24 hour, stored at room temperature. The swelling ratio was calculated by taking the ratio of the swollen volume to the initial bulk volume 13.

**In Vitro evaluation of the prepared tablets**

**Tablet weight variation**
Every individual tablet in a batch should be in uniform weight and weight variation in within permissible limits. The weights were determined to within ±1 mg by using Sartorius balance (BT 124 S). Weight control is based on a sample of 20 tablets. Determinations were made in triplicate 8.

**Tablet thickness**
Ten tablets from each formulation were taken randomly and their thickness was measured with a micrometer screw gauge 8.

**Hardness**
The hardness of the tablets was determined by diametrical compression using a Hardness testing apparatus (Monsanto Type). A tablet hardness of about 4.5 kg/cm² is considered adequate for mechanical stability. Determinations were made in triplicate 8.

**Tablet friability**
Friability of the tablets was determined using Roche Friabilator (Electro lab, India). This device consists of a plastic chamber that is set to revolve around 25 rpm for 4 min dropping the tablets at a distance of 6 inches with each revolution. Preweighed sample of 20 tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F %) is given by the formula 8.

\[
F(\%) = \left(1 - \frac{W_a}{W_b} \right) \times 100
\]

Where, W₀ is weight of tablets before the test and W is the weight of the tablets after test

**In vitro disintegration time**
One tablet from each formulation was placed in USP tablet disintegration apparatus without disk, containing 900 ml of pH 6.8 phosphate buffer at 37±0.5°C, and the time required for complete disintegration was determined 14.

**Wetting time**
Five circular tissue papers of 10-cm diameter were placed in a petri dish with a 10 cm diameter. Ten mL of water at 37±0.5°C containing eosin, a water-soluble dye, was added to the petri dish.

A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time 15, 16.

**Water absorption ratio**
A piece of tissue paper folded twice was placed in a small petri dish containing 6 mL of water. A tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio R, was determined using following equation 16.

\[
R = \frac{W_a - W_b}{W_b} \times 100
\]

Where, W₀ = weight of tablet after absorption, W₁ = Initial weight of the tablet

**In Vitro release studies**
Drug release studies of the prepared Orodispersible tablets with semi synthetic and natural superdisintegrants were performed, in triplicate, in a USP Dissolution Apparatus II (Paddle type) (Electro
The dissolution test was performed using Phosphate buffer pH 6.8 at 37±0.5°C. The speed of rotation of paddle was set at 50 rpm. Aliquots of 1mL were withdrawn from the dissolution apparatus at different time intervals and filtered through a cellulose acetate membrane (0.45µm), and fresh dissolution medium was replenished immediately. Absorbance of solution was checked by UV spectrophotometer (Shimadzu-1800, Kyoto, Japan) at a wavelength of 278 nm and drug release was determined from standard curve ($R^2=0.999$).

### Accelerated stability studies

Stability studies were carried out on optimized formulation. The tablets were stored at 40°C and 75% RH for duration of three months. After for every one month samples were withdrawn and tested for various parameters like hardness, drug content and in vitro drug release.

### RESULTS

#### Drug-Excipients Compatibility Studies

**FT-IR studies**

The FT-IR spectra of Norfloxacin, Croscarmellose sodium, *Plantago ovata* Husk, Sucralose shows all the characteristic peaks for Norfloxacin i.e. N-H stretch at 3430.33 cm⁻¹, C-O at 1342 cm⁻¹. IR spectroscopic studies revealed that drug was compatible with all the excipients (Fig 1a, b, c and d).
DSC studies

The DSC thermo-gram of Norfloxacin exhibited an endothermic peak at 228.30 °C corresponding to its melting point. The DSC thermo-gram of Physical mixture (1:1) of Norfloxacin, Croscarmellose sodium, Plantago ovata Husk, Sucralose showed slight shift in peak. The peak due to the melting of drug was shifted to lower temperature from 228.30 °C to 220.91 °C. (Fig 2 a, b, c, d)

Evaluation of powder blend

The blend of all the batches were evaluated for parameters like angle of repose was found to be between 30.64 and 41.29. Bulk density was found to be between 0.39 and 0.53 (gm/cc) and tapped density between 0.406 and 0.643 (gm/cc). Carr’s Index was found to be in between 15 – 22, Hausner’s ratio ranged between 1.08 and 1.25. All the formulations showed good blend properties for direct compression technology Table 2. Swelling Index for both of the superdisintegrants had been calculated by the official method and it was found that Plantago ovata Husk swells up to 84 % whereas Croscarmellose sodium swells up to 75 % Table 2.

