FORMULATION DESIGN AND EVALUATION OF HERBAL ORAL HYGIENE PRODUCT

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KEYWORDS:
Antimicrobial activity, Buccoadhesive tablet, Andrographis Paniculata nees, Cup plate method.

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ABSTRACT
The present study describes the phytochemical profile and antimicrobial activity of Andrographis paniculata. For the present investigation, A. paniculata extracts, obtained by extraction in methanol, were used for their antimicrobial activity. The herbal based mucoadhesive buccal tablet is good alternative to treat oral diseases. There is no such marketed buccoadhesive tablet formulation of andrographolide for oral diseases treatment. Present formulation provide local as well as systemic effect of drug for prolong period of time. Buccoadhesive formulation prolongs the residence time of the dosage form at the site of action.

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INTRODUCTION:
Maintenance of good oral hygiene is an important, as it affects the overall health. Poor oral hygiene may lead to number of conditions like periodontal diseases, dental caries, gingivitis. Periodontal diseases are group of infections and inflammatory conditions that affect tooth supporting structures. These diseases occur when bacteria from dental plaque invade surrounding tissues and accumulation of plaque at gingival margin induces inflammatory response. Conventional therapy includes removal of the plaque, the inflamed soft tissues and antimicrobial agents. The conventional antibiotic treatment which suffer the limitation of low benefit to high risk as compared to herbal treatment which possess high benefit to low risk ratio. There are number of herbs that help eliminate inflammation and infection associated with periodontal diseases. Andrographolide is an active constituent of Andrographis Paniculata Functions as a potent anti bacterial, anti inflammatory, antioxidant, and antifungal agent. The herbal based mucoadhesive buccal tablet is good alternative to treat oral diseases. There is no such marketed buccoadhesive tablet formulation of Andrographolide for oral diseases treatment. Present formulation provide local as well as systemic effect of drug for prolong period of time and also avoiding hepatic metabolism of drug, thereby making composition effective. Buccoadhesive formulation prolong the residence time of the dosage form at the site of action.

MATERIALS AND METHODS:
Andrographis Paniculata, Carbopol 934P, chitosan, Mannitol, Mg stearate, Talc, Aspartame, Methanol.

Method:
The powdered drug was extracted by continuous hot extraction by using Soxhlet extraction method and the solvent used for extraction was methanol.

Preparation of Tablets:
The buccoadhesive tablet was prepared by direct compression method. Buccoadhesive tablets containing Andrographolide were prepared by using different concentration of polymers such as carbopol 934 P and Chitosan were used as
primary and secondary polymers resp. Mannitol was used as diluent. Talc and magnesium stearate were used as glidants while Aspartame was used as sweetener.

Fig : Soxhlet extraction

**FORMULATION DESIGN :**

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Drug (mg)</th>
<th>CP 934 P</th>
<th>Chitosan</th>
<th>Mg stearate</th>
<th>Talc</th>
<th>Mannitol</th>
<th>Aspartame</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>60</td>
<td>35</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>25.5</td>
<td>2.5</td>
</tr>
<tr>
<td>C2</td>
<td>60</td>
<td>25</td>
<td>20</td>
<td>1</td>
<td>1</td>
<td>25.5</td>
<td>2.5</td>
</tr>
<tr>
<td>C3</td>
<td>60</td>
<td>35</td>
<td>20</td>
<td>1</td>
<td>1</td>
<td>15.5</td>
<td>2.5</td>
</tr>
<tr>
<td>C4</td>
<td>60</td>
<td>25</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>35.5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Table no. 1 : Tablet Formulations

**RESULT AND DISCUSSION :**

**Evaluation of powder blend :**

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Angle of repose</th>
<th>Bulk density (g/mL)</th>
<th>Tapped density (g/mL)</th>
<th>Carr's index</th>
<th>Hausner's ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>30.10</td>
<td>0.324+0.001</td>
<td>0.387+0.005</td>
<td>16.19+1.476</td>
<td>1.19+0.021</td>
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<tr>
<td>C2</td>
<td>29.35</td>
<td>0.327+0.003</td>
<td>0.383+0.002</td>
<td>14.54+1.126</td>
<td>1.17+0.015</td>
</tr>
<tr>
<td>C3</td>
<td>30.30</td>
<td>0.322+0.002</td>
<td>0.389+0.009</td>
<td>17.26+1.575</td>
<td>1.20+0.044</td>
</tr>
<tr>
<td>C4</td>
<td>29.66</td>
<td>0.321+0.002</td>
<td>0.378+0.004</td>
<td>14.89+1.050</td>
<td>1.17+0.013</td>
</tr>
</tbody>
</table>

Table no. 2 : Evaluation parameters of powder blend

**Evaluation of Tablets :**

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Weight variation</th>
<th>Hardness (Kg/cm2)</th>
<th>Thickness (mm)</th>
<th>Friability (%)</th>
<th>Drug content (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Passes</td>
<td>5.23+0.25</td>
<td>1.98+0.015</td>
<td>0.11</td>
<td>99.75+1.27</td>
</tr>
<tr>
<td>C2</td>
<td>Passes</td>
<td>5.13+0.11</td>
<td>2.0+0.010</td>
<td>0.10</td>
<td>100.36+0.72</td>
</tr>
<tr>
<td>C3</td>
<td>Passes</td>
<td>5.60+0.17</td>
<td>2.01+0.015</td>
<td>0.13</td>
<td>99.72+0.62</td>
</tr>
<tr>
<td>C4</td>
<td>Passes</td>
<td>5.00+0.20</td>
<td>1.99+0.020</td>
<td>0.20</td>
<td>99.39+0.75</td>
</tr>
</tbody>
</table>

Table no. 3 : Evaluation parameters of tablets
Surface pH studies:
The surface pH of all formulations was found to be in the range of 6.29\pm0.03 to 6.47\pm0.03. All formulations provide an acceptable pH in the range of salivary pH (5.5 – 7.0) and they could not produce any risk of mucosal damage or irritation.

Mucoadhesive strength determination:
The formulation C3 showed highest mucoadhesive strength(14.73gm) and force of adhesion (0.144N).

In Vitro dissolution study:

The formulation C2 shows maximum drug release 99.03%.

CONCLUSION:
From all results formulation C2 containing 25% carbopol 934P and 20% chitosan was optimized formulation having maximum amount of drug release about 99% within period of 8 hrs with adequate mucoadhesive strength. An optimized formulation C2 is well acceptable, palatable and with better patient compliance in oral hygiene.
REFERENCES:

1. Abhishek Niranjan, SK Tewari and Alok Lehri, Biological activities of kalmegh(Andrographis Paniculata Nees) and its active principles – A review, IJNPR, 2010, 1(2), 125 – 135.


