NAPRA Standards for Non-Sterile Compounding

PharmaClik Rx User Guide

Contents

Look for More Features in PharmaClik Rx 2.5

The information provided in this document reflects PharmaClik Rx 2.4 functionality, and provides recommendations using software that's available to you today. Further enhancements to compounding will be introduced with PharmaClik Rx 2.5. Here are some of the upcoming features:

- New fields in the Mixture folder will allow you to build a **Master Formulation Record** within PharmaClik Rx. These fields will also print on the Mixture Breakdown Report.

- The Mixture Breakdown Report includes a **barcode for batch scanning,** which lets you easily scan and attach the report to the prescription for record keeping.

- Print a **Mixture Breakdown Report** for bulk compounding, directly from the Mixture folder.

- **Mixture attachments** can be flagged to automatically print with prescriptions. This is useful for documents such as downloaded recipes, Master Formulation Records, and counselling leaflets that need to be referenced or provided with each compounded prescription.

- A **supplementary information label** can print with each mixture prescription, ensuring necessary labelling is available for the prescription.

- Mixture ingredients will be included in **interaction checking**, improving overall patient safety.

Introduction

This user guide will help you determine an action plan for updating compound (mixture) records in PharmaClik Rx, in order to align with NAPRA's model standards for pharmacy compounding of non-sterile preparations.

The following NAPRA documents are referenced in this guide[1]:

- Model Standards for Pharmacy Compounding of Non-sterile Preparations
- Guidance Document for Pharmacy Compounding of Non-sterile Preparations
- Printable and Fillable Forms

Getting Ready

ACTION PLAN
1. Download or create your own template for the Master Formulation Record.
2. Establish a file naming convention for the completed Master Formulation Records.
3. If using MS Word, files must be saved in a **.doc** format.
4. Create a folder where the Master Formulation Records will be saved.
5. Create a Master Formulation Record entry in List Maintenance Mixture Attachments
6. Add dispensing containers to List Maintenance > Containers.
7. Develop a plan for updating mixture records in PharmaClik Rx.

Create a Master Formulation Record Template

STANDARD: MASTER FORMULATION RECORDS ARE ESTABLISHED FOR EACH NON-STERILE COMPOUND. REFERENCE **SECTION 6.2.1** – *GUIDANCE DOCUMENT FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS.*

NAPRA provides a fillable form for the Master Formulation Record; your provincial regulatory body may also provide similar templates for download. You can choose to use a downloaded template or create your own template.

- **If creating your own template**, it must contain all fields as outlined in section 5.3.2 of NAPRA's *Guidance Document for Pharmacy Compounding of Non-Sterile Preparations*.

- Ensure there is a field to **record the mixture's negative DIN**, so that you can easily match a completed form to the correct PharmaClik Rx mixture record.

- **Establish a file naming convention** for saving the completed forms.

- If using MS Word, **save the files in a .doc format**, not a .docx format. Other file formats, such as a .pdf, can also be used.

- **Create a folder** on your PharmaClik Rx Server or other secure location where the template and all Master Formulation Records will be saved. This folder should be accessible from PharmaClik Rx.
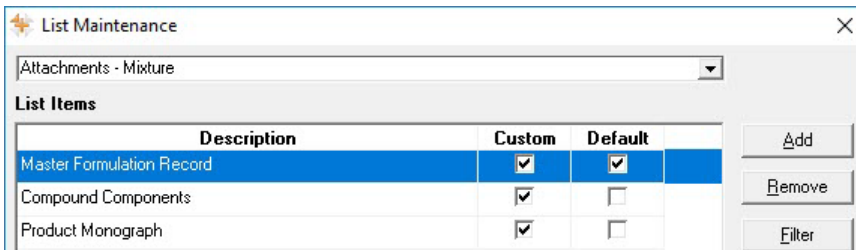
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[1] https://napra.ca/general-practice-resources/model-standards-pharmacy-compounding-non-sterile-preparations

Add 'Master Formulation Record' to List Maintenance

The Master Formulation Record will need to be added to each mixture as an attachment. To ensure it is consistently identified in the Mixture folder, 'Master Formulation Record' can be added to the dropdown list that appears in Mixture Attachments.

To update the Mixture Attachments dropdown list

1. Go to *More > List Maint*.
2. Choose *Attachments – Mixture* from the dropdown list at the top of the window.
3. Press the *Add* function button. A blank row is added to the window.
4. Type **Master Formulation Record** in the *Description* column.
5. Turn ON the *Default* checkbox.

