ABSTRACT
The present work is focused on the development and evaluation of ELETRIPTAN transdermal patches. ELETRIPTAN is used as anti-migraine drug. Matrix types Transdermal Patches were prepared and the technique used is solvent evaporation technique. The transdermal patches were prepared using HPMC K100LV/ K15M grades polymers respectively. A total of 9 formulations were prepared with different quantities of HPMC polymers. These 9 formulations were divided into 3 sets. In 1st set HPMC K100LV polymer 2nd set HPMC K15M and 3rd set combination of HPMC K100LV & K15M. The solvent used for the preparation is water. PEG 400 was used as plasticizer. ELETRIPTAN drug is available in tablet form and its dose is twice a day i.e. 80mg/day. The main work of this development of new technique is to overcome non compliance of tablet dosage form. This formulation is used for the patients who are suffering from acute migraine attack. The tablet form of drug should be administered twice a day i.e. 40mg at a time so to reduce continuous use of tablet this transdermal patch formulation would help to avoid continuous administration of tablet. The % drug release of the best batch i.e. optimized batch F1 was 86.43%. Transdermal patches of Eletriptan may provide sustained transdermal delivery for prolonged periods in the management of migraine, which can be a good way to bypass the extensive hepatic first-pass metabolism.

KEYWORDS: HPMC, ELETRIPTAN, plasticizer.
INTRODUCTION

Eletriptan (trade name Relpax, used in the form of Eletriptan hydrobromide) is a second generation triptan drug intended for treatment of migraine headaches. It is used as an abortive medication, blocking a migraine attack which is already in progress. Eletriptan drug belongs to BCS class I.

Systematic (IUPAC) name
(R)-3-[(1-methylpyrrolidin-2-yl) methyl]-5-(2-phenylsulfonylethyl)-1H-indole.

Bioavailability - 50%
Half-life - 4 hours.

Formula C_{22}H_{26}N_{2}O_{2}S
Mol. mass 382.52 g/mol

Eletriptan is believed to reduce swelling of the blood vessels surrounding the brain. This swelling is associated with the head pain of a migraine attack. It blocks the release of substances from nerve endings that cause more pain and other symptoms like nausea, and sensitivity to light and sound. Eletriptan is a serotonin agonist. Specifically, it is a selective 5-hydroxytryptamine (5-HT) receptor agonist. Eletriptan binds with high affinity to the 5-HT receptors.

A transdermal patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. Often, this promotes healing to an injured area of the body. An advantage of a transdermal drug delivery route over other types of medication delivery such as oral, topical, intravenous, intramuscular, etc. is that the patch provides a controlled release of the medication into the patient, usually through either a porous membrane covering a reservoir of medication or through body heat melting thin layers of medication embedded in the adhesive.

So the main objective was to formulate the transdermal patches for migraine disorder by solvent evaporation technique and to evaluate the films. % release of the drug was calculated. This formulation would help to avoid non-compliance of the tablet dosage form.

CHARACTERIZATION OF DRUG

Description: The sample of Eletriptan was analyzed for physical appearance and powder nature.
**Solubility of the drug:** The solubility test was carried out by *Shake Flask Method*. Eletriptan drug was weighed about 10 mg and was dissolved in 100 mL of distilled water in a conical flask. This conical flask was kept in an orbital shaker for 24 hrs. The conical flask was removed from the shaker after 24 hrs. 1 mL solution was taken and diluted up to 10 mL in distilled water. The solubility of the drug was measured in UV visible spectrophotometer at $\lambda$ max.

**UV scanning of drug**

The standard solution of Eletriptan was prepared by taking different concentrations of solution from the conical flask which was kept in an orbital shaker for 24 hrs. Different dilutions were prepared by taking 2$\mu$g/ml, 4$\mu$g/ml, 6$\mu$g/ml, and 8$\mu$g/ml. (10$\mu$g/ml) dilution was scanned between 200-400 nm on UV spectrophotometer to determine the maximum absorption ($\lambda$ max).

