STUDY OF PIROXICAM GEL STABILITY USING HPMC AND
ACUPEC HV-505 BASES

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ABSTRACT

An investigation on piroxicam gel formulation using HPMC base (1.5, 2.5 and 5%) and
other formula using Aqupec HV-505 bases (0.5, 1 and 1.5%, respectively, had been
carried out to find out the best formula. The stability testing was conducted on
organoleptic, pH, viscosity and, consistency for 28 days of storage. The result showed
that the formula with 1% Aqupec HV-505 bases (F<sub>C2</sub>) was the best one. Further
investigation was conducted with variation of Piroxicam concentrations to know its
influence to gel stability. The additional investigation conducted to the best formula were
microbiology, qualitative and quantitative stability testing using Thin-Layer
Chromatography (TLC) and High Performance Liquid Chromatography (HPLC) for 56
days of storage. The result showed that the best gel formula was that with 1% Aqupec
HV-505 with 0.5% piroxicam (F<sub>C2.2</sub>).

Keywords: Piroxicam, Gel, HPMC, Aqupec HV-505.

INTRODUCTION

Piorexicam is one of the most potent Non Steroidal Antiinflammatory agents that
also have antipyretic activity. Piorexicam is well absorbed following oral administration;
however, its used has been limited by a number of side effect, including bleeding and
ulceration. Transdermal administration of piroxicam can overcome this side effect, and
higher local concentration can be maintained at the target site, which is desirable for the
antiinflammatory agent (Banakar, 1992; Panchagnula, 1997; Doliwa, 2001). Transdermal
drug delivery system has the additional advantages of avoiding hepatic first-pass
metabolism and providing the controlled delivery of the drug for an extended period
(Dallas, 1987).

In light of the side effect associated with the oral use of piroxicam, it was
proposed to the developed the various topical dosage forms of the drug and to study its
stability. The objective of this study was to develop the best topical gel formulation of
piroxicam using HPMC and Aqupec HV-505 as a gelling agent. To optimize the
formulation, the effects of concentration of gelling agent, the effect of concentration of the drug, the pH and viscosity of the gel and drug content were evaluated.

**METHODOLOGY**

### Physical Stability Investigation
- Organoleptic, pH Viscosity

### Drug Content
- Qualitative
- Quantitative

### Microbial Investigation

![Diagram of Methodology]

**Table 1. Formula of Piroxicam Gels with Various Base**

<table>
<thead>
<tr>
<th>INGREDIENTS</th>
<th>FORMULAS *)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( F_{B1} )</td>
</tr>
<tr>
<td>HPMC (%)</td>
<td>1.5</td>
</tr>
<tr>
<td><em>Aqupec HV-505</em> (%)</td>
<td>-</td>
</tr>
<tr>
<td>Piroxicam (%)</td>
<td>0.5</td>
</tr>
<tr>
<td>TEA (%)</td>
<td>3</td>
</tr>
<tr>
<td>Propyleneglycol (%)</td>
<td>20</td>
</tr>
<tr>
<td>Methyl Paraben (%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Propyl Paraben (%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Ethyl Acetat (%)</td>
<td>5</td>
</tr>
<tr>
<td>Aquadest ad</td>
<td>100</td>
</tr>
</tbody>
</table>

*) \( F_{B1} \) = Piroxicam gel with HPMC 1.5%, \( F_{B2} \) = Piroxicam gel with HPMC 2%, \( F_{B3} \) = Piroxicam gel with HPMC 2.5%, \( F_{C1} \) = Piroxicam gel with *Aqupec HV-505* 0.5%, \( F_{C2} \) = Piroxicam gel with *Aqupec HV-505* 1%, \( F_{C3} \) = Piroxicam gel with *Aqupec HV-505* 1.5%
RESULTS AN DISCUSSION

Physical Stability of Gel Base

Based on organoleptic investigation, both HPMC and Aqupec HV 505 gel were pale yellow, clear, transparent and well spreadable. Ideal pH for piroxicam gel was 6-8. HPMC gels which fulfilled the pH requirements was only FB1 while others had too high pH value. The pH of gel base exhibited in Figure 1 while Figure 2 showed the viscosity of gel base during storage periods.