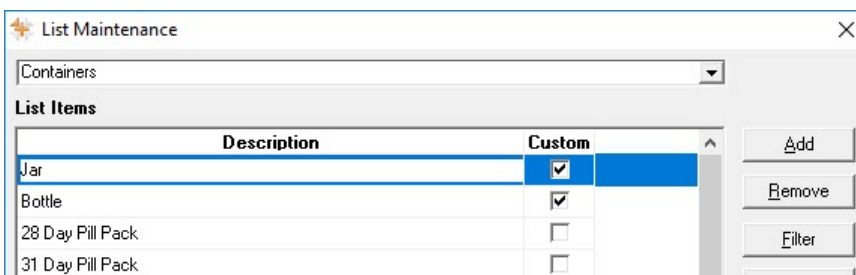6. Press the *OK* function button. The window closes and your changes are saved.

Turning ON the *Default* flag ensures 'Master Formulation Record' will always be defaulted when you add a new attachment to a mixture (in the Mixture folder > Attachments tab). **This will save time when you start to update the mixture records.**

Add Dispensing Containers to List Maintenance

The type of dispensing container can be selected in Rx Detail and print on the Mixture Breakdown Report. Add all of your non-sterile compounding containers to the Containers list in List Maintenance.

To update the Containers dropdown list

1. Go to *More > List Maint*.
2. Choose *Containers* from the dropdown list at the top of the window.
3. Highlight any row in the window, <u>other than the top row</u>.
4. Press the *Add* function button. A blank row is added to the window.
5. Add a container type (e.g. Jar)

6. Repeat steps 4-5 for each container to be added.
7. Press the *OK* function button. The window closes and your changes are saved.

Develop an Action Plan to Update PharmaClik Rx

Decide how you want to tackle updating the mixture files in PharmaClik Rx.

Here are a few recommendations:

- **Create a Master List**: Print a list of all the mixtures that currently exist in PharmaClik Rx and use this as your "to do" list for reviewing the mixture files. Cross a mixture off the list once it is updated in PharmaClik Rx. To create the list, see Q1 in the *Questions & Answers* at the end of this guide.

- **Prioritize:** Start with your most frequently dispensed mixtures and work your way down to the less commonly used mixtures. Use the Mixture Movement Report to create this list (see Q2 in the *Questions & Answers* at the end of this guide).

- **Inactivate Old Mixtures:** Take this opportunity to inactivate any mixtures that are outdated and no longer used. See Q3 and Q4 in the *Questions & Answers* for more information.

Updating Mixtures

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ACTION PLAN
1. Attach a completed Master Formulation Record to each mixture.
2. Add the Beyond Use Date and Lot #.
3. Add auxiliary labels.
4. Use mixture notes to document supplementary labelling information.
5. Use mixture notes to document any additional information required for compounding.

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Attach the Master Formulation Record to the Mixture

STANDARD: MASTER FORMULATION RECORDS MUST BE KEPT IN A FORMAT THAT IS READILY ACCESSIBLE FOR NON-STERILE COMPOUNDING PERSONNEL. REFERENCE **SECTION 6.2** – *GUIDANCE DOCUMENT FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS*.
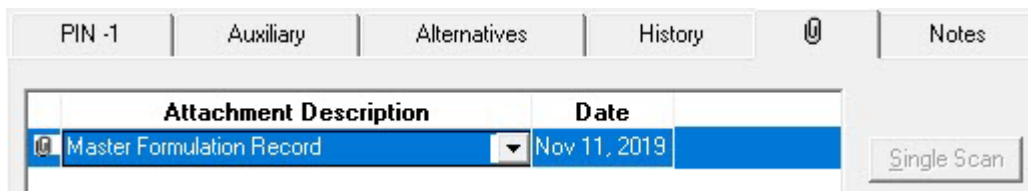
Once a Master Formulation Record is created for mixture, a copy of the record can be attached to the Mixture folder. This ensures the Master Formulation Record is always readily accessible.

When a Master Formulation Record is attached to the mixture:

- It will be included in the daily PharmaClik Rx backup.
- It cannot be modified, meaning there's no risk of it being updated incorrectly.
- If it needs to be updated, you can update the original master file and attach a new copy to the Mixture folder.

To attach the Master Formulation Record to a mixture

1. Go to *More > Mixture.*
2. Search for and select the mixture to be updated. The mixture folder opens.
3. Press the *Attachments* (paperclip) tab.
4. Press the *Add* function button. The Select Attachment widow opens.
5. Choose **All Office Files** from the *Files of type* dropdown list located at the bottom of the window.
6. Browse for and select the completed Master Formulation Record for the mixture.
7. Press the *Open* function button.
8. The screen returns to the Attachments tab. The document is attached with the description **Master Formulation Record**.