**Construction of calibration curve of Eletriptan**

**Preparation of Phosphate Buffer saline solution pH 7.4**

Dissolve the following in 800 ml distilled water. 8 g of NaCl, 0.2 g of KCl, 1.44 g of Na$_2$HPO$_4$, 0.24 g of KH$_2$PO$_4$. Adjust pH to 7.4 or 7.6 with HCl. Adjust volume to 1 L with additional distilled water.

**Stock solution**

Eletriptan 10 mg was dissolved in 100 ml Phosphate buffer saline pH 7.4 solutions. This gives 100 $\mu$g/ml. Suitable dilutions were made and finally scanned for maximum absorbance by UV spectrophotometer (Double beam) in range from 200 to 400 nm.

**Serial dilutions**

Pipette out 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml, 1 ml, 1.2 ml, 1.4 ml, 1.6 ml, 1.8 ml and 2 ml from stock solution and further diluted up to 10 ml with Phosphate buffer saline pH 7.4 solution. This gives 2 $\mu$g/ml, 4 $\mu$g/ml, 6 $\mu$g/ml, 8 $\mu$g/ml, 10 $\mu$g/ml, 12 $\mu$g/ml, 14 $\mu$g/ml, 16 $\mu$g/ml, 18 $\mu$g/ml and 20 $\mu$g/ml respectively.

**COMPATIBILITY BETWEEN DRUG AND EXCIPIENTS**

**FTIR spectra analysis:** FTIR spectroscopy is one of the qualitative analytical techniques, which offers the possibility of detecting chemical interaction. FTIR spectra of Eletriptan and formulations were determined on Fourier Transform Infrared Spectrophotometer. The FTIR was performed on Eletriptan, HPMC K100LV and mixture of Eletriptan with HPMC.
PREPARATION OF MATRIX TYPE OF TRANSDERMAL PATCHES

The patch formation were initially done with drug 80 mg and different solvents such chloroform, acetone, methanol and ethanol with different concentrations as the solubility of the drug and polymers were good in this solvents but after formation of the patches it may show some crystals formation which may lead to the saturation of the drug. So the dose of the drug was reduced from 80 mg to 40 mg. Finally the patches were formed with no crystals and solvent was distilled water as both drug and polymer are completely soluble in distilled water.

Preparation of Model Patches

The model transdermal patches were prepared using HPMC K100LV polymer by solvent evaporation method. 250 mg, 300 mg and 350 mg of HPMC K100LV polymer was weighed accurately and kept aside. 40 mg of Eletriptan was weighed accurately and is dissolved in 50 mL of distilled water in 4 different beakers. Keep the beakers on the magnetic stirrers for continuous stirring at room temperature. While stirring add the different quantity polymer into the beakers slowly. As the drug and polymer both are hydrophilic in nature they get completely dissolved in solvent.

PEG 400 (polyethylene glycol 400) is added to the solution about 0.1 mL as it has good Penetrating Enhancer and Plasticizer properties. The whole solution was mixed thoroughly with the help of a magnetic stirrer for 30 minutes. The aluminum foil was placed over a flat petri plate. The whole solution was poured into the aluminum foil. An inverted funnel was placed over the aluminum foil to avoid sudden evaporation.

Then the petri plates were kept for 12 hours in hot air oven at 40°C for drying. After careful examination, the dried patches were removed from the aluminum foil checked for any imperfections or air bubbles and cut into 2.5 x 2.5 cm patches using a specially fabricated circular stainless steel cutter and preserved in aluminum foil and in a desiccator.

