Children's Hospital Of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: PROPRANOLOL 5 mg/mL ORAL SUSPENSION

Date Prepared: _____________________ FINAL PRODUCT CHECKED BY: _________________________

EXPIRY DATE: _____________________

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>MANUFACTURER</th>
<th>LOT #</th>
<th>MAN. EXPIRY DATE</th>
<th>FORMULA QUANTITY</th>
<th>QUANTITY USED</th>
<th>MFG BY</th>
<th>CHK BY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propranolol 40 mg tablet</td>
<td>Apotex</td>
<td></td>
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<td>Ora-Blend® SF</td>
<td>Paddock</td>
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<td>qs to 120 mL</td>
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</table>

EQUIPMENT

- Mortar and pestle
- Graduated cylinder

MANUFACTURING DIRECTIONS

1. Crush tablets to make a fine powder in a mortar.
2. Levigate powder with a small amount of the vehicle to make a fine paste.
3. Continue to add vehicle until product liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with vehicle and add to product in graduated cylinder.
5. QS to final volume with vehicle.
6. Dispense in amber plastic bottles. Refrigerate or Room Temperature

FINAL APPEARANCE

Opaque light green suspension

SAMPLE LABEL

PROPRANOLOL 5 MG/ML ORAL SUSPENSION
Shake well. Refrigerate or Room Temperature.
Date Prepared: Date Expired:

STABILITY

120 days in fridge (4°C) or room temperature (25°C)

“Propranolol suspension 5 mg/mL stored at 25°C maintained at least 94.7% of initial concentration for 120 days, and suspension stored at 4°C maintained at least 93.9% of initial concentration for 120 days. There were no notable changes in pH, and all samples remained physically unchanged except for a slight change in colour, around day 70, of suspensions stored at room temperature.”

REFERENCE(S)


Master Sheet Dates: Dec. 2013 Final Approval By: ND/CB

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