



SUPPOSITORY MOLD RR 2159
Instruction Manual
 Version 2.0

Contents	Page
Overview / Environmental Conditions / Website References	2
Parts Identification / Markings	3
Operating Instructions	4
Materials of Construction	7
Cleaning	7
Frequently Asked Questions	9
Troubleshooting	10
Weights and Dimensions	11
Contact Information	12

Overview

The Suppository Mold makes rocket-shaped suppositories. This unique suppository design allows the medication to remain at the site for several hours, unlike suppositories of other shapes. The tapered tip allows for easy insertion and the flare at the bottom allows the suppository to remain in contact with the anal sphincter and external perianal area.

Environmental Conditions

Formation: Temperature affects suppositories during both formation and storage. Suppositories should be made at a room temperature of 15° – 27° C (60° – 80° F). Further details about formation can be found in the websites at the bottom of this page.

Storage: Suppositories should be stored individually, separate from each other, and in a tightly closed container.

Cocoa butter suppositories should be stored below 30° C (86° F) and preferably in a refrigerator.

Polyethylene glycol suppositories should be stored below 35° C (95° F).

Glycerinated gelatin suppositories should be stored between 20° and 25° C (68° to 77° F).

Web Site References

For more information on suppository bases, calibration, calculation of density factor and estimation of ingredients, visit the following websites*.

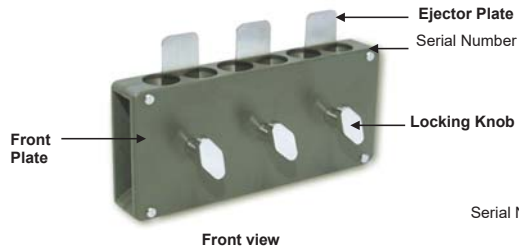
Information on suppository base properties - <http://pharmlabs.unc.edu/labs/suppository/bases.htm>

Calibration of suppository mold - <http://pharmlabs.unc.edu/labs/suppository/labs.htm>

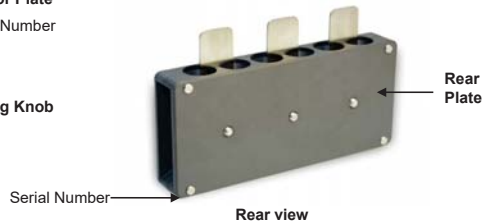
Density Factor of ingredients: <http://pharmlabs.unc.edu/labs/suppository/prep.htm>

Estimation of ingredients by calculation <http://pharmlabs.unc.edu/labs/suppository/estimation.htm>

*These links are provided as a service to our customers and do not imply any endorsement from the University of North Carolina or Dr. Robert P. Shrewsbury.



Front Plate has three holes for the Locking Knobs



Rear Plate contains the logo and has 6 locating pins embedded inside it.



Lubrication and Assembly



Photo of Rear Plate

1. Using a cotton swab apply lubricant to cavities on the inner side of both plates.



2. Apply Lubricant to both sides of Ejector Plates. See Tip 1.



3. Place Ejector Plates on locating pins of Rear Plate.



4. Place Front Plate onto locating pins of Rear Plate.



5. First lightly tighten all three Locking Knobs, then fully tighten all three Knobs to prevent leakage during filling.



6. Suppository Mold is ready for filling.

Tip 1: To ensure easy removal of suppositories, lubricate entire inner surface of mold plates and Ejector Plates. Light liquid paraffin and glycerin are the most commonly used lubricants. Check lubricant properties to ensure it will not interact with the suppository base or active ingredients.

Fill Suppositories



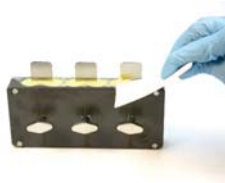
7. Melt required quantity of suppository base in hot water bath or on hot plate. Add active ingredients. See Tip 2.
8. Pour melted mixture into mold cavities. Fill cavities until there is a slight overflow onto the top surface of the mold. This allows for shrinkage after solidifying.
9. Allow suppository mixture to cool at room temperature for 30 minutes.

Tip 2: Check the suppository base handling recommendations and avoid overheating. For example, cocoa butter & glycerinated gelatin base should not be heated above 35° C and 90 - 95° C, respectively.

Remove Suppositories



10. Check whether suppositories are solidified. See Tips 3 and 4.



11. Use plastic scraper to scrape excess material off surface of mold.



12. Unscrew the Locking Knobs.



13. Separate the mold plates slowly. See tip 5.



14. To remove suppository, lift the Ejector Plate and slide suppository as shown.



15. Suppositories are ready to use. Store in a sealed container in refrigerator or at proper temperature.

Tip 3: To test if suppositories are solidified, touch the suppository or the overflow material with your finger or plastic scraper. It should be firm, not soft.

Tip 4: If the suppository base does not solidify at room temperature, refrigerate mold for 30 minutes. Do not place in freezer. If the mold is stored in a refrigerator, let it sit at room temperature for 10-15 minutes before continuing with step 11.

Tip 5 - Never try to separate mold plates with knife, spatula, or other instrument as damage may occur. Damage to mold plates may result in leakage during subsequent use.