Evaluation of oro-dispersible tablets

Results for hardness, friability, content uniformity, and disintegration time are indicated in Table 3 and were found to be well within the limits (USP).

Swelling Index

The swelling index of Husk, determined in phosphate buffer pH 6.8 was 84 %. There was a significant change in swelling by the end of the study, which indicated that the mucilage had excellent swelling properties, Table 4.
Fig. 2: DSC curve of a) Norfloxacin, b) physical mixture of Norfloxacin and Croscarmellose sodium, c) Norfloxacin and Plantago ovata Husk, d) Norfloxacin and Sucralose.

### Table 2: In vitro evaluation data of Powder blends

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Bulk Density (gm/cc) ± S.D.</th>
<th>Tapped Density (gm/cc) ± S.D.</th>
<th>Angle of Repose (θ)</th>
<th>Carr’s index ± S.D.</th>
<th>Hausner’s Ratio* ± S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0</td>
<td>0.51</td>
<td>0.631</td>
<td>30.64</td>
<td>17</td>
<td>1.23</td>
</tr>
<tr>
<td>C1</td>
<td>0.52</td>
<td>0.601</td>
<td>32.43</td>
<td>16</td>
<td>1.08</td>
</tr>
<tr>
<td>C2</td>
<td>0.53</td>
<td>0.632</td>
<td>34.29</td>
<td>15</td>
<td>1.15</td>
</tr>
<tr>
<td>C3</td>
<td>0.53</td>
<td>0.643</td>
<td>35.11</td>
<td>17</td>
<td>1.16</td>
</tr>
<tr>
<td>F1</td>
<td>0.40</td>
<td>0.406</td>
<td>40.41</td>
<td>20</td>
<td>1.03</td>
</tr>
<tr>
<td>F2</td>
<td>0.41</td>
<td>0.429</td>
<td>39.55</td>
<td>22</td>
<td>1.25</td>
</tr>
<tr>
<td>F3</td>
<td>0.41</td>
<td>0.462</td>
<td>41.29</td>
<td>21</td>
<td>1.11</td>
</tr>
</tbody>
</table>

Value are expressed as Mean ± SD *n = 3  
C0 = Control formulation, C1-3 = Formulation of Croscarmellose sodium, F1-3 = Plantago ovata Husk

### Stability studies

The stability of the optimized formulation was known by performing stability studies for three months at accelerated conditions of 40°C±7.5 % RH on optimized formulation. The formulation was found to be stable, with insignificant change in the hardness, disintegration time, and in vitro drug release pattern the data have been given in Table 5.

### Table 3: In vitro evaluation data of Norfloxacin Oro Dispersible Tablets

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Thickness (cm)</th>
<th>Weight Variation (mg)***</th>
<th>Hardness (Kg/cm²)*</th>
<th>Friability (%w/w)*</th>
<th>Disintegration Time (secs)**</th>
<th>Drug content (%)</th>
<th>Water absorption ratio (%)**</th>
<th>Wetting Time (secs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0</td>
<td>4.31±0.24</td>
<td>258±0.91</td>
<td>4.91</td>
<td>0.33</td>
<td>145</td>
<td>98.87±1.00</td>
<td>32±0.40</td>
<td>170</td>
</tr>
<tr>
<td>C1</td>
<td>4.25±0.22</td>
<td>258±0.60</td>
<td>4.88</td>
<td>0.36</td>
<td>22</td>
<td>98.93±1.01</td>
<td>55±0.55</td>
<td>45</td>
</tr>
<tr>
<td>C2</td>
<td>4.26±0.22</td>
<td>258±0.55</td>
<td>4.90</td>
<td>0.35</td>
<td>16</td>
<td>98.88±0.11</td>
<td>59±0.41</td>
<td>25</td>
</tr>
<tr>
<td>C3</td>
<td>4.25±0.22</td>
<td>258±1.0</td>
<td>4.86</td>
<td>0.35</td>
<td>11</td>
<td>98.34±1.10</td>
<td>74±0.12</td>
<td>20</td>
</tr>
<tr>
<td>F1</td>
<td>4.62±0.24</td>
<td>258±1.10</td>
<td>4.81</td>
<td>0.35</td>
<td>17</td>
<td>98.37±0.61</td>
<td>60±0.51</td>
<td>30</td>
</tr>
<tr>
<td>F2</td>
<td>4.60±0.24</td>
<td>258±0.92</td>
<td>4.90</td>
<td>0.35</td>
<td>13</td>
<td>98.97±0.14</td>
<td>74±0.63</td>
<td>21</td>
</tr>
<tr>
<td>F3</td>
<td>4.54±0.24</td>
<td>258±0.93</td>
<td>4.95</td>
<td>0.36</td>
<td>08</td>
<td>99.36±0.40</td>
<td>79±0.64</td>
<td>17</td>
</tr>
</tbody>
</table>

