Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: URSODIOL 50mg/mL SUSPENSION

Date Prepared: ____________________      FINAL PRODUCT CHECKED BY: _________________________

EXPIRY DATE: ____________________

<table>
<thead>
<tr>
<th>INGREDIENTS</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>Ursodiol 250 mg tablet</td>
<td>Axcan</td>
<td>10</td>
<td></td>
<td>10</td>
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<tr>
<td>Ora-Blend®</td>
<td>Paddock</td>
<td></td>
<td></td>
<td>qs to 50 mL</td>
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</tbody>
</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 is 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.

SAMPLE LABEL

URSODIOL 50 mg/mL Suspension
Shake well. Refrigerate.
Date Prepared: ____________________
Date Expired: ____________________

STABILITY

90 days in fridge or at room temperature.

REFERENCE(S)


Master Sheet Revision Dates: 16 Nov 06   Final Approval By: CM/JH

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