We recommend cleaning when changing formula or at the end of each day. Clean mold using one of the methods below.



Automatic Dishwasher

Anodized Aluminum mold may be cleaned in an Automatic Dishwasher on rinse only with **no** automatic dishwasher detergents. Dishwasher detergents can discolor anodized aluminum. Innox Ejector Plates are fully dishwasher safe using detergent.



Cleaning Agents

We recommend cleaning using household hand dishwashing liquid. Do not use sodium hypochlorite (household bleach) or any other caustic substance. See hand washing instructions below.



Isopropyl Alcohol

Isopropyl Alcohol can be used to speed dry all parts. Wipe parts with a cloth dipped in isopropyl alcohol, then immediately wipe dry with a clean cloth.



Hot Air Drying

Safe for hot air drying.



Autoclave

All parts are autoclave safe at 121°C / 250°F, 15 psi pressure for 15 minutes.

HAND WASHING INSTRUCTIONS

1. Dismantle parts and soak in warm water with detergent for 5-10 minutes.
2. Clean using nylon brush, sponge or wash cloth.
3. Wipe with dry cloth or paper towel. Always dry parts fully before using mold.
4. To speed drying, use a cool or hot air dryer.

AVOID DAMAGE TO SURFACE OF PARTS

Do not use acidic cleaning solutions.

Do not clean with abrasive cloth, gritty materials, or steel wool. Use only plastic brushes or nylon pads.

Do not apply excess force when cleaning parts.



Do not use a knife, spatula, or other similar instrument for cleaning. Damage to inside surface of mold plates may result in leakage during subsequent use.

1. *What is the weight of the suppositories formed?*

The weight of the suppositories depends on the suppository base and ingredients used. The suppository formed by cocoa butter weighs approximately 6.2 g. See page 10 for suppository dimensions.

2. *What will be weight variation of the suppositories formed?*

The weight of all suppositories formed in one cycle will be $\pm 5\%$ of average weight.

3. *How do I calibrate the suppository mold?*

See the website references on page 2.

4. *How can I calculate the amount of base and active ingredients?*

Each suppository cavity has an approximate volume of 7 ml for a total volume of approximately 42 ml for the 6-suppository mold. See the website references on page 2 for calculation details.

5. *Can the Suppository Mold be cleaned in an automatic dishwasher?*

Anodized aluminum parts are dishwasher safe if NO automatic dishwashing detergent is used. See page 7 for details.

6. *What is the Suppository Mold made of?*

Mold plates are Anodized Aluminum. Ejector Plates and Locking Knobs are Inox (SS316).

7. *Why might I need to refrigerate the mold?*

Refrigeration is required if suppositories do not solidify at room temperature.

8. *What are the shipping weight and size of the mold?*

See page 10.

9. *What are maintenance requirements?*

We recommend cleaning all parts after completion of each batch. No special maintenance is required.

Things that are normal with your Suppository Mold:

The surface finish of suppositories may be textured. This is normal.

Troubleshooting:

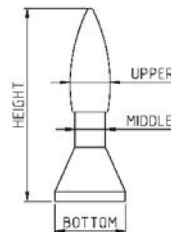
	Observation	Possible Cause	Remedies
1	Excessive leakage of ingredients outside the mold	a. Locking Knobs are not fully tightened.	Tighten Locking Knobs until 2 plates of mold are pressed firmly together.
		b. Ejector Plate bent.	Bent Ejector Plate should be flattened or replaced.
		c. Inside surface or edges of Suppository Mold are damaged.	Replace the Suppository Mold.
2	Suppository sticks to mold	a. Incomplete lubrication to mold.	Lubricate entire surface of mold inner cavities and Ejector Plates.
		b. Lubricant used may not be appropriate.	Use another lubricant. Be sure the lubricant does not react with the suppository ingredients.
3	Suppository not formed	a. Cooling time is too short.	Cool suppositories for longer time or place in refrigerator. (See page 6, tips 3 and 4).
		b. While melting the suppository base and other ingredients, temperature was raised above the recommended limit.	Check the characteristics of suppository base and other ingredients. Do not heat above recommended temperature.
		c. Suppository base and other ingredients are incompatible with each other.	Check ingredients for compatibility. Change ingredients or formula as necessary.
4	Mold Plates do not fit together properly	a. Locating pins of Rear Plate may be bent or missing.	Straighten the pins if bent or replace the Suppository Mold.

Technical Specifications of Mold:

Approximate Volume of one Suppository Cavity	7.0 ml
Net Weight (With Ejector Plates & Locking Knobs)	1 kg / 2.2 lbs
Shipping Weight	1.2 kg / 2.6 lbs
Length x Width x Height (mm)	180 x 52 x 108 mm
Length x Width x Height (Inches)	7 x 2 x 4.3 inches

Dimensions of Suppositories Formed:

Parameter		Approximate Dimensions	
		mm	inches
Height		59.4	2.33
Diameter	Upper	12.1	0.47
	Middle	9.2	0.36
	Bottom	21.4	0.84



Weight Variation:

The weight of all suppositories formed in one cycle will be $\pm 5\%$ of average weight.

The suppository formed by cocoa butter weighs approximately 6.2 g.

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