



|                   |   |     |             |
|-------------------|---|-----|-------------|
| Suggested Formula | Aloe Vera 0.2%, Tacrolimus 0.03% Topical Shampoo (Solution, 100 mL) | FIN | F 006 821v2 |
|-------------------|---|-----|-------------|

### SUGGESTED FORMULATION

| Ingredient Listing                        | Qty.          | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---------------|------|-------|----------|------------|-------------|
| Aloe Vera (Powder) (Freeze Dried)         | 0.200         | g    |       |          |            |             |
| Tacrolimus 5% Stock Powder Blend†         | 0.600         | g    |       |          |            |             |
| Ethoxy Diglycol                           | 1.0           | mL   |       |          |            |             |
| Medisca U-Mild™ Shampoo Base              | 70.0          | mL   |       |          |            |             |
| Purified Water, USP                       | q.s. to 100.0 | mL   |       |          |            |             |
|   |               |      |       |          |            |             |
| † <b>Tacrolimus 5% Stock Powder Blend</b> |               |      |       |          |            |             |
| Tacrolimus, USP                           | TBD           |      |       |          |            |             |
| Lactose (Monohydrate), NF                 | q.s. to 2.00  | g    |       |          |            |             |

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible): Aloe Vera, Tacrolimus

**Hygroscopic** (protect from moisture whenever possible): Aloe Vera, Ethoxy Diglycol

**Heat sensitive** (protect from heat whenever possible): Tacrolimus

**Narrow Therapeutic Index**: Tacrolimus

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

**Tacrolimus has a Narrow Therapeutic Index.**

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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**SUGGESTED PREPARATION (for 100 mL)**

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing                        | Qty.          | Unit | Multiplication factor (*): ____ | Processing Error | Qty. to measure |
|---|---------------|------|---------------------------------|------------------|-----------------|
| Aloe Vera (Powder) (Freeze Dried) §       | 0.200         | g    |                                 |                  |                 |
| Tacrolimus 5% Stock Powder Blend † §      | 0.600         | g    |                                 |                  |                 |
| Ethoxy Diglycol §                         | 1.0           | mL   |                                 |                  |                 |
| Medisca U-Mild™ Shampoo Base              | 70.0          | mL   |                                 |                  |                 |
| Purified Water, USP                       | q.s. to 100.0 | mL   |                                 |                  |                 |
|   |               |      |                                 |                  |                 |
| <b>† Tacrolimus 5% Stock Powder Blend</b> |               |      |                                 |                  |                 |
| Tacrolimus, USP §                         | TBD           |      | ---                             | ---              |                 |
| Lactose (Monohydrate), NF                 | q.s. to 2.00  | g    | ---                             | ---              |                 |

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.



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**Preparatory Instruction**

**1. Ingredient quantification:**

A. Determine the potency of Tacrolimus based on the certificate of analysis:

|  |         |
|--|---------|
|  | 100%    |
| MINUS  |         |
| Water Content (from certificate of analysis)                   | _____ % |
| DIVIDED BY   | 100     |
| EQUALS   |         |
| Quantity of water free Tacrolimus, in decimal                  | _____   |
| MULTIPLIED BY  |         |
| Assay on anhydrous basis result (from certificate of analysis) | _____ % |
| DIVIDED BY   | 100     |
| EQUALS   |         |
| <b>i. Potency of Tacrolimus, in decimal</b>                    | _____   |

**2. Ingredient quantification:**

A. Determine the quantity (in g) of Tacrolimus to make a Tacrolimus 5% Stock Powder Blend, batch size (2 g):

|   |         |
|---|---------|
| Quantity of Tacrolimus required for 2 g         | 0.100 g |
| DIVIDED BY                                      |         |
| Potency of Tacrolimus, in decimal (Step 1Ai)    | _____   |
| EQUALS  |         |
| <b>i. Quantity of Tacrolimus needed for 2 g</b> | _____ g |



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|    |   |
|----|---|
| 3. | <p>† <b><u>Tacrolimus 5% Stock Powder Blend preparation:</u></b></p> <p>A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Tacrolimus (amount determined in Step 2Ai)</li> <li>-Lactose (Monohydrate) (q.s. to 2.00 g)</li> </ul>   |
| 4. | <p><b><u>Powder-liquid preparation:</u></b></p> <p>A. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Tacrolimus 5% Stock Powder Blend (0.600 g plus processing error adjustment)</li> <li>-Aloe Vera (Powder) (Freeze Dried)</li> </ul> <p>B. Levigate the homogeneous powder blend (Step 4A) with the Ethoxy Diglycol.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p> |
| 5. | <p><b><u>Medium preparation:</u></b></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 4B) to the U-Mild™ Shampoo Base.</p> <p><u>Specifications:</u> Continuously mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>   |
| 6. | <p><b><u>Filling to volume:</u></b></p> <p>A. Add Purified Water to the mixture (Step 5A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>   |
| 7. | <p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>  |



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**SUGGESTED PRESENTATION**

|                           |  |  |  |   |
|---------------------------|--|--|--|---|
| Estimated Beyond-Use Date | 30 days, as per USP.   | Packaging Requirements   | - Tightly closed, light-resistant topical dispensing bottle.<br>- To be administered with a metered-dose measuring device. |   |
| Auxiliary Labels          | 1  | Use as directed. Do not exceed prescribed dose.  | 6  | Cap tightly after use.  |
|                           | 2  | Keep out of reach of children.   | 7  | Protect from light.   |
|                           | 3  | Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use. | 8  | For external use only.  |
|                           | 4  | Keep at room temperature (20°C – 23°C).  | 9  | Keep in a dry place.  |
|                           | 5  | May impair mental and/or physical ability. Use care when operating a car or machinery.   | 10   | Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants. |
| Pharmacist Instructions   | Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.  |  |  |   |
| Patient Instructions      | Contact your pharmacist in the event of adverse reactions.<br><b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied. |  |  |   |



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## REFERENCES

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