

2.3 PROCEDURE – FOR CUTTING PILLS & BLISTER PACKS

GOAL

Procedure for preparing certain drugs to replenish SynMed® containers or to be added by Production Technicians.

STAFF

Pharmacy Technical Assistants

INSTALLATION AND REQUIRED MATERIALS

Work in as pristine an environment as possible, with adequate lighting, in order to minimize risk of error.

- ✓ Pill counter
- ✓ Pill cutter
- ✓ Empty vials
- ✓ Self-adhesive labels
- ✓ Pencils
- ✓ Rubber bands
- ✓ Isopropyl alcohol in a vaporizer bottle
- ✓ Paper tissues
- ✓ Gloves
- ✓ Baskets
- ✓ Scissors
- ✓ Adhesive tape as needed

CUTTING PILLS INTO SMALLER ($\frac{1}{2}$, $\frac{1}{4}$) SIZES

1. Consult the list of pills to be cut which has been prepared by the team in charge of producing the blister packs.
Note: This list must be verified by a pharmacist, who can confirm that these pills can be cut without compromising their efficacy or stability.
2. Take out the drug jars you will need (containing the drugs to be cut) and place them in a basket to your left.
3. Put on safety gloves.
4. Take the first drug jar. If more than one jar is needed, ensure that lot numbers and expiry dates match. If not, handle one lot at a time.
5. Count out the number of pills needed, according to the prescribed quantities, with the help of a pill counter that has already been sterilized with isopropyl alcohol.
6. Use a pill cutter to cut the pills in two (or four) units (do not perform this task directly on the counter). Some pills are easier to separate by hand. It is important that pills are cut as accurately as possible with the utmost precision.
7. The $\frac{1}{2}$ (or $\frac{1}{4}$) pills are placed into the pill counter.
8. Prepare the vial, and identify cut pills by including the following information on the label to be affixed to the vial:
 - a. Name of drug
 - b. Strength
 - c. Expiry date indicated on vial
 - d. Lot number

- e. Current date
- f. Initials of technician
- g. Quantity if needed

Note: If more than one lot is needed for the same drug, individual vials must be prepared for each of the lots.

9. Place the ½ (or ¼) sized pills in the appropriate vial.
10. Deposit the original container AND the vial containing the cut pills (and attach both with an elastic band) in a separate basket to your right.
11. Sterilize the pill counter with isopropyl alcohol.
12. Take the next drug jar.
13. Repeat steps 5 through 12 until all required drugs have been cut.
14. Make sure each label is double checked by a pharmacist or a Production Technician who is already mandated to do so according to DCCV standards, and who is required to co-initial the label.
15. Sort original jars once the verification procedure has been completed.
16. Attach vials of cut pills to original jars, and bring them to the blister pack production work station.

PREPARING DISTRIBUTION OF PILLS FOR BLISTER PACKS (FOR UNCAPPING)

1. Consult the list of drugs to be uncapped, prepared by the team in charge of producing the blister packs.

Note: This list must be verified by a pharmacist, who ensures that the pills can be uncapped without compromising their efficacy or stability.

2. Remove the drugs you will need (that must be uncapped) from their containers, one at a time, and place them into a basket to your left.
3. Put on safety gloves.
4. Take a pill counter.
5. Select the first drug.
6. Use required number of containers, according to requested quantities.
7. Proceed to uncap pills and place them on the pill counter.
8. Prepare a vial to identify uncapped pills, and include the following information on the label to be affixed to the vial:

- a. Name of drug
- b. Strength
- c. Expiry date indicated on original package
- d. Lot number
- e. Quantity prepared
- f. Current date
- g. Initials of technician

Note: If more than one lot is needed for the same drug, individual vials must be prepared for each of the lots.

