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|-------------------|--|-----|-------------|
| Suggested Formula | Ketoprofen 50 mg Oral Capsules (Powder Blend, 35 x Size #1 Capsules) | FIN | F 004 198v2 |
|-------------------|--|-----|-------------|

## SUGGESTED FORMULATION

| Ingredient Listing    | Qty.        | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|-----------------------|-------------|------|-------|----------|------------|-------------|
| Ketoprofen, USP       | 1.750       | g    |       |          |            |             |
| Medisca CapsuBlend™-P | TBD         |      |       |          |            |             |
| Sodium Chloride, USP  | As required |      |       |          |            |             |

## SPECIAL PREPARATORY CONSIDERATIONS

### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible):

*Ketoprofen*

**Hygroscopic** (protect from moisture whenever possible):

*CapsuBlend™-P*

### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error /

Testing Considerations:

Special Instruction:

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

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

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 35 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing      | Qty.        | Unit | Multiplication factor (*): ____ | Processing Error | Qty. to measure |
|-------------------------|-------------|------|---------------------------------|------------------|-----------------|
| Ketoprofen, USP §       | 1.750       | g    |                                 |                  |                 |
| Medisca CapsuBlend™-P § | TBD         |      |                                 |                  |                 |
| Sodium Chloride, USP    | As required |      |                                 |                  |                 |

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

§ Weigh / measure just prior to use.

| Preparatory Instruction |  |
|-------------------------|--|
| 1.                      | <b><u>CapsuBlend™-P requirements for 35 x size #1 capsules</u></b><br>A. Calculate the amount of CapsuBlend™-P required for the batch. Refer to attached appendix for details.   |
| 2.                      | <b><u>Powder preparation:</u></b><br>A. Triturate the Ketoprofen to form a fine, homogeneous powder.<br>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:<br>-Fine, homogeneous powder (Step 2A)<br>-CapsuBlend™-P (amount determined in appendix, (I))   |
| 3.                      | <b><u>Product transfer:</u></b><br>Fill each of 35 Size #1 capsules with the mixture (Step 2B). Close each capsule tightly.<br>Clean each capsule by placing the capsules in a container filled with Sodium chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium chloride to pass through. Finally, roll the capsules on a cloth-covered surface. |
| 4.                      | <b><u>Validation technique (average capsule weight):</u></b><br>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding the amount in appendix (G) + 0.050 g together.   |
| 5.                      | <b><u>Product transfer:</u></b><br>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).  |



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## SUGGESTED PRESENTATION

| Estimated Beyond-Use Date | 6 months, as per USP  | Packaging Requirements  | Tight, transparent capsule shells packaged in light-resistant vials. |  |
|---------------------------|---|---|--|--|
| Auxiliary Labels          | 1   | Use as directed. Do not exceed prescribed dose.                               | 6  | Keep in a dry place.   |
|                           | 2   | Keep out of reach of children.  | 7  | Cap tightly after use.   |
|                           | 3   | Keep at room temperature (20°C – 23°C).                                       | 8  | Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use. |
|                           | 4   | Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants. | 9  | May impair mental and/or physical ability. Use care when operating a car or machinery.   |
|                           | 5   | Protect from light.   |  |  |
| Pharmacist Instructions   | Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary. |   |  |  |
| Patient Instructions      | Contact your pharmacist in the event of adverse reactions.  |   |  |  |

## REFERENCES

|    |   |
|----|---|
| 1. | Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 127. |
| 2. | Sodium Chloride. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2009: 637.              |
| 3. | Ketoprofen (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #5305.                    |
| 4. | Ketoprofen. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 3<sup>rd</sup> Edition</i> . American Pharmaceutical Association; 2005: 240.       |
| 5. | Ketoprofen (Monograph). <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2739.            |
| 6. | USP <795>. <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.                          |

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|          |  |  |  |
|----------|--|--|--|
| Appendix | Calculating the quantity of excipient required for the batch |  |  |
|----------|--|--|--|

| Procedure                        |  |  |  |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
|----------------------------------|--|--|--|--------------------|--|--|--|---------------|---------|---------|---------|------------------|--|---------|--|----------------------------------|--|--|-------------|
| 1.                               | <p><b><u>Capsule filling:</u></b></p> <p>a. For <u>each</u> ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an <u>average</u> capsule fill weight. Also, triturate the ingredient powder first if required in formulation</p> <p>Plug each amount into Step 2, column B.</p>   |  |  |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
| 2.                               | <p><b><u>Volume Percent Occupied:</u></b></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; width: 35%;"><u>Ingredients</u></th> <th style="text-align: center; width: 20%;">Column A<br/>Quantity Required<br/>per capsule</th> <th style="text-align: center; width: 20%;">Column B<br/>Average capsule<br/>fill weight</th> <th style="text-align: center; width: 25%;">Column C<br/>A/B x 100 equals<br/>percent filled</th> </tr> </thead> <tbody> <tr> <td>a. Ketoprofen</td> <td style="text-align: center;">0.050 g</td> <td style="text-align: center;">_____ g</td> <td style="text-align: center;">_____ %</td> </tr> <tr> <td>b. CapsuBlend™-P</td> <td></td> <td style="text-align: center;">_____ g</td> <td></td> </tr> <tr> <td>c. Total (add column C together)</td> <td></td> <td></td> <td style="text-align: center;">_____ % (D)</td> </tr> </tbody> </table> |  |  | <u>Ingredients</u> | Column A<br>Quantity Required<br>per capsule | Column B<br>Average capsule<br>fill weight | Column C<br>A/B x 100 equals<br>percent filled | a. Ketoprofen | 0.050 g | _____ g | _____ % | b. CapsuBlend™-P |  | _____ g |  | c. Total (add column C together) |  |  | _____ % (D) |
| <u>Ingredients</u>               | Column A<br>Quantity Required<br>per capsule   | Column B<br>Average capsule<br>fill weight | Column C<br>A/B x 100 equals<br>percent filled |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
| a. Ketoprofen                    | 0.050 g  | _____ g                                    | _____ %  |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
| b. CapsuBlend™-P                 |  | _____ g                                    |  |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
| c. Total (add column C together) |  |  | _____ % (D)                                    |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |
| 3.                               | <p><b><u>Calculate the quantity of CapsuBlend™-P required for the batch:</u></b></p> <p>a. Percent of CapsuBlend™-P required = 100% – (D) _____ % (E)</p> <p>b. Average capsule fill weight of CapsuBlend™-P (from column B, Step 2b): _____ g (F)</p> <p>c. Quantity of CapsuBlend™-P required per capsule = [(E) ÷ 100 × (F)] _____ g (G)</p> <p>d. Total quantity of CapsuBlend™-P required for the batch = 35 capsules × (G) _____ g (H)</p> <p>e. Total quantity of CapsuBlend™-P <i>plus</i> processing error = (H) x 1.05-1.09 _____ g (I)</p>  |  |  |                    |  |  |  |               |         |         |         |                  |  |         |  |                                  |  |  |             |

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