

ProFILLER RDT

MOLD INSTRUCTION MANUAL



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This manual is intended for use by qualified compounding personnel engaged in the service, inspection, maintenance and handling of the equipment.

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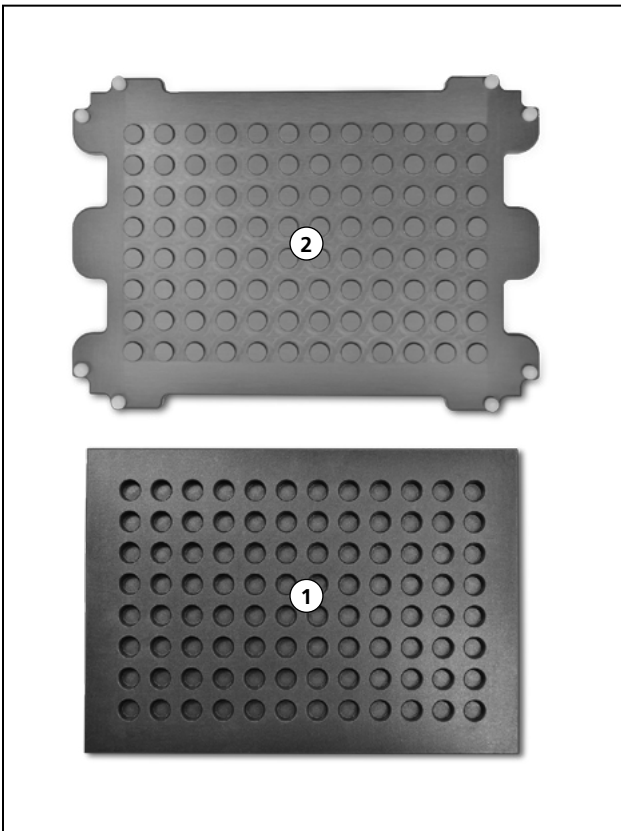
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MEDISCA's ProFiller RDT Mold is developed to provide quick, convenient and consistent medicated dosages. When used in conjunction with MEDISCA's Medi-RDT Base, it provides an easier and efficient way to dispense your RDTs with sufficient mechanical strength and quick disintegration in the mouth.

SECTION A : PROFILLER RDT MOLD



Mold, ProFiller Rapid Dissolve Tablet, 96 Cavities, 0.94mL (ProMold-RDTM) (Prod No.: 6707)

1. Cavity Plate
2. Tamper Plate

Picture 1

Other Devices / Equipment Required

1. Sieve, 50 Mesh, Full Height 2-5/8", Brass/Brass (Product No: 7310)
2. Sieve Receiver Pan, Brass, 8" Dia. (Product No: 9652)
3. Hot Hand Protector, Gripper, Red (Product No: 7315)
4. Convection Oven, Mechanical, High Temperature, 1.9cu.ft. (Product No: 7840)
5. Blister Packs, Medi-RDT, w/Label & Sleeve (Product No: 7219)
6. Mini Mallet, Non-marring, 3/4" diameter Plastic Head (Prod No.: 7106)

SECTION B : PREPARATORY INSTRUCTIONS FOR COMPOUNDING RAPID DISSOLVE TABLETS CONTAINING API

1. Weigh API(s), Medi-RDT Base and other ingredients of formulations (*Fig. 1*).

NOTE : • The API used in formulation must be stable at 115°C temperature. Refer to drug reference guide or call technical service department.

- To account for processing error, it is suggested to measure an additional 5-9 % of the required quantities of ingredients to compound a prescribed formula.
- The amount of Medi-RDT Base will vary with the API content. Refer to sample formula to correctly determine the required amount of Medi-RDT Base and other ingredients of the formulation
- Preheat Convection Oven to 110°C.