9. Place uncapped pills into appropriate vial.
10. Deposit the original jars AND the vials identifying uncapped pills in a basket to your right.
11. Sterilize pill counter with isopropyl alcohol.
12. Take the next drug jar.
13. Repeat steps 6 through 12 until all pills have been uncapped.
14. Make sure each label is double checked by a pharmacist or a Production Technician who is already mandated to do so according to DCCV standards, and who is required to co-initial the label.
15. Hold onto original jars once verification has been completed, since they will have to be scanned during the next replenishment cycle (and in case you need them to complete your orders).
16. Bring containers of uncapped pills along with original jars to the blister pack production work station.

REPARATION OF PILLS DISTRIBUTED IN BLISTER PACKS (SINGLE PACKAGING TO BE CUT UP)

Note: Packaging for certain drugs (like ODT®) must be cut out and unfolded in a particular way. The team in charge of producing blister packs must be consulted.

1. Take the list of drugs to be processed in this manner as prepared by the team in charge of producing the blister packs.
2. Take a pill counter.
3. Remove the drug jars needed (for which packaging must be cut out) and place them in a basket to your left.
4. Select the first drug.
5. Use required number of vials, according to requested quantities.
6. Begin to cut out (and unfold as needed) single packaging and deposit onto pill counter.
7. Prepare a vial containing the following information to identify drugs whose packaging has been thus separated:
 - a. Name of drug
 - b. Strength
 - c. Expiry date printed on original package
 - d. Lot number
 - e. Quantity if needed
 - f. Current date
 - g. Initials of technician
8. Place cut up drug units into labelled container.
9. Deposit original jars AND those identifying drugs thus handled into another basket to your right.
10. Take next drug jar.
11. Repeat steps 5 through 10 until all drugs have been sorted.
12. Make sure the drugs have been double checked by a pharmacist or a Production Technician who is already mandated to do so according to DCCV standards, and who is required to co-initial the label.
13. Hold onto original jars once a final check has been made (if this is how you normally process orders).
14. Bring containers of separated drugs along with original jars to the blister pack production work station.

No special training is required to complete this procedure. The help of an experienced Production Technician suffices.

2.4 PROCEDURE FOR SECURE SYNIMED® SET UP

1 GOAL

This procedure for preparing blister packs with SynMed® is intended for Technician Managers and Production Technicians

2 STAFF

Pharmacy Technical Assistants who received SynMed® training

3 INSTALLATION AND REQUIRED MATERIALS

Work in as pristine an environment as possible in order to minimize risk of error.

- ✓ Technological tools: computer with access to patient profiles, computer with SynMed® software, SynMed® robot
- ✓ Master patient profiles (binders)
- ✓ SynMed® tray
- ✓ Blank blister packs
- ✓ Plastic blisters cards
- ✓ Paper clips
- ✓ Tweezers
- ✓ Gloves

BLISTER PACK PRODUCTION STEPS

PREPARATION

Step 1: Sending files to SynMed®

PRE-PRODUCTION

Step 2: Manual insertions with SynMed-Assit

PRODUCTION

Step 3: Blister pack production is completed by the robot

POST-PRODUCTION

Step 4: Scan blister packs – post-production

Step 5: Cell count and sealing of blister packs

PREPARATION

STEP 1: SENDING FILES TO SYNMED® SOFTWARE

Important: Files should be sent from the pharmacy system to the SynMed® computer at the beginning of the production day or at the end of the day before the date of production. It is unadvisable to send the files before that time as there could be changes in patient medications before the production date, resulting in unnecessary handling.

Procedure

1. Send files in batches from the pharmacy system to the SynMed® computer.
2. If desired, conduct a quick check of the number of drugs included in the production cycle in the sent files by comparing patient profiles to the master record.
3. Send files to the SynMed® robot.

PRE-PRODUCTION

STEP 2: MANUAL INSERTIONS BASED ON SYNMED-ASSIST

Important – 1: The use of **protective gloves or tweezers** is mandatory for this step of the preparation process.