Value are expressed as Mean ± SD, ***n = 20, **n = 6, *n = 3
Table 4: Swelling Index comparison of Natural and semi synthetic Superdisintegrant

<table>
<thead>
<tr>
<th>Name of Superdisintegrant</th>
<th>Swelling Index (% V/V)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plantago ovata husk</td>
<td>84</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>75</td>
</tr>
</tbody>
</table>

Table 5: Stability study data for optimized formulation F2

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Time in months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 (initial)</td>
</tr>
<tr>
<td>Hardness (kg/cm²)</td>
<td>4.90</td>
</tr>
<tr>
<td>Disintegration time (sec)</td>
<td>13</td>
</tr>
<tr>
<td>Drug content (%)</td>
<td>98.97</td>
</tr>
<tr>
<td><em>In vitro</em> drug release (%)</td>
<td>90.45</td>
</tr>
</tbody>
</table>

**In-Vitro release studies**

The *in-vitro* drug release studies were performed on the formulations prepared using either natural or semi synthetic superdisintegrants, drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The percent drug release from the Fast dissolving tablets of Norfloxacin using Croscarmellose sodium as superdisintegrants presented 91 percent release in fifteen minutes (15 mins) at concentration 6 percent, whereas Fast dissolving tablets of Norfloxacin using Plantago ovata husk presented 90.64 percent release in just ten minutes (10 mins).

**DISCUSSION**

**FT-IR Studies**

The IR spectra reveal the presence of the characteristic peaks and relative intensities of Norfloxacin. The infrared peak intensity of Norfloxacin appeared 1730 and 1348 cm⁻¹ assigned to the C=O and C-O groups of carboxylic acid. The infrared peak intensity at 2846 and 2556 cm⁻¹ corresponding to asymmetric and symmetric CH₂ stretch. Furthermore, the peaks corresponding to asymmetric and symmetric CH₂ groups from 2968 and 2837 cm⁻¹. A broad peak from 3676.6 to 3431.48 cm⁻¹ assigned to the NH₂⁻ also appeared clearly. The peak corresponding to aromatic -CH appeared at 3030.27 cm⁻¹. The main functional groups of Norfloxacin are COOH, NH Figure 1 A. The FT-IR spectra of Norfloxacin, Croscarmellose sodium and *Plantago ovata* Husk shows all the characteristic peaks for Norfloxacin i.e N-H stretch at 3303 cm⁻¹, C-O at 1342 cm⁻¹ Fig 1 B.C. Whereas the FT-IR spectra of Norfloxacin and Sucralose supports proper coating of the drug with sucralose, this can be attributed with slight decrease in the intensities of the percent transmittance, although all the characteristic (3432 cm⁻¹ for NH₂⁻ appeared clearly, 1348 cm⁻¹ for C=O appeared clearly of Norfloxacin, and also peak from 774.04 to 540 cm⁻¹ corresponding to C-Cl linkage in Sucralose), IR absorption peaks remains intact Fig 1 D.

**DSC studies**

The DSC thermo-gram of Norfloxacin exhibited an endothermic peak at 228.30 °C corresponding to its melting point Figure 2 A, slightly shift in Fig 2 B may be attributed due to some impurity but could not correspond to drug polymer interactions. Endothermic peak at 154.84 °C could correspond to evaporation of water in *Plantago ovata* Husk Fig 2 C. The DSC thermo-gram of the drug and sucralose shows characteristics for both Norfloxacin and Sucralose, which can be attributed by the thermal decomposition of Sucralose at 134.18 °C, similarly peak for Norfloxacin decomposition at 224.94 °C Fig 2 D.