(Fig. 1)

2. Triturate API(s) and other ingredients of the formulation (*Fig. 2*). Sieve through 50 mesh test sieve (*Fig. 3*) and mix geometrically all the ingredients of the formulation to obtain uniform mixture (*Fig. 4*). The Medi-RDT Base should not be crushed or triturated. It should only be sieved and mixed geometrically with the APIs and the other ingredients using a mortar and pestle (*Fig. 5*).



Fig. 2



Fig. 3



Fig. 4



Fig. 5

SECTION C : FILLING OF MOLDS

3. Fill the cavities of the mold with the powder mixture. To fill the mold cavities, pour approximately half of the powder mixture and spread over the cavities with the use of a powder scraper. Gently tap the cavity plate on the counter to allow the powder to settle and add more powder mixture as needed. Remove excess powder mixture and reserve it. It is important to completely fill the cavities (*Fig. 6*).



Fig. 6

4. Compact the powder in the cavity with the tamper plate. Remove the tamper plate and fill the cavities with the portion of remaining powder mixture from step-3. Remove excess powder and reserve it. Compact again with the tamper plate. Repeat above steps at least three times in order to completely fill the cavities (*Fig. 7* and *Fig. 8*).



Fig. 7



Fig. 8

SECTION D : BAKING

5. Place the filled mold (only the cavity plate) on the middle rack of a convection oven preheated at 110°C for 15 minutes. The baking time must be very specific (if necessary, use a timer for this procedure).



Fig. 9

6. Carefully remove the mold from the oven with the use of a hot hand protector.



Fig. 10

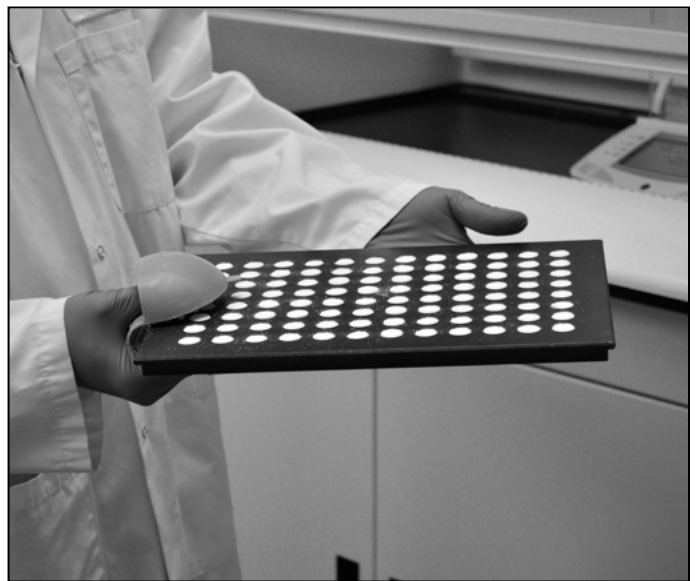


Fig. 11

SECTION E : REMOVAL OF RDTs FROM MOLD

7. Immediately place a sheet of wax paper over the filled cavities (*Fig. 12*). Allow the mold to cool at room temperature between 1 - 2 minutes before removing the tablets. If waiting time exceeds 2 minutes, the removal of the tablets may become difficult.