Preparation of Eletriptan – HPMC K100LV patches

Transdermal patches were prepared using polymer along with the drug and a suitable solvent. The Transdermal patches of Eletriptan were prepared using HPMC K100LV polymer by solvent evaporation method. 250 mg, 300 mg and 350 mg of HPMC K100LV polymer was weighed accurately and kept aside. 40 mg of Eletriptan was weighed accurately and is dissolved in 50 mL of distilled water in 3 different beakers. Keep the beakers on the magnetic stirrers for continuous stirring at room temperature. While stirring add the different quantity...
polymer into the beakers slowly. As the drug and polymer both are hydrophilic in nature they get completely dissolved in solvent.

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Then the petri plates were kept for 12 hours in hot air oven at 40° C for drying. After careful examination, the dried patches were removed from the aluminum foil checked for any imperfections or air bubbles and cut into 2.5 x 2.5 cm patches using a specially fabricated circular stainless steel cutter and preserved in aluminum foil and in desiccators.

**Preparation of Eletriptan – HPMC K15M patches**

Transdermal patches were prepared using polymer along with the drug and a suitable solvent. The Transdermal patches of Eletriptan were prepared using HPMC K15M polymer by solvent evaporation method. 250 mg, 300 mg and 350 mg of HPMC K15M polymer was weighed accurately and kept aside. 40 mg of Eletriptan was weighed accurately and is dissolved in 50 mL of distilled water in 3 different beakers. Keep the beakers on the magnetic stirrers for continuous stirring at room temperature. While stirring add the different quantity polymer into the beakers slowly. As the drug and polymer both are hydrophilic in nature they get completely dissolved in solvent.

PEG 400 (polyethylene glycol 400) is added to the solution about 0.1 mL as it has good Penetrating Enhancer and Plasticizer properties. The whole solution was mixed thoroughly with the help of a magnetic stirrer for 30 minutes. The aluminum foil was placed over a flat petri plate. The whole solution was poured into the aluminum foil. An inverted funnel was placed over the aluminum foil to avoid sudden evaporation.

Then the petri plates were kept for 12 hours in hot air oven at 40° C for drying. After careful examination, the dried patches were removed from the aluminum foil checked for any imperfections or air bubbles and cut into 2.5 x 2.5 cm patches using a specially fabricated circular stainless steel cutter and preserved in aluminum foil and in a desiccator.
**Preparation of Eletriptan - HPMC K15M & HPMC K100LV patches**

Transdermal patches were prepared using polymer along with the drug and a suitable solvent. The Transdermal patches of Eletriptan were prepared using HPMC K15M&HPMC K100LV combination polymer by solvent evaporation method. 150 mg HPMC K100LV + 100 mg HPMC K15M, 200 mg HPMC K100LV + 50 mg HPMC K15M and 150 mg of HPMC K15M + 100 mg HPMC K100LV polymer were weighed accurately and kept aside. 40 mg of Eletriptan was weighed accurately and is dissolved in 50 mL of distilled water. Keep the beakers on the magnetic stirrers for continuous stirring at room temperature. While stirring add different quantity of polymer into the beakers slowly. As the drug and polymer both are hydrophilic in nature they get completely dissolved in solvent.

PEG 400 (polyethylene glycol 400) is added to the solution about 0.1 mL as it has good Penetrating Enhancer and Plasticizer properties. The whole solution was mixed thoroughly with the help of a magnetic stirrer for 30 minutes. The aluminum foil was placed over a flat petri plate. The whole solution was poured into the aluminum foil. An inverted funnel was placed over the aluminum foil to avoid sudden evaporation.

Then the petri plates were kept for 12 hours in hot air oven at 40° C for drying. After careful examination, the dried patches were removed from the aluminum foil checked for any imperfections or air bubbles and cut into 2.5 x 2.5 cm patches using a specially fabricated circular stainless steel cutter and preserved in aluminum foil and in a desiccator.

