Formulation And In Vitro Evaluation Of Sumatriptan Succinate Oral Thin Films

K. Vijaya Sri*, D. Ravishanker, P. Rohini, M. Subbarao
*Department of Pharmaceutics, Malla Reddy College of Pharmacy, Secunderabad, Andhra Pradesh, India-500014

ARTICLE INFO

ABSTRACT

Sumatriptan succinate is an antimigraine drug. Fast dissolving drug delivery system offers a solution for those patients having difficulty in swallowing tablets/capsules etc. The present investigation was undertaken with the objective of formulating sumatriptan succinate fast dissolving oral thin films allowing fast reproducible drug dissolution in oral cavity thus bypassing first pass metabolism, to enhance the convenience and compliance by the elderly and pediatric patients. Sumatriptan succinate oral thin films were prepared by solvent casting method with using different film-forming agents like HPMC, PVP, PEG 400, glycerol as a plasticizer and mannitol as filler and sweetener. Oral thin films were evaluated for mechanical properties, weight variation, thickness, drug content, disintegration time, and in-vitro dissolution studies. Sumatriptan succinate fast dissolving oral thin films based on evaluation studies HPMC showed optimum performance against other formulations. The prepared films were clear, transparent, smooth surface and stable. It was concluded that the fast dissolving oral thin films of sumatriptan succinate can be made by solvent casting technique with enhanced dissolution rate, better patient compliance and effective therapy.

Corresponding author

Dr. K. Vijaya Sri

Associate professor,
Malla Reddy College of Pharmacy
(Affiliated to Osmania University)
Maissamaguda, Secunderabad -500014
Andhra Pradesh, India.
Email: vijayasree_2002@yahoo.co.in


Copyright © 2013 This is an Open Access article distributed under the terms of the Indo American journal of Pharmaceutical Research, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.
INTRODUCTION

Fast-dissolving oral delivery systems are solid dosage forms, which disintegrate or dissolve within 1 min when placed in the mouth without drinking or chewing. The first developed fast-dissolving dosage form consisted of tablet form, and the rapid disintegrating properties were obtained through a special process or formulation modifications [1]. More recently, fast-dissolving films are gaining interest as an alternative to fast-dissolving tablets to definitely eliminate patients’ fear of chocking and overcome patent impediments. Fast-dissolving films are generally constituted of plasticized hydrocolloids or blends made of thereof that can be laminated by solvent casting or hot-melt extrusion [2]. According to the film forming material characteristics, the manufacture of the dosage forms can present different critical issues. Common problems are caused by foaming during the film formation due to the heating of the material or solvent evaporation, the flaking during the slitting and the cracking in the cutting phase. Furthermore, the films should be stable to moisture overtime. Finally, to facilitate the handling they have to be flexible and exhibit a suitable tensile strength and do not stick to the packaging materials and fingers.

Formulation of these systems is usually straightforward; the polymer and drug are dissolved in a solvent and a film is cast by solvent evaporation [3,4]. Most commercially available oral thin formulations, such as Oral film TM, 1 (benzocaine) or Theraflu ®, 2 (dextromethorphan / Phenylephrine HCl or Diphenhydramine HCl) are designed to deliver locally acting drugs or for mouth-freshening (such as Listerine Pocket Paks TM, 3).

Sumatriptan succinate (STS) is a potent and selective 5-HT agonist [5]. It is an effective agent in the treatment of acute migraine attack. It provides rapid symptomatic relief in about 85-90% of migraine patients within 2h of treatment. However, oral bioavailability is poor with only 14% of the dose reaching systemic circulation [6]. This is likely due to extensive pre-systemic clearance on first pass.

The aim of the study was to formulate sumatriptan succinate fast dissolving oral thin films allowing fast reproducible drug dissolution in oral cavity thus bypassing first pass metabolism, to enhance the convenience and compliance by the elderly and pediatric patients. In the present study, we developed oral thin films of STS and evaluated to study the various formulation variables that affect in vitro performance. Since critical issues in the development of a fast-dissolving film are mainly related to its mechanical properties, the influence of the type and the concentration of polymers on flexibility, and tensile strength were preliminarily evaluated.

