Look to Paddock for All of Your Compounding Needs

POLYBASE™

Water Soluble - Water Miscible Suppository Base

Applications
Polybase is used as a pharmaceutical base in the preparation of suppositories when a water-soluble or water-miscible base is preferred.

How to Use - TIPS:
• Be sure that the suppository mold is clean and completely dry before use.
• Do not refrigerate or freeze mold before pouring, since the cold temperature may cause surface fissuring or fracturing of suppositories.
• Coating of suppository mold with lubricant is not necessary with Polybase. Polybase has excellent mold release characteristics.

Suppository Directions:
• Weigh Polybase and place it in a Pyrex® beaker, stainless-steel beaker, crucible or another appropriate container with a pouring lip.
• Melt Polybase 60°C-71°C (140°-160°F) using a water bath, hot plate, burner, or another temperature-controlled heating device. Polybase is very heat stable and can be heated to 93°C (200°F) without affecting its chemical characteristics.
• Stir the melted Polybase with a spatula or stirring rod while incorporating the medication into the melted Polybase. Mix until a homogeneous suspension is formed.
• When the homogeneous suspension is 43°C (110°F), pour mixture into the suppository mold. Slightly overfill the mold to account for contraction while cooling.
• Refrigerated suppositories will set up in 15-30 minutes. Do not freeze.
• Trim suppositories with a razor blade or spatula. Break the mold apart carefully and remove the finished suppositories.

Polybase is a pre-blended suppository base used to simplify the process involved in the extemporaneous compounding of suppositories.

• The recommended storage for suppositories is in a glass container or a chipboard suppository box under refrigeration.

CAUTION: Suppositories made with Polybase should not be stored or dispensed in polystyrene containers.

Properties
Polybase consists of a homogeneous mixture of various molecular weight polyethylene glycols. These specific polyethylene glycols exhibit excellent stability at room temperature due to their high melting points. Polybase releases medication by dissolving in the rectal or vaginal canal rather than melting, providing a longer disintegration time.

Ingredients
Polyethylene glycol 400, polyethylene glycol 8000, polysorbate 80

Specifications
Appearance: White solid
Odor: Mild polyethylene glycol odor
Specific Gravity: 1.177 @ 24°C (75°F)
Moisture: 2% MAX
Form: Solid @ 24°C (75°F)
POLYBASE Formulating & Compounding Examples

CHLORAL HYDRATE 500 mg/suppository, 12 each (2.20 gram blanks)

Chloral hydrate 6.00 gm
Polybase 20.53 gm

1. Heat Polybase to melting, 140°-160°F.
2. Add chloral hydrate to melted Polybase, slowly stirring until uniform.
3. Quickly pour into molds.* Cool and dispense.

INDOMETHACIN 50 mg/suppository, 12 each (2.20 gram blanks)

Indomethacin powder 0.50 gm
Polybase 25.87 gm

1. Heat Polybase to melting, 140°-160°F.
2. Add indomethacin to melted Polybase, slowly stirring until uniform.
3. Quickly pour into molds.* Cool and dispense.
*Calibrate your molds before use.

Sample Suppository Formulas

(Assuming blank weight 2.2 gm**)

Using Polybase and density factor 1.00

<table>
<thead>
<tr>
<th>Suppository Size</th>
<th>Increased by 10%***</th>
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<tbody>
<tr>
<td>25 mg Suppositories</td>
<td>100-count yield</td>
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<tr>
<td>Polybase 217.50 gm</td>
<td>239.25 gm</td>
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<tr>
<td>Medicament 2.50 gm</td>
<td>2.75 gm</td>
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<tr>
<td>TOTAL 220.00 gm</td>
<td>242.00 gm</td>
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<td>Polybase 215.00 gm</td>
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<td>5.50 gm</td>
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<td>Polybase 210.00 gm</td>
<td>231.00 gm</td>
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<tr>
<td>Medicament 10.00 gm</td>
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**Calibrate your molds before use.
***Increased by 10% to allow for overfill and shrinkage.

Contraindications
Polybase is contraindicated in persons who have shown hypersensitivity to any of the listed ingredients.

All information presented is intended to demonstrate the application of Paddock vehicles for compounding. Paddock products are sold on the understanding that purchasers will make their own determinations as to the suitability, safety and effectiveness of their applications. The uses presented by Paddock are only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by Paddock Laboratories. Paddock Laboratories does not warrant against infringements of patents of third parties by reason of any uses made of the vehicles in combination with other material or in the operation of any process, and purchasers assume all risks of patent infringement by reason of any such use, combination or operation.

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