**Table 6: Formulation of Eletriptan transdermal patches**

<table>
<thead>
<tr>
<th>Ingredients(per patch)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eletriptan (mg)</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>HPMC K100 LV (mg)</td>
<td>250</td>
<td>300</td>
<td>350</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>250</td>
<td>300</td>
<td>350</td>
</tr>
<tr>
<td>HPMC K15M (mg)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>250</td>
<td>300</td>
<td>350</td>
<td>350</td>
<td>300</td>
<td>250</td>
</tr>
<tr>
<td>Water (mL)</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>PEG 400 (mL)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Total Weight (mg)</td>
<td>320</td>
<td>350</td>
<td>410</td>
<td>315</td>
<td>375</td>
<td>414</td>
<td>645</td>
<td>658</td>
<td>655</td>
</tr>
</tbody>
</table>

**Note:** The viscosity of HPMC K100LV is much lesser than HPMC K15M but both the polymers were taken into consideration because the half-life of drug is about 4 hours. So in this formulation we have to consider the releasing factor of drug in both the polymers and combination to get required effects and release of drug in the body.
RESULTS AND DISCUSSION

Preformulation Study

Eletriptan drug is a white powder, odourless and bitter taste. The melting point was found to be 169-171 °C which is matching with reported value. Solubility of Eletriptan drug in distilled water is 0.39 mg/ml and in Phosphate buffer saline 7.4 is 0.35 mg/ml.

Fig: FTIR of Eletriptan
Fig: FTIR of Eletriptan & HPMC K100LV

Fig: FTIR of Eletriptan & HPMC K15M
Fig: Determination of wavelength (λ max) of Eletriptan drug in water

The solubility of Eletriptan shows the absorbance at respective concentrations and shows the linearity of the points which gives y= 0.007x-0.002 equation and R² = 0.995.

Physiochemical parameters

1) **Thickness**: The thickness of the transdermal patch ranges between 0.13-0.18 mm.
2) **Tensile strength**: Tensile strength ranges between 0.180- 0.320 kg/mm².
3) **Folding endurance**: Folding endurance ranges between 20-35.
4) **% swelling index**: Swelling index of all formulations ranges between 18-29 %.
5) **% moisture absorbed**: All the % moisture absorbed of all formulations ranges between 1.433- 3.334.
6) **% moisture loss**: All the % moisture loss of all formulations ranges between 0.36-0.82.
7) **Drug content**: All the formulation contents the drug ranging 38.4-39.6 mg.
8) **Flatness**: All the patches were evaluated with 100 % flatness.
Table 7: Diffusion (% Release)