MATERIALS AND METHODS

Materials

Sumatriptan succinate (STS) was received as a gift sample from Aurabindo Pharmaceuticals, Hyderabad, India. Two grades of HPMC i.e. HPMC E 15 LV, and HPMC E 50 LV were supplied from NP CHEM (Mumbai, India) and Preimum Burgoyme (Mumbai, India) respectively. Poly vinyl pyrrolidine (PVP), poly vinyl alcohol (PVA), methyl cellulose (MC) and PEG 400 were purchased from Sigma-Aldrich (Bangalore). Mannitol, glycerol (GLY) and citric acid were obtained from Carlo Erba Reagents. Menthol flavours were kindly gifted by Kerry Ingredients & Flavours (I). All solvents were of analytic grade.

Methods

Preparation of sumatriptan succinate oral thin films

The oral thin films of STS were prepared in laboratory using HPMC by solvent casting method [7]. Hydroxy propyl methyl cellulose (HPMC) is known for its good film forming properties and has excellent acceptability. Hence, various grades of HPMC namely Methocel E3 and Methocel E15 Premium LV were evaluated as primary film formers. For the fabrication of films, propylene glycol was used as a plasticizer, glycerin as humectant and mannitol was used as a sweetener. The required quantity of STS was dissolved in 10
ml of distilled water containing various grades of HPMC to form polymeric dispersion. Briefly, propylene glycol, glycerin, aspartame and various polyhydric alcohols were dissolved in 5 ml of 50% v/v ethanol. Alcoholic solution and the polymeric dispersion were mixed to obtain a homogeneous dispersion and 20 ml of the dispersion was cast onto each polypropylene petriplate. The composition of various films is shown in Table 1. The dispersion was dried at 40–45 °C. The films were carefully removed from petriplates and stored in an air tight glass bottle. The films were evaluated for imperfections and cuts, peel ability without rupturing, folding and cracking endurance and surface roughness.

Table 1: Different formulations of sumatriptan succinate oral thin films.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>SF1</th>
<th>SF2</th>
<th>SF3</th>
<th>SF4</th>
<th>SF5</th>
<th>SF6</th>
<th>SF7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sumatriptan succinate (mg)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>HPMC e 15 LV (mg)</td>
<td></td>
<td>80</td>
<td>-</td>
<td>20</td>
<td>-</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>HPMC e 50 LV (mg)</td>
<td>-</td>
<td>50</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PVA (2% w/v) (2ml)</td>
<td>-</td>
<td>-</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PVP (mg)</td>
<td>-</td>
<td>-</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>MC 360-400cps (mg)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Ethanol (ml)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Glycerol (ml)</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>PEG 400 (ml)</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Mannitol (5% w/v) (ml)</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Menthol (ml)</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
</tr>
<tr>
<td>Water upto (ml)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

*Q.S- Quantity Sufficient

Evaluation of the STS oral thin films

FTIR Studies

Compatiblity of STS and polymers was studied using Fourier Transform Infrared (FTIR) spectroscopy. FTIR Spectra were recorded between 500-4500 cm\(^{-1}\) using Shimadzu 160a, Kyoto, Japan by KBr Disc method.

Mechanical Properties

To avoid mechanical failure of the film and to ensure that film can bear the stress during transportation and storage, the following mechanical properties [8] such as film thickness, percentage moisture absorption, percentage moisture loss, swelling percentage, percentage elongation, weight variation, surface pH of film, folding endurance were measured.

