



Medi-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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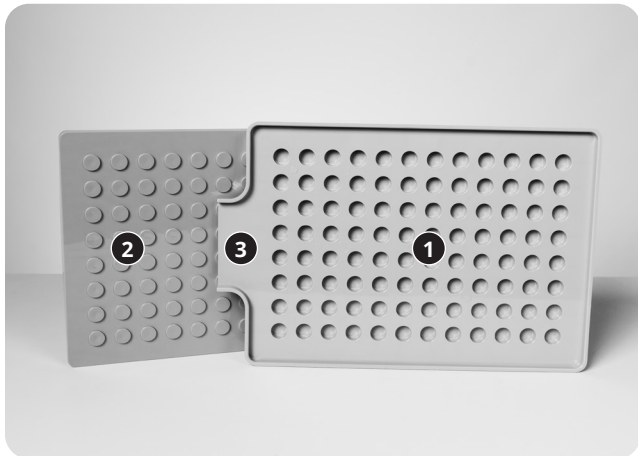
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Section A: Medi-RDT™ Mold

The new Medisca Medi-RDT Mold is developed to provide quick, convenient and consistent medicated dosages. When used in conjunction with the Medisca Medi-RDT™ Base, they provide an easier and efficient way to prepare rapid dissolve tablets (RDTs) with sufficient mechanical strength and quick disintegration in the mouth. Medisca offers two different customized molds.

Mold, Medi-RDT, PC, 96 Cavities, 750mg (7314)

1. Base Cavity Plate
2. Top Compression Plate (Tamper, 2 x Handles, Not Oven Safe)
3. Lateral Containment System



Supporting Accessories

4. Sieve, 50 Mesh, Full Height 2-5/8", Brass/Brass (7310)
5. Sieve Receiver Pan, Brass, 8" Dia. (9652)
6. Hot Hand Protector, Gripper, Red (7315)
7. Convection Oven, Mechanical, High Temperature, 1.9cu.ft. (7840)
8. Blister Packs, Medi-RDT™, w/Label & Sleeve (7219)
9. Blister Mini Mallet (7106)
10. Blister Powder Scraper (9675)



Section B: Preparatory Instructions for Compounding Rapid Dissolve Tablets

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

Note

- The API used in formulation must be stable at 100°C temperature. Refer to drug reference guide or call contact Medisca Compounding Services.
- 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.

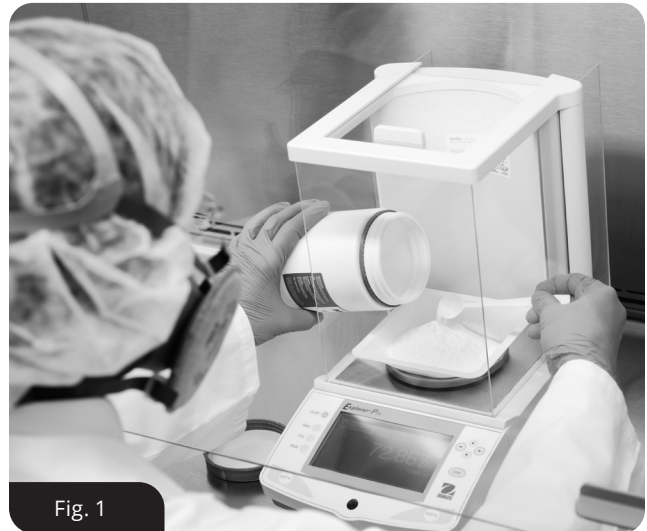


Fig. 1

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 Mold

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 through the lateral containment system and reserve it. It is important to completely fill the cavities (Fig. 6).



4. Compact the powder in the cavity with the top compression plate. Remove the top 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 top plate. Repeat above steps at least three times in order to completely fill the cavities (Fig. 7 and Fig. 8).

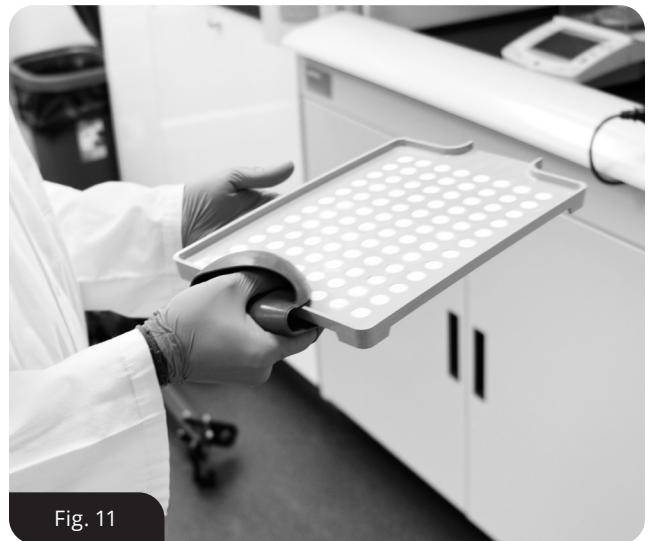


Section D: BAKING

5. Place the filled mold (only the base 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).



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

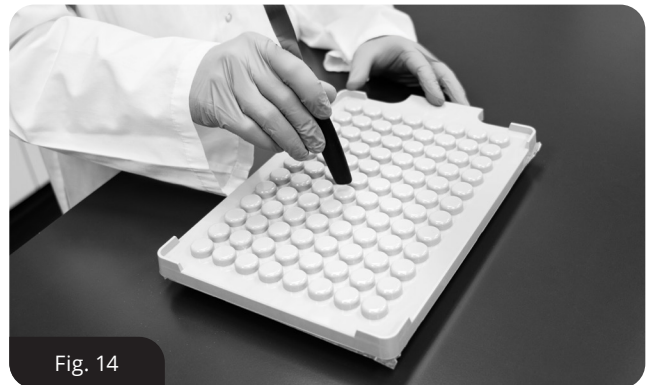


Section E: Removal of RDTs from Mold

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.



8. Invert (upside down) cavity plate on wax paper as shown in (Fig. 13). Release the tablets by gently tapping with mini mallet, spatula handle, 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.



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



Section F: Dispensing RDTs

- For unit dose packaging, transfer the RDTs into an Amber Circular Blister Sheets, attach the adhesive foil tamper labels and place in to blister sleeve (Medi-RDT™ Blister Packs (7219)).



Fig. 16



Fig. 17

Section G: Mold Cleaning & Maintenance

- Soak the molds in warm water-soap solution for a few minutes to facilitate cleaning.
- Wash the molds using warm water, liquid soap and a soft brush or sponge.
- Rinse and drain off cavity mold and top compression plate.
- Use 40% alcohol for final wipe down.
- Let dry.

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. Dishwasher can be used with all the above precautions.

Section H: Sample Formulas

Formula No.	API & Dosage	Base	Website
F 005 468	Progesterone 100mg Oral Rapid-dissolve Tablets	Medi-RDT™ Base	https://www.medisca.net/pdf/rdt/F%200005%20468v5%20Progesterone%20100%20mg%20Oral%20Rapid-Dissolve%20Tablets.pdf
F 006 495	F 006 495 Biotin 5mg Oral Rapid-dissolve Tablets	Medi-RDT™ Base	https://www.medisca.net/pdf/rdt/F%200006%20495v2%20Biotin%205%20mg%20Oral%20Rapid-Dissolve%20Tablets.pdf