RESEARCH ARTICLE

Formulation and evaluation of oral medicated jelly of meclizine HCl

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ABSTRACT

The present study is conducted with the aim of formulating and evaluating an oral medicated jelly of meclizine hydrochloride for the treatment of motion sickness, nausea, and vomiting. Jellies are thick viscous fluid to semisolid in nature. The jellies form can be swallowed easily without water and they are soft and smooth. Medicated jellies of meclizine hydrochloride were formulated using polymers such as gelatin, pectin, and sodium alginate. The prepared medicated jellies were evaluated for their physico-chemical properties such as appearance, stickiness, pH, viscosity, drug release, and drug content.

KEY WORDS: Gelatin, Jellies, Meclizine HCl, Pectin, Sodium alginate

INTRODUCTION

Advancement in drug delivery to oral route remains preferred for the administration of therapeutic agents; the low cost of therapy and ease of administration lead to patient compliance. Hence, most of the formulations are also available in various types of oral dosage forms, such as syrups, suspensions, reconstituted powders, dispersible tablets, and mini tablets, but so many problems are associated with the usage of those types of formulations. Jellies have a thick viscous fluid-to-semisolid consistency and consist of a sub-microscopic part in plastic vehicle or rigid form. The jellicious dosage forms are swallowed easily without water.[1,3,5,6,12]

The present study is focused on developing a stable, elegant, and acceptable meclizine HCl medicated oral jelly to treat nausea, vomiting, and dizziness associated with motion sickness. Meclizine HCl is an antihistamine.[7,9]

Advantages

- Flexibility in design
- Improve patient compliance
- Easily manufacturing and lower cost
- Improve bioavailability or bypass first-pass metabolism
- Medicated jelly is feasible in the local treatment of diseases of the oral cavity as well as systemic conditions
- Highly acceptable by children
- Excellent for acute medication.

Disadvantages

- Risk of overdosage with medicated jelly compared with chewable tablets or lozenges that can be consumed in a considerably larger number and within a much shorter period of time
- Sorbitol that presents in medicated jelly formulation causes flatulence and diarrhea.

Disease: Vomiting and nausea[7,8]

Vomiting is an uncontrollable reflux that expels the contents of the stomach through the mouth. It is also
Preparation of medicated jelly

All ingredients are weighted accurately. In one beaker, sucrose syrup was prepared by adding the required amount of sugar to the beaker and increasing the volume up to 100 mL, heating this solution until the sucrose was completely dissolved. In another beaker, polymer with specific quantity of polymer, citric acid and propylene glycol were taken and heated to completely dissolved. In another beaker, polymer with proper stirring. This solution was boiled for few minutes. Sodium benzoate was added to this solution. The drug was dissolved in a small amount of solvent and then added to the previously prepared polymeric solution with proper stirring. A coloring and flavoring agent was also added to the solution. This whole solution was transferred into the mold and allowed for cooling and settling undisturbed by proper covering of the mold. After jellies are set, it is wrapped in butter paper and stored in a dry place.

Formulations/composition of jellies

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug (Meclizine HCl)</td>
<td>1.35</td>
</tr>
<tr>
<td>Gelatin</td>
<td>-</td>
</tr>
<tr>
<td>Pectin</td>
<td>-</td>
</tr>
<tr>
<td>Sodium alginate</td>
<td>-</td>
</tr>
<tr>
<td>Sucrose</td>
<td>60</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>3</td>
</tr>
<tr>
<td>Citric acid</td>
<td>1</td>
</tr>
<tr>
<td>Water</td>
<td>30</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Evaluation of medicated jellies

Appearance

The medicated jelly was examined for physical appearance in terms of clarity, texture, and consistency.

Stickiness and Grittiness

The texture of medicated in terms of stickiness and grittiness had been evaluated by the visual inspection of the jellies or mildly rubbing jellies in between the two fingers.

Weight variations

The average weight of 10 jellies was taken to determine the weight variation. Individual jellies are taken out from the mold and then weighed.

Motion sickness

It is a form of physiologic vertigo. Perspiration, increased salivation, yawning, and malaise are described by patients with motion sickness. Hyperventilation can lead to hypomania, and venous pooling can predispose to hypotension and syncope. The sight and smell of food can exacerbate nausea. Motion sickness is readily diagnosed by history. This is a common syndrome that can occur in automobiles, airplanes, or sea. Exaggerated self-generated movement can cause motion sickness by forcing rapid and inappropriate changes in vestibular function.

MATERIALS AND METHODS

The meclizine HCl drug was obtained from Live Pharmaceutical Ltd., Bangaluru, India, as a gift sample. Pectin, gelatin, and sodium alginate (Yarrow Chemical Pvt. Ltd., Mumbai, India) were purchased for research purposes. All other ingredients and reagents have an analytical grade.

Preparation of medicated jelly

All ingredients are weighted accurately. In one beaker, sucrose syrup was prepared by adding the required amount of sugar to the beaker and increasing the volume up to 100 mL, heating this solution until the sucrose was completely dissolved. In another beaker, polymer with citric acid and propylene glycol were taken and heated to dissolve polymers and citric acid with continuous stirring.

Prepared sugar syrup was added to the polymeric solution with proper stirring. This solution was boiled for few minutes. Sodium benzoate was added to this solution. The drug was dissolved in a small amount of solvent and then added to the previously prepared polymeric solution with proper stirring. A coloring and flavoring agent was also added to the solution. This whole solution was transferred into the mold and allowed for cooling and settling undisturbed by proper covering of the mold. After jellies are set, it is wrapped in butter paper and stored in a dry place.

