Accelerated study of extemporaneously compounded test batches of ascorbic acid

**Bases Include:**
- Vaniply™ Ointment
- Vanicream™ Skin Cream

**Compounds Tested:**
- L-Ascorbic Acid, 5%
- L-Ascorbic Acid, 10%
- L-Ascorbic Acid, 15%
- L-Ascorbic Acid, 20%

**Assay Method Used:**
- USP Titration with Iodine
- Standard Solution

**Conditions:**
- Three months with observation
- 40°C and 75% Relative Humidity (RH) Chamber

**Results:**
The assay values for all products containing ascorbic acid in Vaniply™ Ointment remain within ±10% of the initial assay values, and the physical characteristics based on organoleptic measures conform. Rheology measurements remain within the accepted range for Vaniply™ Ointment throughout the study. According to the Consumer Healthcare Products Association, completion of 3 months at 40°C and 75% RH provides a tentative expiry date of up to 24 months.

Ascorbic acid was found to be incompatible with the base Vanicream™ Skin Cream.

<table>
<thead>
<tr>
<th>L-Ascorbic Acid in Vaniply</th>
<th>Appearance</th>
<th>Recommended Tentative Expiry Date (months)</th>
<th>Recommended Packaging</th>
<th>Other Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>Yellow, opaque ointment</td>
<td>24</td>
<td>Protect ointment from light</td>
<td>N/A</td>
</tr>
<tr>
<td>10%</td>
<td>Yellow, opaque ointment</td>
<td>24</td>
<td>Protect ointment from light</td>
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**Disclaimer:**
This data is provided for informational purposes only, representing the results of a study of product stability with various active pharmaceutical ingredients. It does not serve, and cannot be construed, as representation of guarantee of product performance. In all cases the pharmacist is advised to consult recognized pharmaceutical compendia and other sources for product formulation, characteristics and methods used, including stability. Pharmaceutical Specialties,
ASSIGNING BEYOND-USE DATES ACCORDING TO USP <795>

In the absence of stability information that is applicable to a specific drug and preparation, the following maximum beyond-use dates are recommended for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated.

Non-Sterile Preparations
For Nonaqueous Liquids and Solid Formulations—
Where the Manufactured Drug Product is the Source of Active Ingredient—The beyond-use date is not later than 25% of the time remaining until the product’s expiration date or 6 months, whichever is earlier.

Where a USP or NF Substance is the Source of Active Ingredient-
The beyond-use date is not later than 6 months.

For Water-Containing Formulations (prepared from ingredients in solid form)-The beyond-use date is not later than 14 days for liquid preparations when stored at cold temperatures between 2° and 8° C (36° and 46° F).

For All Other Formulations-
The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.