SpecializedRx
3787 95th Ave NE, Ste 100
Circle Pines, MN. 55014 USA
888.512.1209
www.specializedrx.com

SUGGESTED PROCEDURE

Item	Estradiol 1mg Rapid Dissolve Tablet	Formula Date	30 April 2024
API(s)	Estradiol, USP (Micronized)	Procedure No.	P2630
Base	Excell-RDT™ SF	Revision	R2
Volume/Quantity	196 Tablets - X-TABB™ 800mg RDT	Compound Type	Anhydrous Rapid Dissolve Tablet

Rx	Weight (g)	Percent	Comment
Estradiol, USP	0.196	0.125%	
Excell-RDT™ SF	155.036g	98.875%	
SpecializedRx Powdered Flavor Concentrate	0.784g	0.5%	To taste
Natural Food Color Powder	0.784g	0.5%	
Total	156.8g	100%	

To account for processing error considerations during preparation, it is suggested to measure an additional **10%** of the required quantities of ingredients.

- Internal calibration of the tablet mold is recommended prior to preparing this formula. The amount of Excell-RDT™ SF Base will vary with API content. Displacement of the base will be determined by subtracting 70-100% of the other ingredients from the weight of the Excell-RDT™ SF Base.
- The API(s) must be stable at the selected temperature for the duration of the heating cycle, i.e. 110°C for 15 minutes.
- Use only soft plastic, rubber scrapers or brushes when manipulating powders over surface of coated RDT molds to prevent scratching surface. Do not use metal scrapers or brushes as they can permanently damage the mold coating.

Suggested Method of Preparation

1. Determine the total quantity to be prepared and accurately weigh/measure each of the ingredients. Subtract the weight of the API from the amount of the Excell RDT™ SF base. This is the calculated weight of the Excell-RDT™ SF which should be used per tablet. When using the X-TABB™ 196 cavity RDT mold, you will need to multiply all ingredients per tablet 196 times to account for accurate filling of the mold. Note the API handling precautions.
2. Pre-heat X-TABB™ Base Heating Plate (E0612-00) to 110°C depending on formula preference/API.
3. Weigh API, flavor and Excell-RDT™ SF base, triturate and mix thoroughly by geometric dilution in a mortar and pestle or planetary-style mixer.
4. Transfer approximately one-half of formula powder onto the cavity plate (on the quarter score plate) and begin filling the cavities using a plastic or rubber spatula. Add enough powder to ensure an even first layer, remove and reserve excess powder.
5. Using tamper plate (E0610-00), press powder firmly. Remove tamper plate and fill cavities again with reserved powder from step 4. Remove excess powder again and reserve. Repeat process until all powder has been pressed into the bottom plate after final press. Generally, 3 filling and tamping events is appropriate.
6. Place the filled cavity/score plates (E0608-00/E0609-00) onto the heated base plate, verifying it has reached prescribed temperature. Place tamper plate (flat side down) over the filled cavity plate. This will allow the heat to stay contained to the filled RDT cavities. General heating cycle is 110°C for approximately 15 minutes based on API content, final tablet hardness, RDT base used, temperature requirements, etc. This is a general guide that can vary from formula to formula. Consideration should be accounted for acclimating the temperature of the X-Tabb score plate and cavity plate combination once placed on the heated base heating plate. It is recommended to add an additional 2-5 minutes to allow for the filled cavity and score plates to acclimate to temperature.

   RDT removal procedure is based on user preference taking into consideration RDT temperature and allowed cooling time duration. The suggested removal procedure is outlined below:

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7. Once heating is achieved, using hot hand protectors, remove the 3 plates from the base heating plate (tamper plate, cavity plate and score plate) and place on a heat protected surface, then remove the tamper plate exposing the doses. Allow doses to cool for approximately 30 minutes prior to separating the cavity plate from the score plate.
8. Separate the cavity plate from the quarter score plate using the cavity corner tab features and scraper/pry tool. When the plates are separated, it is common for the finished doses to either stay with the quarter score plate, cavity plate or a combination of both. RDTs can be removed by either of the two methods below:

- Pressing each dose carefully out of the cavity plate. Tip: To help with RDT removal from the cavity plate, RDTs can be partially removed by inverting the tamper plate with bosses facing up on a flat surface, aligning the cavity plate (score marks facing down), and gently pressing the cavity plate down. Remove RDTs by gently pressing them out of the cavity plate.

- Using the ejector plate, placed on a flat surface with bosses facing up, align the cavity plate over the ejector plate and gently press down, releasing the RDTs from the cavity plate.

9. It is recommended to allow tablets to fully cool for 30 minutes at room temperature and relative humidity before handling and packaging.
10. Final product should be a square Rapid Dissolve Tablet with an average weight of 0.8g
11. Suggested Quality assessments
    a. Appearance and feel
    b. Quantity
    c. Label - auxiliary labels, storage, BUD, compounded medication.

Packaging: Tight, light-resistant, child-resistant container or blister packs.
Estimated Beyond Use Date: 180 days per USP 795*
Labeling: Keep out of reach of children. Use only as directed. Protect from moisture and light.
Stability: Anhydrous formulation.
Note: Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).

***Beyond-Use Date should be based on the current USP General Chapter <795>.** Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist. Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

WARNING! Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.