Note: The default description only appears if you followed the steps on page 3 to add 'Master Formulation Record' to List Maintenance.

9. Optional: Update the attachment description.
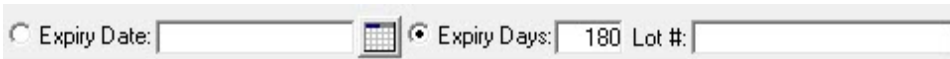10. Press the *Save* action button.

Add the Beyond Use Date and Lot

> **STANDARD**: BEYOND-USE DATES ARE APPROPRIATELY ASSIGNED BASED ON APPROPRIATE EVIDENCE AND LITERATURE.
> REFERENCE **SECTION 6.1** – *GUIDANCE DOCUMENT FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS*.

Use the expiry date or expiry days field in the Mixture folder to set the current beyond use date for a compound. If dispensing from a pre-mixed compound, you can also enter a lot #. When a prescription is filled for the mixture, the expiry date and lot # will print on the first auxiliary label.

To add a beyond use date and lot # to a mixture

1. Go to *More > Mixture.*
2. Search for and select the mixture to be updated. The mixture folder opens.
3. Go the PIN tab.
4. Choose *Expiry Date* or *Expiry Days*, according to the general guidelines for assigning beyond-use dates.

   - *Expiry Date:* Enter the date or select a date from the calendar.
   - *Expiry Days:* Enter the number of days the mixture will take to reach its expiration.
5. Enter a *Lot #*. (optional)
   Note: This field is available with PharmaClik Rx 2.4 and is used for recording the current lot # of a pre-mixed compound.
6. Press the *Save* action button.

Add Auxiliary Labels

Use auxiliary labels to document any storage needs or special precautions that need to appear on the prescription. Any information that cannot fit on auxiliary labels should be added to the supplementary label.

TIP A maximum of five auxiliary labels can print per prescription. The first auxiliary label is used for the beyond use date and Lot #. Your store may have other auxiliary labels reserved for barcodes.

To add auxiliary labels to a mixture

1. Go to *More > Mixture.*
2. Search for and select the mixture to be updated. The mixture folder opens.
3. Press the *Auxiliary* tab.
4. In the *Choose From* section, highlight the auxiliary labels to print with the prescription.
5. Press the *Add* function button. The labels are added to the top of the window.
6. Press the *Save* action button.

Document Supplementary Labelling Information

STANDARD:	THE PRESCRIPTION LABEL SHOULD IDENTIFY ALL ACTIVE INGREDIENTS AND THE CONCENTRATION OF EACH ACTIVE INGREDIENT, THE BEYOND USE DATE, AS WELL AS SPECIAL STORAGE AND HANDLING INFORMATION IF APPLICABLE. THIS INFORMATION CAN PRINT ON A SUPPLEMENTARY LABEL AND AUXILIARY LABELS IF IT CANNOT FIT ON THE REGULAR PRESCRIPTION LABEL. REFERENCE **SECTION 6.7** – *GUIDANCE DOCUMENT FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS*.

When a prescription is filled for a mixture, the vial label prints two lines of the mixture name, while the lot # and expiry date (beyond use date) print on auxiliary labels. A supplementary prescription label can be used if more information is required on the package than will fit on the regular vial label and auxiliary labels.

To save time and ensure accuracy, create a mixture note containing the supplementary information. At the time of dispensing, the note will appear in Rx Detail and can be copied and pasted into the Additional Instructions label.

To create a mixture note for a supplementary label

1. Go to *More > Mixture.*
2. Search for and select the mixture to be updated. The mixture folder opens.
3. Press the *Notes* tab.
4. Press the *Add* action button. A blank note line is created.
5. Enter the heading **SUPPLEMENTARY LABEL** and then any additional information that does not fit on the regular vial label.

6. Flag the note to *Print*.
7. Press the *Save* action button.

Add Notes to Document Additional Information

Mixture notes can be used to document any additional information required by compounding personnel. When notes are flagged to print, they will appear on the Mixture Breakdown Report, as well as in eVerify.

To create a mixture note

1. Go to *More > Mixture.*
2. Search for and select the mixture to be updated. The mixture folder opens.
3. Press the *Notes* tab.
4. Press the *Add* action button. A blank note line is created.
5. Enter the information to be documented.
6. Flag the note to *Print*.
7. Press the *Save* action button.