Important – 2: Certain drugs (i.e. cytotoxic drugs, such as: Methotrexate®, Avodart®, etc., or potentially highly allergenic drugs, such as: penicillin, sulfates, etc.) must be handled with additional safety precautions. The list of dangerous drugs compiled by NIOSH is included in this binder (Document 1.8 – List of dangerous drugs as listed by NIOSH). Protective gloves must be discarded after use and tweezers must be sterilized with a special cleaning wipe (not with alcohol).

Important – 3: Clean the counters with an antiseptic solution at least twice a day.

Preparatory steps to facilitate the preparation of trays containing external drugs

- Make sure that ½ and ¼ pills are cut in advance and in accordance with established procedures (the pharmacist must confirm that these drugs are stable when pills are cut).
- Make sure that pills are removed (uncapped) from blister packs in advance and in accordance with established procedures (the pharmacist must confirm that these drugs are stable when pills are uncapped).
- Make sure that packaging of drugs that are sensitive to light and humidity is cut in advance and in accordance with established procedures.

The following documents are automatically printed out during file transmission:

- o Bar code label for tray corresponding to this production;
- o Producing Pharmacy/Distributing Pharmacy Report, depending upon the situation;
- o Drugs Report

Procedure:

1. Place one of the two SynMed® trays in the work area provided for that purpose (pre-production).
2. Place all plastic blister cards on the SynMed® tray.

Affix the bar code label printed during transmission of production data for that tray and scan the barcode with the SynMed-Assist scanner.

4. If another generic drug manufacturer must be used, because the one indicated on the printed blister pack card is no longer available, the drug will be requested on SynMed-Assist. Keep the Override Report to take note of this change

and bring this report to the post-production work area (final cell count work station). At this stage, it is important to affix label on blister pack indicating change of product brand.

5. Certain drugs should not be removed from their packaging, as per pharmacist instructions (e.g. Zyprexa Zydis[®], Prevacid Fastabs[®], Pradox[®], etc.). These drugs must be inserted in blisters in their packaging or in a Ziploc[®] bag attached to the blister card.
6. No drugs may be handled with bare hands. In particular, certain drugs must never be handled with bare hands for security reasons (i.e. hormones, cytotoxic and teratogenic drugs, etc.; refer to the list compiled by NIOSH, which is included in this binder). Always use tweezers or wear protective gloves.
7. The operator must slide the bottle under the barcode scanner to ensure the correct drug is being inserted. If the UPC code of the scanned bottle is correct, that is, if it corresponds exactly with the UPC codes saved for this drug in the SynSoft database (*Drugs* tab), the following page will automatically display. Note: If pills must be cut before their insertion into blisters, use a pill cutter and perform this task on a pill counter to avoid the risk of drug particles falling into cells.
8. When inserting pills, pay close attention to drug quantity. This step must be undertaken with great care and not performed automatically.
9. Complete manual insertions for all cells indicated before moving forward.
10. Once manual insertions of the first drug are completed, place the original drug jar in another basket at the right of trays.
11. Repeat steps for all drugs.
12. Put back the jars on shelves after inserting the tray in SynMed[®] and once production has started.