Film thickness

STS films were evaluated for thickness by using calibrated digital Vernier Callipers. Three readings were taken and mean thickness was evaluated.
**Percentage Moisture Absorption (PMA)**

The PMA test was carried out to check the physical stability of films at high humid conditions. In the present study the moisture absorption capacities of the STS films were determined by keeping the preweighed films in a desiccator at room temperature for 72 hours. Then they were taken out and exposed to 79.5% relative humidity (saturated solution of aluminum chloride). Average percentage moisture absorption of three films can be calculated by following equation

\[ \text{Percentage moisture absorption} = \frac{(\text{Final weight} - \text{Initial weight}) \times 100}{\text{Initial weight}}. \]

**Percentage Moisture Loss**

Percentage moisture loss was also carried to check the integrity of STS films at dry condition. Three 2cm diameter films were cut and weighed accurately and kept in desiccators containing fused anhydrous calcium chloride. After 72 hours the films were removed and weighed. Average percentage moisture loss of three films was found out.

\[ \text{Percentage moisture loss} = \frac{(\text{Initial weight} - \text{Final weight}) \times 100}{\text{Final weight}} \]

**Swelling Percentage**

The swelling percentage of STS thin films was calculated by using the following formula:

\[ \% \, S = \frac{(X_t - X_0) \times 100}{X_0} \]

Where, \( \% \, S \) - swelling percentage, \( X_t \) - the weight of swollen film after time, \( X_0 \) - weight of the film at zero time zero.

**Percentage elongation**

This study was conducted only for the optimized STS film formulations. Generally elongation of film increases as the plasticizer content increases.

\[ \text{Percent Elongation} = \frac{L}{L_0} \times 100 \]

Where, \( L \) = Increase in length of film; \( L_0 \) = Initial length of film.

**Weight Variation**

Weight variation was studied by individually weighing 10 randomly selected STS films and calculating the average weight. The individual weight should not deviate significantly from the average weight.

**Surface pH**

The surface pH of STS fast dissolving oral thin films was determined in order to investigate the possibility of any side effects *in vivo*. As an acidic or alkaline pH may cause irritation to the oral mucosa, it was determined to keep the surface pH as close to neutral as possible. A combined pH electrode was used for this purpose. Oral strip was slightly wet with the help of water. The pH was measured by bringing the electrode in contact with the surface of the film.

**Folding Endurance**

Folding endurance of the STS oral thin film was determined by repeatedly folding a small strip of film (2 cm x 2 cm) at the same place until it broke. The number of times the film could be folded at the same place without breaking gives the value of folding endurance.
Drug content

Drug content of all batches of STS thin films was determined by UV- spectrophotometric method. For this purpose, one strip of 4 cm² was dissolved in 100ml of pH 6.8 buffer. Then the solution was suitably diluted and the absorbance was recorded at 227 nm.

Uniformity of drug content

The uniformity of dosage units of the oral film preparation was tested using 10 preparations, and the content of sumatriptan succinate was determined by UV-spectrophotometry. The acceptance value (AV) of the preparation is less than 15%, according to the JP15. While in USP27, the contents of preparations are between 85% and 115% and the relative standard deviation is less than or equal to 6.0%. AV for JP15 was calculated according to the following equation:

$$AV = |M - X| + ks$$

Where, M is label claim (100%), X the average (%) of individual contents, k the acceptability constant (2.2), and s is the standard deviation.

STS oral thin films solid state evaluation

In vitro disintegration time

Disintegration test of STS thin films was performed in the USP disintegration time testing apparatus and simulated salivary fluid (pH 6.8) was used as medium. The films were placed in the tube of the container and disintegration time was recorded.

In vitro dissolution studies

The dissolution rate of STS films was studied in 900 ml of pH 6.8 buffer using USP dissolution test apparatus with basket stirrer at 50 rpm. A temperature of 37°C ± 1°C was maintained throughout the study. One film containing 25 mg of STS was used in each test. Samples of dissolution media (5 ml) were withdrawn at predetermined intervals suitably diluted and assayed for sumatriptan succinate at 227 nm. The sample of dissolution fluid withdrawn at each time was replaced with fresh dissolution fluid. The dissolution experiments were conducted in triplicate. Drug percent dissolved at 10 min (DP₁₀), values were calculated from the dissolution data given Table 4.

Kinetic modeling of oral thin films

The dissolution profile of STS oral thin films followed first order to ascertain the kinetic modeling of the drug release.