Filling Mixture Prescriptions

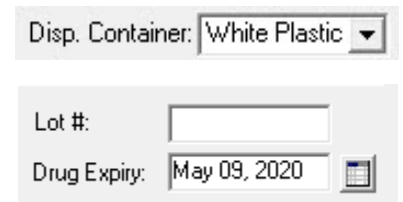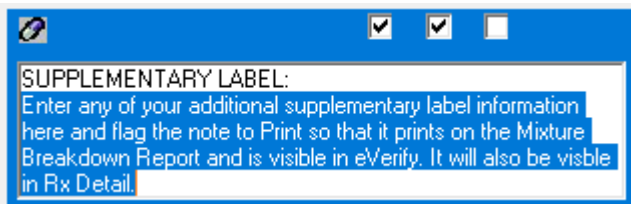<div style="background-color:orange;">

ACTION PLAN

1. Use the Additional Instructions label to create a supplementary packaging label.
2. Update the expiry date and lot #.
3. Document on the Mixture Breakdown Report.
4. Scan and attach the Mixture Breakdown Report to the prescription.

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Create the prescription

When filling a prescription for a mixture, use the additional instructions label to create a supplementary packaging label if needed. The additional instructions will be retained for refills. The lot # and beyond use date should also be confirmed.

To fill a new prescription for a mixture

1. Create a new prescription as usual.
2. When the prescription opens in Rx Detail, enter the QA, Qty, SIG and all other information required for dispensing.
3. Set the dispensing container and confirm the expiry date and Lot #:
    a. Press the magnifying glass icon located in the label preview. Administration Details opens.
    b. At the top of the window, choose the dispensing container from the *Container* dropdown list.
    c. Enter or update the *Lot #*, located in the lower right corner of the window.
    d. Confirm or update the *Expiry Date*.
    e. Press *OK*.

4. Use additional instructions to create the supplementary packaging label.
    a. Press the *Notes* tab.
    b. Find the SUPPLEMENTARY LABEL note. Use the mouse to highlight the information that you want to copy to the additional instructions label

    c. Press **CTRL+C** on the keyboard to copy the content.
    d. Return to the main tab in Rx Detail.
    e. Press the *Rx* action button.
    f. Press *Add'l Instructions*. The Additional Instruction Label window opens with the cursor in the top pane.
    g. Press **CTRL+V** on the keyboard to paste the note.
    h. Press *Preview*. Review the content and make any edits.
    i. Press *OK*.

5. Continue to fill the prescription as usual.

Document on the Mixture Breakdown Report and Attach it to the Prescription

STANDARD: THE PHARMACY KEEPS A COMPLETE COMPOUNDING RECORD FOR EACH INDIVIDUAL PRESCRIPTION. REFERENCE **SECTION 6.4** – *GUIDANCE DOCUMENT FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS*.

All information associated with the prescription compounding record should be documented on the Mixture Breakdown Report or a copy of the Master Formulation Record. Once the prescription is verified, all documents should be scanned and attached to the prescription.

Information to document includes, but is not limited to:

- Sources, lot number and expiry dates for ingredients
- Name of the person who prepared the compound
- Name of the person who performed quality control procedures
- Name of the person who approved the preparation
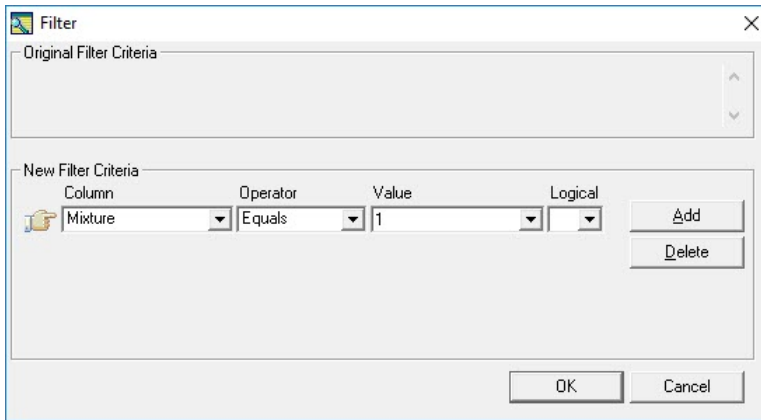- Results of quality control procedures

Affix a barcode auxiliary label to the Mixture Breakdown Report, so it can be batched scanned and attached to the prescription for record keeping. If your pharmacy uses thermal printing, a second set of auxiliary labels (including the barcode) prints with the additional instructions label that contains the supplementary packaging information.