PRODUCTION

STEP 3: BLISTER PACK PRODUCTION BY THE ROBOT

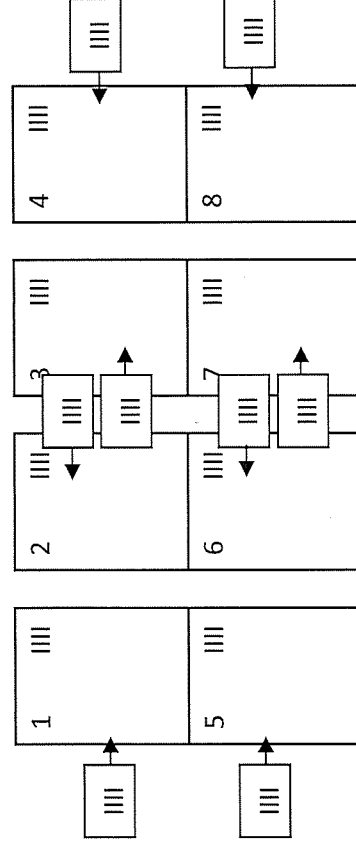
1. Take the tray prepared in the pre-production work area and insert it in SynMed[®] once all manual insertions are completed.
2. Set the tray drawer in start mode and scan the SynMed[®] tray bar code to start production.
3. Once production is completed, remove the tray from SynMed[®] and place it in the post-production work area provided for that purpose (for cell count and sealing).
4. The following documents are automatically generated and must be printed after these steps; to print the report, click the "Print" button.
 - The blister pack headers are printed with the colour printer.
 - The Production Events Report indicates any operation anomalies, insufficient drug quantities, etc. (It is not necessary to print this report if no event was reported.)
 - The Cell Count Report shows the expected quantities in each cell
 - The Statistics Report shows details of the production for a given file (number of trays, number of blister packs, name of Production Technician, production time, etc.).

POST-PRODUCTION

STEP 4: SCAN BLISTER PACKS – POST-PRODUCTION

Once the filling process has been completed, scan and affix blister card headers and count all blister pack cells, in accordance with the procedure laid out in the next step.

Scanning positions of the blister pack and blister cards



1. Take the blister cards which were automatically printed by the SynMed® software
2. Important: When events are reported on the Production Events Report, it is important to resolve the issues before placing the blister cards.
Place the blister cards in the correct original position. Fasten blister cards in positions 5 and 8 by inserting the cards in the guides (small protrusions) in order to hold them temporarily and to prevent slippage (for Dispill).
3. Scan the tray bar code first.
4. Scan the blister cards starting with position 1 on the tray, then card 1, followed by position 2 on the tray, then card 2, etc., until all positions are scanned.
5. Once scanning is completed, affix the top portion of each blister card in order to secure positions. Start with the bottom row and affix the upper row, slightly bending the top part of blister cards in the bottom row that overlap the row above.

POST-PRODUCTION
STEP 5: CELL COUNT AND SEALING BLISTER PACKS

Important: Conducting a careful cell count is critical. Cell count is the only way to find jumpers, duplicates and broken pills before sealing blister packs. Blister packs should only be moved after they are sealed, to avoid displacement of drug units during handling.

1. Start the cell count of blister packs in the bottom row to avoid unnecessary handling (headers of the blister pack in lower tray overlap those in the upper tray) –Dispill-.
2. Look at the header of each blister pack (read the Indications or General Comments field) to know the details pertaining to a specific patient (i.e. cut pill in half, insert in sachet, etc.).
3. Handling one blister pack at a time and, count the number of pills IN EACH CELL, ATTENTIVELY, to identify any cell count anomalies and broken pills. For example, for a cell containing ten pills (four white, two yellow and four pink pills), conduct a cell count for 10 drug units and look for each colour. Also look for ½ pills. The number should be the same as the quantity indicated on the back of the blister pack.
Note: Use an empty vial or a hand-held large cap to temporarily hold large tablets; this allows for an accurate count of used cells.
4. Seal the blister pack as soon as the cell count is completed and correct.
5. Repeat steps 2 through 4 for each blister card.
6. Fill out the SynMed® Error Sheet (Document 2.6 – SynMed® Error Sheet) to compile jumpers, duplicates, breakages, etc.

- Important:** When the Production Technician selects proper lids, there should never be duplicates.
7. Initial SynMed® Producing Pharmacy Report for corresponding patients in the "Prod. Tech." column.
 8. Move the tray to another section of the work area to allow for preparation of the next tray.

2.5 SECURE SYNIMED® REPLENISHMENT PROCEDURE

This procedure lists in chronological order all steps of the SynMed® drug containers replenishment cycle. For additional technical details, please refer to the SynMed® User Manual provided by Synergy Medical.