![Figure 1. pH of Piroxicam Gel with Various Base](image1)

![Figure 2. Viscosity of Piroxicam Gel with Various Base](image2)

Further investigation were conducted by variating the piroxicam concentration on 1% Aqupec HV-505. All Piroxicam with Aqupec HV–505 gels fulfilled the pH requirement. In general, the viscosity was significantly changed during the 56 days of storage. The results showed that increasing piroxicam concentration caused the
significant decrease on gel viscosity. The pH of Piroxicam gels in Aqupec HV-505 Base during 56 days of storage time exhibited in Figure 3, while Figure 4 showed the viscosity of gels during storage periods.

**Figure 3.** pH of Piroxicam Gels in Aqupec HV-505 Base during storage time (FC2.0 = 1% Aqupec HV-505 Gel base without Piroxicam, FC2.1 = 1% Aqupec HV-505 Gel base with 0.25% Piroxicam, FC2.2 = 1% Aqupec HV-505 Gel base with 0.5% Piroxicam, FC2.3 = 1% Aqupec HV-505 Gel base with 1% Piroxicam)

**Figure 4.** Viscosity of Piroxicam Gels in Aqupec HV-505 Base during storage time (FC2.0 = 1% Aqupec HV-505 Gel base without Piroxicam, FC2.1 = 1% Aqupec HV-505 Gel base with 0.25% Piroxicam, FC2.2 = 1% Aqupec HV-505 Gel base with 0.5% Piroxicam, FC2.3 = 1% Aqupec HV-505 Gel base with 1% Piroxicam)
Qualitative and Quantitative determination of piroxicam in Gels

Figure 5. TLC Chromatograms of Piroxicam Gels at first day of formulation (A) and after 56 days of storage (B) (FC2.1 = 1% Aqupec HV-505 Gel base with 0.25% Piroxicam, FC2.2 = 1% Aqupec HV-505 Gel base with 0.5% Piroxicam, FC2.3 = 1% Aqupec HV-505 Gel base with 1% Piroxicam, K = Piroxicam)

Table 2. R_f of Piroxicam in Gels

<table>
<thead>
<tr>
<th>Formula</th>
<th>R_f (Room Temp.) at days of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st</td>
</tr>
<tr>
<td>Piroxicam control</td>
<td>0.5393</td>
</tr>
<tr>
<td>Piroxicam F_C2.1</td>
<td>0.5169</td>
</tr>
<tr>
<td>Piroxicam F_C2.2</td>
<td>0.5169</td>
</tr>
<tr>
<td>Piroxicam F_C2.3</td>
<td>0.5169</td>
</tr>
</tbody>
</table>

Table 3. Piroxicam Content in Gels

<table>
<thead>
<tr>
<th>Formula</th>
<th>Piroxicam content (%) at days of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>F_C2.0</td>
<td>0</td>
</tr>
<tr>
<td>F_C2.1</td>
<td>120.55</td>
</tr>
<tr>
<td>F_C2.2</td>
<td>115.23</td>
</tr>
<tr>
<td>F_C2.3</td>
<td>107.86</td>
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</table>

HPLC Chromatograms showed no additional peaks, indicating stability of the drug in the gel system. But addition in concentration of piroxicam after storage happened. It was interpreted that these change were due to secretation of gel base which caused unhomogeneity in the drug content.
Microbial Investigation

It was found that no bacterial growth happened after 14 days of investigation which can be concluded that the preservative are effectively worked in the gels.

CONCLUSION

Among all the formulation, the 0.5% Piroxicam in 1% Aqupect-HV 505 gave the highest stability and quite preferable. The study support the evidence that stability was exhibited in physical, qualitative, quantitative and microbiological characteristic. This can serve as the basis for developing topical formulation of piroxicam with the best stability.

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REFERENCES