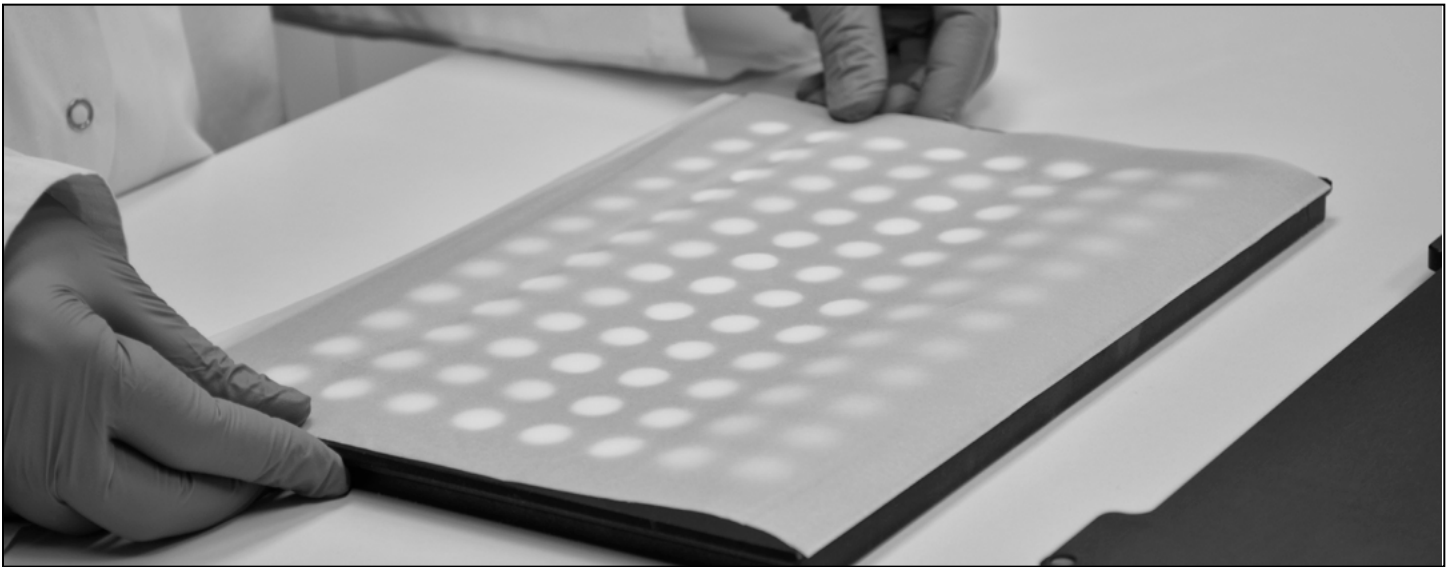


Fig. 12

8. Place the flat backside of the tamper plate on the top of cavity plate covered with wax paper. Hold both plates together and invert (upside down) on to the counter as shown in (*Fig. 13*). Release the tablets by **gently** tapping with a non-marring mini-mallet w/plastic head or your hands against the bottom of the cavity plate (*Fig. 14*). Lift the cavity mold up allowing the tablets to remain on the wax paper.



Fig. 13



Fig. 14

9. Allow tablets to cool for an additional 15 - 30 minutes at controlled temperature and relative humidity, before packaging.



Fig. 15

SECTION F : DISPENSING RDTs

10. For unit dose packaging, transfer the Rapid Dissolve Tablet in Amber Circular Blister Sheets, attach the adhesive foil tamper labels and placed in to blister sleeve (*Medi-RDT Blister Packs – Product No.: 7219*).



Fig. 16



Fig. 17

SECTION G : MOLD CLEANING AND MAINTENANCE

1. Rinse the cavity plate under running lukewarm tap water. If necessary, soak the mold in warm water-soap solution for few minutes to facilitate cleaning.
2. Wash the molds using warm water, liquid soap and a soft brush or sponge. Do not use acidic or caustic cleaning solutions.
3. Rinse and drain off cavity mold and tamper plate.
4. Use 50% alcohol for final wipe down.
5. Let dry. May be dried in a hot air oven.

ATTENTION : Avoid use of metal utensils (spoon, spatulas, scrapper, brush, etc.) and cleaning aids with abrasive surface at any time due to potential risk of damaging coating of the molds.

ProFiller Mold can be cleaned in dishwasher on rinse cycle mode only without the use of dishwasher detergents and with all the above precautions.

This mold is autoclave safe.

SECTION H : SAMPLE / BLANK FORMULA



To view a Medi-RDT sample formula, visit : www.medisca.net/rdt