GOAL

Procedure for the replenishment of drug containers in SynMed® by Production Technicians.

STAFF

Pharmacy Technical Assistants who received SynMed® training

INSTALLATION AND REQUIRED MATERIALS

Work in as pristine an environment as possible in order to minimize risk of error.

- ✓ Technological tools: SynMed® computer
- ✓ Barcode scanner
- ✓ Pill counter
- ✓ Isopropyl alcohol in a vaporizer bottle
- ✓ Paper tissues
- ✓ Protective gloves, when needed
- ✓ Tweezers

FUNDAMENTAL RULES GOVERNING THE REPLENISHMENT OF SYNIMED® CONTAINERS

1. Strict compliance with these SynMed® replenishment procedures is critical to ensure safety and to avoid risks of error when handling drugs.
2. Production Technicians must ALWAYS enter their user name and password in the identification prompt screen. This electronic signature is recorded for each replenishment and the task is associated with the Production Technician who inputs the codes. This signature remains active as long as the user is not relieved and for the duration of the session (until the software session is closed or lock).
3. Always use a barcode scanner during the replenishment cycle and when returning containers to the robot. Never override scanning prompts, as the scanner is the safest system to prevent drug-related errors.
4. Always use sealed drug containers (jars, boxes, packs) from the manufacturer, that is, new jars (never opened).
5. When it is impossible to completely empty a drug jar from the manufacturer at once into a SynMed® container, use a security seal to ensure the content is intact and remains untouched until the next replenishment, and indicate LOADED on the jar (or box). Place this jar (or box) in a space dedicated for these products. The next time these drugs are replenished, it is important to indicate "0" as the quantity to be added, as the content of a full jar was inserted during the initial replenishment.
6. Under no circumstances should you place in SynMed® containers any drugs that are not in their original sealed packaging from the manufacturer.

Standard Replenishment Out of the Production Cycle (specifics)

1. Schedule 30 minutes each day to replenish containers running low on pills.
2. This 30-minute time slot must be accounted for in the regular schedule, either in the morning before the start of production or at the end of the day, after production.
3. Use the *Inventory Management Report*.
4. Select the Inventory Tab and the Replenishment Sub-tab.
5. **One at a time**, select the drugs to be added to the container selected for the replenishment cycle.
6. Follow the steps displayed on the SynMed® computer screen.

Standard Replenishment during Production (specifics)

1. Replenishment during production should occur only occasionally after the usual daily replenishment routine is established.
2. If production is regularly interrupted because of missing drugs in containers, it is time to review the replenishment cycle (inventory management) in place and the strict compliance to its application.
3. The system issues an audible and visual alarm when a drug container must be replenished during production.
4. A window appears on the SynMed® computer screen, displaying the number of the container to be replenished.
5. If the container is not empty, shake it to distribute its contents evenly and click the "Try again" button.
6. If the container is empty, click the "Replenish" button.
7. Follow the steps displayed on the SynMed® computer screen.

STEPS TO REPLENISH CONTAINERS (OUT OF THE PRODUCTION CYCLE)

Note: This step is based on the *Inventory Management Report* generated by the SynMed® software. This report takes into account the quantities of drugs dispensed during a given period. This report may be used to assess optimal inventory levels based on actual production data (quantities to be held in containers inserted in the SynMed® store).