Methodology

Preparation of medicated jelly

Preparation of medicated jelly
**Determination of pH**

A digital pH meter is used to determine the pH of prepared jellies at room temperature (25 ± 5°C). Weigh 1 gm of prepared medicated jelly and it was dispersed in 100 mL of distilled water to make a 1% aqueous solution and pH was noted.

**Viscosity**

The viscosity of jelly is carried out using the Brookfield viscometer. The freshly prepared medicated jellies were squeezed out from the gelatin paper bag by making a cut in uniform size on the mold. Viscosity is measured using a spindle PF at a fixed time of 3 min at 3, 1 rpm at 25 ± 1°C.

**Content uniformity**

Content uniformity ensured that every dosage form must contain equal amount of drug. In every batch, one jelly was dissolved in the phosphate buffer 6.4. From this solution, a 2 to 10 µg/mL solution was prepared, and absorbance was measured at 231.5 nm using a UV visible spectrophotometer.

**In-vitro dissolution study**

*In-vitro* dissolution study of jelly performed with USP type II apparatus using phosphate buffer pH6.4. The dissolution medium was kept under 37°C ± 0.5°C and 50 rpm. A 5 mL sample was withdrawn from the dissolution vessel at a specific time interval of 5, 10, 15, 20, 25, and 30 min and replaced with fresh media. From this sample, an appropriate dilution was prepared, and absorbance was measured with the help of a UV-visible spectrophotometer. \[^{10,11,19,20}\]

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**RESULTS AND DISCUSSION**

**Physical observation**

As per visual inspection, the appearance of prepared jellies batch F1–F6 was carried out and found following observation.

**Appearance**

<table>
<thead>
<tr>
<th>Test</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>Transparent</td>
<td>Opaque</td>
<td>Turbid</td>
<td>Opaque</td>
<td>Turbid</td>
<td></td>
</tr>
<tr>
<td>Texture</td>
<td>Smooth</td>
<td>Smooth</td>
<td>Smooth</td>
<td>Smooth</td>
<td>Smooth</td>
<td></td>
</tr>
<tr>
<td>Consistency</td>
<td>Thick</td>
<td>Thick</td>
<td>Thick</td>
<td>Thin</td>
<td>Thin</td>
<td></td>
</tr>
</tbody>
</table>

**Stickiness and grittiness test**

<table>
<thead>
<tr>
<th>TEST</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stickiness</td>
<td>Slightly sticky</td>
<td>Non sticky</td>
<td>Non sticky</td>
<td>Non sticky</td>
<td>Non sticky</td>
<td>Non sticky</td>
</tr>
<tr>
<td>Grittiness</td>
<td>No Grittiness</td>
<td>No Grittiness</td>
<td>No Grittiness</td>
<td>No Grittiness</td>
<td>No Grittiness</td>
<td>No Grittiness</td>
</tr>
</tbody>
</table>

**pH of jelly**

<table>
<thead>
<tr>
<th>pH</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.38±0.04</td>
<td>6.57±0.05</td>
<td>6.28±0.026</td>
<td>6.54±0.04</td>
<td>5.85±0.05</td>
<td>6.74±0.06</td>
<td></td>
</tr>
</tbody>
</table>

**Weight variation test**

The weight variation was found to be 1.78 ± 0.03 and 1.79 ± 0.08 in all prepared jelly formulations.

**Drug content**

The drug content of the prepared meclizine hydrochloride was evaluated by a UV-visible spectrophotometer, and the drug content range was found to be 90.16%–98.33%.
Viscosity

The viscosity of jelly was found to be 53303–239935 cps and varied depending upon the type and concentration of polymer.

<table>
<thead>
<tr>
<th>Viscosity (cps)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>239395</td>
<td>53326</td>
<td>173903</td>
<td>53303</td>
<td>57698</td>
<td>66947</td>
<td></td>
</tr>
</tbody>
</table>

In vitro dissolution studies

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>22.2±0.72</td>
<td>18.9±0.9</td>
<td>14±0.5</td>
<td>17.1±0.9</td>
<td>18.6±0.5</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>44.06±0.90</td>
<td>529.06±0.4</td>
<td>27±0.9</td>
<td>26.85±0.729.33±0.4</td>
<td>30.26±0.5</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>57.93±0.85</td>
<td>70.5144.66±0.57</td>
<td>42.18±0.9440.08±0.9</td>
<td>51.33±0.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>65.4±0.5</td>
<td>63±0.9</td>
<td>54±0.9</td>
<td>53.6±0.5</td>
<td>55.5±0.5</td>
<td>64.2±1</td>
</tr>
<tr>
<td>25</td>
<td>75.6±0.7</td>
<td>74.4±0.6</td>
<td>65.1±0.5</td>
<td>63.0±0.9</td>
<td>65.4±0.5</td>
<td>75.6±0.4</td>
</tr>
<tr>
<td>30</td>
<td>84.8±0.4</td>
<td>82.5±0.5</td>
<td>78.86±0.7</td>
<td>77.16±0.7</td>
<td>80±0.6</td>
<td>78.4±0.6</td>
</tr>
</tbody>
</table>
CONCLUSION

The jelly loaded with meclizine hydrochloride was successfully formulated using pectin, gelatin, and sodium alginate as gelling agents. All evaluation parameters concluded that prepared medicated jelly is more organoleptically accepted by patients.

REFERENCES