<table>
<thead>
<tr>
<th>Time (Hrs)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.11± 1.05</td>
<td>2.45± 0.25</td>
<td>0.80± 0.43</td>
<td>1.22± 0.3</td>
<td>1.08±0.15</td>
<td>1.35± 0.35</td>
<td>1.22± 0.21</td>
<td>0.80±0.21</td>
<td>0.94±0.32</td>
</tr>
<tr>
<td>2</td>
<td>4.37± 0.4</td>
<td>4.27±0.08</td>
<td>1.73± 0.54</td>
<td>2.60±0.34</td>
<td>2.04±0.14</td>
<td>2.28± 1.3</td>
<td>2.12±0.43</td>
<td>1.73±0.65</td>
<td>1.4±0.54</td>
</tr>
<tr>
<td>4</td>
<td>9.05± 0.14</td>
<td>8.84±0.37</td>
<td>5.02±0.23</td>
<td>4.76±0.43</td>
<td>4.31±0.65</td>
<td>4.21±0.32</td>
<td>4.32±0.21</td>
<td>4.02±0.15</td>
<td>2.88±0.12</td>
</tr>
<tr>
<td>6</td>
<td>13.12±0.39</td>
<td>13.9±0.25</td>
<td>10±0.26</td>
<td>8.01±0.12</td>
<td>6.86±0.17</td>
<td>7.29±0.54</td>
<td>7.09±0.43</td>
<td>6.79±0.54</td>
<td>4.98±0.54</td>
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<tr>
<td>8</td>
<td>17.88±0.16</td>
<td>18.5±0.08</td>
<td>14.80±0.43</td>
<td>11.08±0.43</td>
<td>10.14±0.54</td>
<td>11.01±1.15</td>
<td>10.77±0.43</td>
<td>9.10±0.32</td>
<td>7.69±0.65</td>
</tr>
<tr>
<td>10</td>
<td>22.59± 0.25</td>
<td>25.6±0.37</td>
<td>19.04±0.32</td>
<td>14.70±0.35</td>
<td>13.70±0.14</td>
<td>13.74±0.32</td>
<td>14.01±0.54</td>
<td>12.08±0.18</td>
<td>10.46±0.12</td>
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<tr>
<td>12</td>
<td>28.20±0.39</td>
<td>35.79±0.3</td>
<td>26.52±0.5</td>
<td>18.59±0.5</td>
<td>17.15±0.45</td>
<td>17.67±0.54</td>
<td>17.47±0.45</td>
<td>15.56±0.32</td>
<td>12.36±0.54</td>
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<tr>
<td>14</td>
<td>34.37±0.29</td>
<td>41.13±0.49</td>
<td>35.29±0.34</td>
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<td>19.33±0.25</td>
<td>16.64±0.37</td>
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<tr>
<td>16</td>
<td>41.70±0.35</td>
<td>46±0.32</td>
<td>42.07±0.54</td>
<td>26.68±0.54</td>
<td>25.88±0.23</td>
<td>26.35±0.54</td>
<td>25.87±0.54</td>
<td>23.11±0.65</td>
<td>21.62±0.65</td>
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<tr>
<td>18</td>
<td>49.30±0.32</td>
<td>50.34±0.4</td>
<td>48.91±0.45</td>
<td>31.5±0.65</td>
<td>30.33±0.4</td>
<td>31.48±0.54</td>
<td>30.06±0.54</td>
<td>27.95±0.64</td>
<td>26.31±0.12</td>
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<tr>
<td>20</td>
<td>58.15± 0.5</td>
<td>58.92±0.54</td>
<td>57.42±0.14</td>
<td>36.64±0.32</td>
<td>35.35±0.21</td>
<td>37.37±0.21</td>
<td>35.02±0.12</td>
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<tr>
<td>22</td>
<td>71.30±0.24</td>
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<td>42.22±0.12</td>
<td>41.04±0.3</td>
<td>43.31±0.14</td>
<td>40.54±0.54</td>
<td>37.45±0.42</td>
<td>36.16±0.45</td>
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<tr>
<td>24</td>
<td>86.43±0.21</td>
<td>84.66±0.23</td>
<td>79.88±0.32</td>
<td>48.62±0.43</td>
<td>47.24±0.43</td>
<td>50.47±1.43</td>
<td>46.70±0.65</td>
<td>42.92±0.12</td>
<td>40.89±0.65</td>
</tr>
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</table>

*All values are mean ± SD, (n=3)
Table 8: Kinetics of *in-vitro* diffusion studies