**Oro-dispersible tablet properties**

The hardness of the tablets was found to be 4.86 and 4.95 kg/cm² and friability was found to be below 1% indicating good mechanical resistance. The drug content was found to be 98.34 ± 1.10% and 99.36 ± 0.40%.

**In-Vitro disintegration**

The most important parameter that needs to be optimized in the development of Orodispersible tablets is the disintegration of tablets. In the present study disintegration time of all the batches were found to be in the range of 8 to 17 secs for formulations having *Plantago ovata* Husk as superdisintegrant fulfilling the official requirements (3mins) while in the range of 11 to 22 secs for formulations having croscarmellose sodium as superdisintegrant. The control formulation showed disintegration time of 145 secs the data have been.

Disintegration behavior of the prepared Oro Dispersible Tablets in Phosphate buffer 6.8 pH have been shown in the Figure 3. The rapid disintegration of the oral dispersible tablets may be attributed by the fact that quicker penetration of buffer into the pores of the tablets, which might have lead to the swelling of superdisintegrant to create enough hydrodynamic pressure for quick and complete disintegration. Formulation F2 was selected as optimized containing *Plantago ovata* Husk as superdisintegrant. It showed less disintegration time of 13 sec may be due to swelling at faster rate upon contact with buffer as compared with Croscarmellose sodium. Husk containing formulation showed less disintegration time also with reasonable mechanical strength. It was also observed that formulations having Croscarmellose sodium showed lesser disintegration time at 7% concentration.
Chaturvedi et al.  

**Wetting time**

Wetting time is closely related to the inner structure of the tablets and to the hydrophilicity of the excipients therefore it was used as a measure to correlate with disintegration time in oral cavity. Since the dissolution process of a tablet depends upon the wetting time, followed by disintegration it could be predicted that wetting time can be the cause of disintegration. The wetting time was in the range of 17 to 30 sec for Husk, whereas 20 to 45 sec for Croscarmellose sodium, it can be depicted by the relation shown in the Figure 4.

**Water-absorption ratio**

Water absorption ratio was performed for ensuring the moisture sorption and water uptake properties of superdisintegrants. It was observed that water absorption ratio increased to a considerable extent and disintegration and wetting time was decreased when superdisintegrant concentration was increased. The water absorption ratio of the formulated tablets were found in the range of 60 – 79% for formulation having Husk, while for Croscarmellose it was in the range of 55 – 74%. Figure 5 shows the relation.

![Image of Figure 4: Wetting time of different formulation with different concentration](image)

**In–Vitro drug release**

The in-vitro drug release studies were performed on the formulations prepared using either natural or semi synthetic superdisintegrants, drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The percent drug release from the Oro Dispersible tablets of Norfloxacin using Croscarmellose sodium as superdisintegrants presented 91 percent release in fifteen minutes (15 mins) at concentration 6 percent, whereas Oro Dispersible tablets of Norfloxacin using Plantago ovata husk presented 90.64 percent release in just ten minutes (10 mins).

Figure 6 shows the percentage cumulative drug release.

![Image of Figure 6: Comparison of in vitro drug release of different formulations having either of superdisintegrants with control](image)
CONCLUSION
Oro dispersible tablets transform into easy-to-swallow suspension on contact with the saliva, after ingested in mouth. These are particularly useful for pediatric or geriatric patients, can be taken without liquids and facilitate treatment of Urinary tract infections. The developed formulations have suitable characteristics that distinguish them from common solid dosage forms, such as rapid disintegrating; combining advantages of both liquid and conventional tablet formulations, ease of swallowing and possible taste-masking components for an acceptable taste in the mouth. From the results obtained it can be concluded that Plantago ovata husk showed sufficient promise to warrant its use as natural superdisintegrant, as shown by the faster in-vitro release from the formulations containing Husk as superdisintegrant. From this study, results revealed that it is possible to enhance dissolution rate by using direct compression technique using different concentrations of Plantago ovata husk as superdisintegrants.

REFERENCES
8. Indian Pharmacopoeia Volume. 2. 3. 2007 New Delhi: Controller of Publication 2007, 355-356, 1407