Zero order

In many of the modified release dosage forms, particularly sustained or controlled release dosage forms (those dosage forms that release the drug in planned, predictable and slower than the normal manner), is zero-order kinetic.

$$m = k * t$$

Where, k is zero-order constant, m is the % drug unreleased and t is the time. The plot of % drug unreleased (released) versus time is linear.
First order

Most conventional dosage forms exhibit this dissolution mechanism. Some modified release preparations, particularly prolonged release formulations, adhere to this type of dissolution pattern.

\[ m = ea * e^{bt} \]

Where, \( a \) is the intercept and \( b \) is the slope. It assumes that the drug molecules diffuse out through a gel like layer formed around the drug during the dissolution process. A plot of log % drug release versus time is linear.

Stability Studies

For stability testing the optimized formulation (SF7-HPMC E 15 LV+MC) were stored under controlled conditions of 40°C±2°C and 75%±5% RH over a period of 3 months according to the ICH guidelines. During storage the films were evaluated for their physical appearance, disintegration time, drug content and in-vitro dissolution studies.

RESULTS AND DISCUSSION

The FT-IR spectra of STS and its physical mixtures are shown in Figure 1. The FTIR spectrum of STS depicts a characteristic absorption band at 3512 cm\(^{-1}\) and 2300 - 2400 cm\(^{-1}\) representing the presence of OH group and NH\(_2\). Hence, there was no chemical and physical change in the functional groups present in STS.

![Figure 1: FTIR studies. IR spectra of a) Sumatriptan succinate , b) HPMC E 50 LV, c) HPMC E 15 LV, d) Physical mixture of polymers and sumatriptan succinate.](image)

Evaluation parameters of sumatriptan succinate oral thin films results were shown in Table2 and Table 3. Percentage moisture absorption varied within the range of 3.5 to 4.1%. It indicates that the films were stable. Percentage moisture loss was carried out to know the integrity of the film. Percentage moisture loss varied within the range of 1.53 to 2.84%. SF7 showed less percentage moisture loss i.e. 1.53% and formulation SF6 showed more percentage moisture loss i.e. 2.84%. Swelling percentage varied within the range of 17.9 to
38.9%. It was found to be more for formulation SF7 i.e. 38.9%. More swelling percentage indicates that the drug release is more and hence rapid onset of action. Percentage elongation varied within the range of 9.93 to 17.5% which indicates plasticity of the films.

As all the formulations contained different polymers, the thickness varied in the range of 0.22mm to 0.33 mm. Weight variation was carried out and this varied within the range of 33.4 to 47.0 mg. As per USP requirements, the formulations were found to meet the criteria for weight variation. The surface pH of the strips was ranging from 6.75 to 6.96. Since surface pH of films was found to be around neutral pH, there will not be any kind of irritation to the mucosal lining of the oral cavity. Folding endurance is determined by folding the films of uniform cross section area and thickness until it breaks. It was measured manually and all the formulations showed good folding endurance. As all the formulations showed folding endurance nearest to 300, it indicates good plasticity. Increase in number of folds was due to elasticity nature of polymer. Drug content was evaluated and it varied within the range of 93.6 to 99.6%. Three film strips of 1cm² were cut from each film and estimated for drug content using UV-Spectrophotometric method. It was found that the drug was uniformly distributed throughout the film. In vivo disintegrating time is defined as the time (seconds) at which a film breaks when brought into the contact with water or saliva. All the formulations were found to disintegrate within 60 sec. Formulation SF7 showed less disintegration time i.e. 21.6 sec and formulation SF1 showed more disintegration time i.e. 59.0 sec.

