SUGGESTED FORMULATION

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>NDC #</th>
<th>Supplier</th>
<th>Lot Number</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyox™ WSR-301</td>
<td>1.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypromellose (4000 CPS) (Methocel E4M), USP</td>
<td>9.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SPECIAL PREPARATORY CONSIDERATIONS

**Ingredient-Specific Information**

*Hygroscopic (protect from moisture whenever possible):* Polyox™ WSR-301, Hypromellose

**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 0 to 0% of the required quantities of ingredients.

**Special Instruction:** This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed official implementation date of December 31st, 2019.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP 795 and USP 800, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to; lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GIFIs) and Compliance Policy Guides (CPGs).

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.
SUGGESTED PREPARATION (for 10 g)

Weigh and / or measure the following ingredients when appropriate:

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>Multiplication factor (*):</th>
<th>Processing Error</th>
<th>Qty. to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyox™ WSR-301</td>
<td>1.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypermellose (4000 CPS) (Methocel E4M), USP §</td>
<td>9.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Powder preparation:**
   A. Pass the Polyox™ WSR-301 through a 40 or 50 mesh sieve and weigh the required quantity.
   B. Combine and mix (DO NOT TRITURATE), using a manual tumbler mixer, the following ingredients together to form a homogeneous powder blend:

   - Polyox™ WSR-301
   - Hypermellose (4000 CPS) (Methocel E4M)

   Note: Do not use excessive force as Polyox™ WSR-301 should not be trituated.

2. **Product transfer:**

   Transfer the final product into the specified dispensing container (see “Packaging requirements”).
**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months, as per USP*</td>
<td>Tightly closed suitable powder package.</td>
</tr>
</tbody>
</table>

1. Use as directed. Do not exceed prescribed dose.
2. Keep in a dry place.
4. Cap tightly after use.
5. For external use only.
6. Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.

**Pharmacist Instructions**

Note: This non-sterile formulation, as per USP <3>, should not be applied to an open wound or burned area. If this formulation will be applied to an open wound or burned area, it must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP <797>. Also, in consideration of the overall formulation make-up and following the manufacturer’s specifications, the suggested method of end-stage sterilization is gamma irradiation. The resulting BUD will be 30 days, as per USP <797>, based on a successful sterility test result.

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.

**IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
## Suggested Formula

<table>
<thead>
<tr>
<th>Polyox™ WSR-301 10% Topical Adhesive Powder (Powder Blend, 10 g)</th>
</tr>
</thead>
</table>

**REFERENCES**

