Accelerated study of extemporaneously compounded test batches of hydroquinone

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

Compounds Tested:
- Hydroquinone, 4%

Assay Method Used:
- Modified USP Spectrophotometry

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

Results:
Hydroquinone is compatible with the base Vaniply™ Ointment based on organoleptic measures. However, the assay values for hydroquinone dispersed in Vaniply™ Ointment were above ±10% of the initial assay value at the 1 and 3 month time points of the accelerated study. Rheology measurements remain within the accepted range for Vaniply™ Ointment throughout the study. Hydroquinone was found to be incompatible with the base Vanicream™ Skin Cream.

<table>
<thead>
<tr>
<th>Hydroquinone 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>4%</td>
<td>White, opaque ointment</td>
<td>Assign BUD according to USP &lt;795&gt;</td>
<td>Amber, glass jar</td>
<td>Use a fine hydroquinone powder or mill crystalline solid before compounding</td>
</tr>
</tbody>
</table>

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, Inc. makes no warranties or representations with regard to the appropriateness of this product in any compounded formulation and is solely at the discretion and liability of the pharmacist and practitioner relationship.

Additional Reference Information:
(1) Secundum Artem Volume 15 Number 3
By Lloyd Allen Jr. Ph.D. R.Ph

http://www.perrigo.com/business/pdfs/Sec%20Artem%2015.3.pdf

Below is an excerpt:
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.