**Table 2:** Evaluation of oral thin films of sumatriptan succinate.

<table>
<thead>
<tr>
<th>Formulations</th>
<th>% moisture absorption</th>
<th>% moisture loss</th>
<th>Swelling %</th>
<th>% Elongation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF1</td>
<td>2.09 (0.036)</td>
<td>3.95 (0.032)</td>
<td>37.65 (0.052)</td>
<td>17.45 (0.050)</td>
</tr>
<tr>
<td>SF2</td>
<td>2.41 (0.015)</td>
<td>4.17 (0.025)</td>
<td>35.85 (0.015)</td>
<td>12.90 (0.100)</td>
</tr>
<tr>
<td>SF3</td>
<td>2.68 (0.015)</td>
<td>3.66 (0.023)</td>
<td>17.90 (0.045)</td>
<td>9.93 (0.050)</td>
</tr>
<tr>
<td>SF4</td>
<td>2.52 (0.015)</td>
<td>3.83 (0.030)</td>
<td>21.08 (0.158)</td>
<td>19.83 (0.150)</td>
</tr>
<tr>
<td>SF5</td>
<td>2.44 (0.020)</td>
<td>3.73 (0.030)</td>
<td>32.11 (0.158)</td>
<td>9.93 (0.150)</td>
</tr>
<tr>
<td>SF6</td>
<td>2.84 (0.005)</td>
<td>3.84 (0.015)</td>
<td>23.10 (0.102)</td>
<td>17.50 (0.050)</td>
</tr>
<tr>
<td>SF7</td>
<td>1.53 (0.020)</td>
<td>3.53 (0.020)</td>
<td>38.90 (0.037)</td>
<td>12.50 (0.001)</td>
</tr>
</tbody>
</table>

Values in parentheses represent SD, n=3.
Table 3: Evaluation of oral thin films of sumatriptan succinate.

<table>
<thead>
<tr>
<th>Formulations</th>
<th>Film thicknessa</th>
<th>Folding endurancea</th>
<th>Disintegration time(sec)b</th>
<th>Surface pHb</th>
<th>%drug contentc</th>
<th>Weight variationc</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF1</td>
<td>0.23 (0.01)</td>
<td>300.3 (3.51)</td>
<td>59.00 (2.00)</td>
<td>6.94 (0.03)</td>
<td>93.6 (0.10)</td>
<td>47.0 (0.01)</td>
</tr>
<tr>
<td>SF2</td>
<td>0.28 (0.07)</td>
<td>296.0 (6.08)</td>
<td>23.33 (1.52)</td>
<td>6.87 (0.11)</td>
<td>96.5 (0.20)</td>
<td>33.4 (0.04)</td>
</tr>
<tr>
<td>SF3</td>
<td>0.33 (0.01)</td>
<td>292.00 (2.64)</td>
<td>39.66 (0.57)</td>
<td>6.85 (0.02)</td>
<td>95.4 (0.15)</td>
<td>35.6 (0.06)</td>
</tr>
<tr>
<td>SF4</td>
<td>0.26 (0.01)</td>
<td>298.00 (1.00)</td>
<td>28.33 (1.52)</td>
<td>6.96 (0.15)</td>
<td>96.9 (0.15)</td>
<td>46.6 (0.05)</td>
</tr>
<tr>
<td>SF5</td>
<td>0.23 (0.01)</td>
<td>286.66 (1.52)</td>
<td>22.00 (1.00)</td>
<td>6.85 (0.02)</td>
<td>93.6 (0.10)</td>
<td>43.3 (0.06)</td>
</tr>
<tr>
<td>SF6</td>
<td>0.22 (0.01)</td>
<td>273.66 (3.21)</td>
<td>39.00 (1.00)</td>
<td>6.75 (0.07)</td>
<td>99.6 (0.11)</td>
<td>36.5 (0.04)</td>
</tr>
<tr>
<td>SF7</td>
<td>0.25 (0.01)</td>
<td>296.66 (1.52)</td>
<td>21.66 (1.52)</td>
<td>6.88 (0.03)</td>
<td>98.4 (0.11)</td>
<td>37.3 (0.03)</td>
</tr>
</tbody>
</table>


*In vitro* drug release was carried out in USP basket type dissolution apparatus using phosphate buffer pH 6.8. SF7 formulation released more amount of drug i.e. 94.55% and formulation SF3 released less amount of drug i.e. 76.86% as showed in Figure 2. Dissolution rate increases with decrease in disintegration time. More amount of drug release indicates rapid onset of action and hence faster relief.

