

Form: 0.25ml Dott Suppositories (Pebble Beach Mold)

Quantity to Make: 100

Time to Make: 30 min

Route: Vaginal

Log Entry Date: 04/23/2023

Beyond Use Date: 180 Days*

Technology: Pebble Beach Molds

Pebble Shaped Cavities: 0.25 mL

SKU: PB100-025

Chemical Ingredients	Units	NDC
ACTIVE INGREDIENT	X g	
MBK™ (FATTY ACID) - PCCA	23 g - (APIs)	
PEBBLE BEACH MOLD (0.25MLX100)	1 EA	

CALCULATIONS:

Calculations are based in making #100 total suppositories in order to compensate for material waste upon spreading and transferring.

BASE: 0.23g/SUPP x 100 SUPP = 23 g

ACTIVE INGREDIENT: Xmg/SUPP x 100 SUPP = Xmg (Xg)

PHARMACY CORRECTION: X G / 92% = X g

DESCRIPTION:

100 Pebble-Shaped Dott Suppositories

INSTRUCTIONS

DON SAFETY GOGGLES AND OTHER PPE & PREPARE A WATER BATH OR HOT PLATE.

GATHER AND WEIGH INGREDIENTS.

ADD BASE TO APPROPRIATE SIZE BEAKER. PLACE BEAKER IN WATER BATH (MELT TO 45°-50° C).

MELTING POINTS VARY FROM BASE TO BASE

ONCE BASE STARTS TO MELT, USE A STIRRING ROD AND GENTLY STIR UNTIL COMPLETELY MELTED

ADD ACTIVE INGREDIENTS TO THE MELTED BASES AND STIR UNTIL FULLY DISSOLVED.

TRANSFER THE MIXTURE ONTO THE PEBBLE BEACH MOLD (MAINTAIN THE TEMPERATURE AT 45°

BY QUICKLY POURING OVER THE TOP ROW OF CAVITIES.

USE A SPREADER TO SPREAD MIXTURE EVENLY UNTIL DESIRED QUANTITY IS FILLED.

WIPE OFF EXCESS MIXTURE INTO THE RUN-OFF TROUGH.

GENTLY TAP THE MOLD ON THE WORK SURFACE TO REMOVE ANY AIR POCKETS

COOL PEBBLE BEACH MOLD AND CONTENTS AT ROOM TEMPERATURE UNTIL PRODUCT IS

SEMI-FIRM, THEN MOVE TO REFRIGERATOR.

TAKE SUPPOSITORIES OUT OF MOLD BY FLIPPING THE MOLD, LIGHTLY TWISTING, AND TAPPING ON SECTIONS

WHERE SUPPOSITORIES DO NOT FALL OUT.

DISPENSE IN AIR-TIGHT, CHILD-RESISTANT PRESCRIPTION VIAL OR PACKAGE OF CHOICE.

FINAL PRODUCT WILL BE A WHITE OPAQUE PEBBLE SHAPED SUPPOSITORY.

DRUG WARNING: KEEP AWAY FROM CHILDREN; HAZARDOUS, DISPOSE OF PROPERLY, KEEP IN FRIDGE, DO NOT FREEZE

**QUALITY ASSURANCE AND INSPECTION PERFORMED BY PHARMACIST AND /OR ANCILLARY STAFF CONFIRMED THIS COMPOUND.

MBK SUPPOSITORY BASE

POWDER DISPLACEMENT WEIGHT CORRECTION ESTIMATION

DWC: (X G) x 80% = X g DISPLACEMENT

23 g - X g = X g SUPPOSITORY BASE

80% displacement was a standard industry estimate. Your organization should determine if this adjustment fits your standard processes.

Dr. Moses Notes: For suppositories, add 15% excess base to account for product loss. Maintain the preparation temperature to at least 45°C when transferring.

0.25mL PEBBLE BEACH MOLD DATA, N=100

Mean 0.232 g

Median 0.23

Std. Dev. 0.00293

MEDIAN: 0.23 g per suppository.
Median was chosen as it is resistant to change
PCCA MBK base was analyzed

***BUD: 180 DAYS PER USP 795 IN THE ABSENCE OF WATER**

Appropriate references should be consulted. Safety and efficacy of these formulas are the responsibility of the compounding pharmacist.

Formulation Disclaimer:

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