Questions & Answers

Q1. **How can I print a list of compounds used at my pharmacy?**

Print a *Free Form/Mixture List* from PharmaClik Rx Reports.

1. Go to More > Reports.
2. In the Select a Report window, highlight **Drug** in the left pane.
3. Highlight *Free Form/Mixture List* in the right pane.
4. Press the *Next* action button. The Sort Options tab opens.
5. Choose **Drug Name** as a sort option.
6. Press the *Preview* action button.
7. Press the *Filter* function button. The Filter window opens.
8. Make the following selections in the Filter window:

    a. Choose **Mixture** from the *Column* dropdown list.
    b. Choose **Equals** from the *Operator* dropdown list.
    c. Enter **1** in the *Value* field.

9. Press *OK*. The report preview refreshes to only show mixture DINs.
10. Press the *Print* action button.

Q2. **How can I determine which compounds are most frequently dispensed at my pharmacy?**

Use the Mixture Movement Report. Sorting this report by Rx Volume lists the most frequently dispensed mixtures at the top of the report.

1. Go to *More > Reports*.
2. In the Select a Report window, highlight **Accounting** in the left pane.
3. Highlight *Mixture Movement* in the right pane.
4. Press the *Next* action button. The report criteria opens.
5. Enter a report period in the *Start Date* and *End Date* fields (e.g. the past 12 months).
6. Press the *Sort Options* tab.
7. Choose *Rx Volume.*
8. Press the *Preview* action button. (optional)
9. Press the *Print* action button.

Q3. There are compounds in my database that are no longer used. How can I prevent them from appearing in searches?

Outdated mixtures can be flagged as inactive. The mixtures will remain in the database, but they will not appear in search results unless you specifically include inactive mixtures in a search.
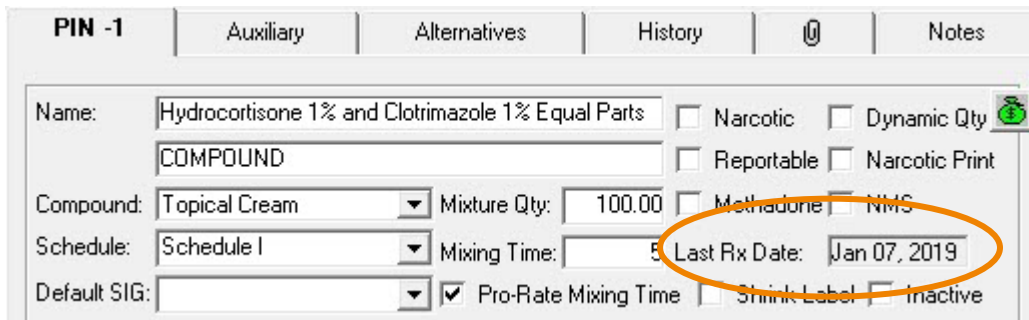
1. Go to *More > Mixture*.
2. Search for and select the mixture to be inactivated. The mixture folder opens.
3. Select the *Inactive* checkbox located in the main tab of the Mixture folder.
4. Press the *Save* action button.

TIP   For record keeping purposes, add a mixture note to explain why the mixture is being inactivated.

Learn more in PharmaClik Rx Help: Inactivating a Mixture

Q4. How can I determine when a mixture was last dispensed?

The *Last Rx Date* in the main tab of the Mixture folder tells you when a prescription was last dispensed for this negative DIN.

Q5. How are lot numbers assigned for pre-mixed compounds?

Choose your own lot number format for compounds that are pre-mixed at your pharmacy. Ensure the naming convention is included in your pharmacy's compounding guidelines and shared with compounding personnel. One option is to use the current date and time as the lot number: YYYYMMDDHHMM.

e.g.   A product that is compounded on October 30, 2019 at 5:35pm would be assigned lot number 201910301735.

Q6. How do I run a report for a product recall?

The Analysis by Drug Report can be used for product recalls.

1. Go to *More > Reports*.
2. Highlight **Analysis by Drug** in the *Select a Report* window.
3. Press the *Next* action button.
4. Enter a report period in the *Start Date* and *End Date* fields to cover a sufficient date range.
5. Enter the recalled mixture PIN(s) in the **Drug** field. If there are **multiple PINs**, separate them with a slash (e.g. -1234/-5436).
6. Press the *Preview* action button. (optional)
7. Press the *Print* action button.