![Figure 2](https://via.placeholder.com/150)

**Figure 2:** Comparative dissolution profile of sumatriptan succinate oral thin films.
Dissolution parameters of STS oral thin films $K^{-1}(\text{min}^{-1})$, $T_{50}$, $r$, $DP_{10}$ drug percent release at 10 min values and $R^2$ values for zero order release and first order release are mentioned in Table 4. The values for first order were closer to 1 than those for zero order. So, it was assumed that all the formulations followed first order kinetics. When the oral film preparations were stored under controlled conditions, no apparent changes in the shape, color or flexibility were observed. Disintegration time, drug content and *in-vitro* dissolution studies were evaluated and showed in Table 5.

**Table 4**: Dissolution parameters and kinetic modeling of sumatriptan succinate oral thin films.

<table>
<thead>
<tr>
<th>Formulations</th>
<th>$K^{-1}(\text{min}^{-1})$</th>
<th>$T_{50}$</th>
<th>$DP_{10}$</th>
<th>First order ($R^2$)</th>
<th>Zero order ($R^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF1</td>
<td>0.046</td>
<td>15.0</td>
<td>54.0</td>
<td>0.966</td>
<td>0.826</td>
</tr>
<tr>
<td>SF2</td>
<td>0.057</td>
<td>12.0</td>
<td>59.8</td>
<td>0.988</td>
<td>0.790</td>
</tr>
<tr>
<td>SF3</td>
<td>0.027</td>
<td>25.0</td>
<td>53.0</td>
<td>0.885</td>
<td>0.678</td>
</tr>
<tr>
<td>SF4</td>
<td>0.041</td>
<td>16.7</td>
<td>58.8</td>
<td>0.894</td>
<td>0.709</td>
</tr>
<tr>
<td>SF5</td>
<td>0.055</td>
<td>12.5</td>
<td>69.4</td>
<td>0.912</td>
<td>0.653</td>
</tr>
<tr>
<td>SF6</td>
<td>0.029</td>
<td>23.1</td>
<td>55.63</td>
<td>0.901</td>
<td>0.642</td>
</tr>
<tr>
<td>SF7</td>
<td>0.071</td>
<td>9.7</td>
<td>66.57</td>
<td>0.925</td>
<td>0.749</td>
</tr>
</tbody>
</table>

**Table 5**: Accelerated stability studies of optimized formulation SF7.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Initial</th>
<th>After 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disintegration time (sec)</td>
<td>21.0</td>
<td>22.0</td>
</tr>
<tr>
<td></td>
<td>1.5</td>
<td>(1.1)</td>
</tr>
<tr>
<td>Drug content</td>
<td>98.4</td>
<td>98.0</td>
</tr>
<tr>
<td></td>
<td>(0.11)</td>
<td>(0.11)</td>
</tr>
<tr>
<td>Invitro Dissolution studies</td>
<td>94.5</td>
<td>94.6</td>
</tr>
<tr>
<td></td>
<td>(0.20)</td>
<td>(0.1)</td>
</tr>
</tbody>
</table>

Values in parentheses represent SD, $n=3$.

**CONCLUSION**

Fast dissolving films fulfill all the aforementioned requirements of potential solid oral dosage form for local delivery of sumatriptan succinate. Fast dissolving film when placed in the oral cavity quickly gets hydrated, sticks onto the site of application and then disintegrates to release the drug [9]. Thus, a fast dissolving film is a unique solid oral dosage form and has valuable advantages [10]. The sumatriptan succinate oral thin film preparation met the criteria of AV in the dosage uniformity test for JP15 and USP27; moreover, it revealed an excellent stability and dissolution profile.

The application of oral thin films now extends beyond traditional immediate release oral dosage forms. Development of topical films, probiotic strips, and controlled-release oral thin films products are new forms made possible through this delivery format’s flexibility, proven robustness and stability. The future of work on STS oral thin formulation and processing is a direct reflection of evolving healthcare needs and determination of pharmacokinetic parameters in animal’s studies.
ACKNOWLEDGEMENT

The authors are thankful to Prof. M. Sudhakar, Principal of Malla Reddy college of Pharmacy, Hyderabad for providing the facilities to carry out the research work. The authors are also thankful to Aurabindo Pharmaceuticals, Hyderabad, India, for providing the gift sample of sumatriptan succinate.

Competing Interests
The authors declare no conflict of interest.

REFERENCES