<table>
<thead>
<tr>
<th></th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero order R</td>
<td>0.9852</td>
<td>0.9876</td>
<td>0.9882</td>
<td>0.9880</td>
<td>0.9885</td>
<td>0.9952</td>
<td>0.9976</td>
<td>0.9929</td>
<td>0.9965</td>
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<tr>
<td>k</td>
<td>3.0298</td>
<td>3.0004</td>
<td>2.8251</td>
<td>1.9836</td>
<td>0.9176</td>
<td>0.9533</td>
<td>0.9563</td>
<td>0.9547</td>
<td>0.9476</td>
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<tr>
<td>1st Order R</td>
<td>0.9121</td>
<td>0.9171</td>
<td>0.9308</td>
<td>0.9612</td>
<td>0.9938</td>
<td>0.9915</td>
<td>0.9934</td>
<td>0.9967</td>
<td>0.9974</td>
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<tr>
<td>k</td>
<td>-0.048</td>
<td>-0.047</td>
<td>-0.0423</td>
<td>0.0252</td>
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<td>-0.001</td>
<td>-0.003</td>
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<td>-0.002</td>
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<tr>
<td>Matrix R</td>
<td>0.8969</td>
<td>0.8767</td>
<td>0.8762</td>
<td>0.8745</td>
<td>0.9561</td>
<td>0.9139</td>
<td>0.9154</td>
<td>0.9132</td>
<td>0.9575</td>
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<tr>
<td>Peppas R</td>
<td>0.9941</td>
<td>0.9943</td>
<td>0.9962</td>
<td>0.9933</td>
<td>0.9986</td>
<td>0.9931</td>
<td>0.9956</td>
<td>0.9976</td>
<td>0.9965</td>
</tr>
<tr>
<td>k</td>
<td>2.4928</td>
<td>2.6532</td>
<td>2.2524</td>
<td>1.636</td>
<td>1.768</td>
<td>1.3868</td>
<td>1.4568</td>
<td>1.5676</td>
<td>1.6045</td>
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<tr>
<td>Hix. Crow R</td>
<td>0.9435</td>
<td>0.9477</td>
<td>0.9553</td>
<td>0.9718</td>
<td>0.9924</td>
<td>0.9937</td>
<td>0.9932</td>
<td>0.9921</td>
<td>0.9954</td>
</tr>
<tr>
<td>k</td>
<td>-0.013</td>
<td>-0.013</td>
<td>-0.012</td>
<td>-0.007</td>
<td>-0.003</td>
<td>-0.004</td>
<td>-0.005</td>
<td>-0.005</td>
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**SUMMARY AND CONCLUSION**

- The transdermal patches of Eletriptan could be prepared using HPMC K100LV as primary polymer alone and HPMC K15M as secondary polymers by solvent evaporation method.
- Transdermal patches of Eletriptan using polymers like HPMC K100LV and HPMC K15M in various proportions and combinations showed satisfactory physiochemical characteristics.
- The FTIR study suggested that there was no drug-polymer and polymer-polymer interaction.
- The transdermal patches showed good swelling, maintaining the integrity of formulation which is required for bio-adhesion.
The proportional amounts of hydrophilic polymers in various formulations have influence on drug release from these formulated Eletriptan transdermal patches.

The *In vitro* release of Eletriptan was extended up to 24 hrs, if HPMC K 100LV and HPMC K 15M used. The *in vitro* release obeyed Peppas order kinetics.

The *Ex vivo* permeation study suggested that HPMC K100LV enhanced the flux and permeability coefficient. The more flux was observed in formulation F1.

Formulation F1 was found to be the best formulation to achieve the aim of this study; hence formulation F1 was optimised and selected as final resultant batch.

From the present investigation, it can be concluded that such transdermal patches of Eletriptan may provide sustained transdermal delivery for prolonged periods in the management of migraine, which can be a good way to bypass the extensive hepatic first-pass metabolism.

**FUTURE PERSPECTIVES**

The primary objectives of transdermal dosage forms are to provide an intimate contact of the dosage form at the absorbing surface and to increase residence time of the dosage form. Transdermal adhesive systems offer innumerable advantages in terms of accessibility, administration and withdrawal, retentively, low enzymatic activity, economy and high patient compliance.

The researchers should look beyond traditional polymer networks to find other innovative drug transport systems. Development in controlled release transdermal drug delivery should be focused on preparation and use of responsive polymeric system using copolymer with desirable hydrophilic/hydrophobic interaction, block or graft polymers, and new biodegradable polymers especially from natural edible sources.

Studies should be carried out to establish the bioavailability and *in vitro-* *in vivo* correlation (IVIVC) needed to be performed to confirm the potential of the formulations for use in human trials. The designed transdermal drug delivery system is found to be promising for further study i.e. stability, and in vivo studies leading to IVIVC for commercialization. Clinical performance and patient acceptance of the transdermal patch formulation in healthy human volunteers should be evaluated so that such kind of formulations may appear in the market in near future.
REFERENCES