1. Start SynMed® software and generate the *Inventory Management Report*.
2. Get the jar containing the drugs to be added in the robot.
 - a. Only one drug at a time may be kept on the counter (there may be several vials of a given product, if needed – gather all required jars).
 - b. If the drugs are in baskets, make sure they are sorted on a counter dedicated to that purpose. This ensures that only one drug is kept on the counter dedicated to container replenishment.
3. Access the INVENTORY Tab.
4. Enter name of drug in the SEARCH field and highlight the selection.
5. Click on REPLENISHMENT.
6. To the question "Do you want that SynMed® positions the picking unit to allow replenishment?":
 - a. Answer YES if the SynMed® drug container is not accessible (SynMed® robot doors are closed);
 - b. Answer NO if the picking unit is already in the correct position.
7. Open robot doors and remove the container bearing the number displayed (selected drug).
8. The REPLENISHMENT window is displayed and shows the numbers of the drug and the container to be replenished.
 - a. Check the KEEP EXISTING LOT(S) box if the drug lot to be added is the same as those displayed on screen.
 - b. Select ADD if the drug lot to be added is different from that appearing on screen but there are still a large quantity of pills. The maximum number of different lots allowed is _____. If the number of lots exceeds _____, the container must be completely emptied to remove all drug units and those must be disposed of according to established procedures (see *Procedure – Maximum Number of Lots Reached* in the following pages) before a new lot may be placed in the container.
 - c. Select REPLACE ALL LOT(S) when the drug lot to be added is different from those appearing on the screen and the container is completely empty.
9. When option "b" or "c" is selected, enter the lot number of the drug to be added in the appropriate field.

10. Enter the expiry date indicated on the manufacturer jar.

Note: In the Parameters Tab, the assigned date should be one year from the date of replenishment.

11. Click on INSERT LOT at the bottom of the page.

12. Click on NEXT.

13. Scan the drug container to be replenished, as per screen prompt.

14. Enter the number of jars (or boxes) used for replenishment.

15. Next, scan the UPC code on the manufacturer drug jar packaging. It is important to scan each jar (box).

Note: When the system sounds an audible alarm, scan again. The audible alarm indicates there was an error. If the alarm sounds again, notify the supervisor (or the pharmacist).

16. Once the code is validated, click on ADD or on SET.

17. Enter the quantity of drug units to be added in the SynMed® container.

a. ADD: Used to simply add pills. Enter the quantity of units added.

Note: Even if the contents of all jars (boxes) scanned do not fit inside the container, the total quantity must be entered. Seal jars (boxes) already opened and scanned and write LOADED on all containers that could not be added during the replenishment cycle.

b. SET: Used when the quantity remaining in the container does not match the quantity displayed on screen or to modify a quantity for any valid reason.

18. Click on NEXT.

19. Replenish the container.

a. If the SynMed® container contains drug units:

i. Take a pill counter and sterilize it with isopropyl alcohol.

ii. Empty the SynMed® container contents into the pill counter.

iii. THEN, empty the manufacturer packaging (jars, boxes, packs) contents into the SynMed® container.

iv. Add to the SynMed® container all drug units that are in the pill counter.

20. Scan the container to be inserted back into SynMed®.

21. Scan its position in the SynMed® store.

22. Place the SynMed® container in its dedicated position.

23. Click on FINISH.

24. Repeat steps 5 through 23 for each drug to be added.

Important: In the event of non-compliance with any of these steps, refer to your immediate supervisor or to the pharmacist on duty.

**COMPLEMENTARY PROCEDURE
HOW TO DISPOSE OF DRUG UNITS REMOVED FROM A SYNMED® CONTAINER
(when maximum number of lots is reached)**

When replenishing a container, in the event a lot must be REPLACED and there are pills in the SynMed® drug container, this container must be emptied completely before adding drugs identified with the new lot number. The drugs removed from the container must be sent to the lab, according to the following procedure.

1. Take an empty vial.
2. In this vial, put all drug units that do not match the number of the new lot added during the replenishment of the container.
3. Identify the vial by including the following information:
 - a. Name of drug
 - b. Strength
 - c. Expiry date
 - d. Number of lot(s)
 - e. Current date
 - f. Initials of technician
4. This vial must be returned where it will be integrated into the regular workflow.
5. This vial must be attached with an elastic band to the original packaging from the manufacturer.
6. Drugs contained in this vial will be dispensed first when this drug is distributed to a patient.

Important: It is important to avoid returning drugs to their jars in order to prevent potential safety and contamination risks, such as the combination of two similar drugs in the same jar, among others.