MASTER FORMULATION RECORDS AND COMPOUNDING RECORDS: *What's the difference?*

The NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations require pharmacies to have policies and procedures as well as quality assurance mechanisms in place to achieve the intended outcomes of enhancing patient safety and protecting compounding personnel.

The gap analysis completed in the implementation Phase 1 may have identified that the pharmacy needs to develop or update existing Master Formulation Records in Phase 2. A Master Formulation Record includes **all necessary information and appropriate procedures** to safely compound a specific non-sterile preparation, whereas the Compounding Record is generated every time that preparation is compounded with prescription- (or batch-) specific information that must be verified before it is dispensed.

The non-sterile compounding supervisor is responsible for ensuring that Master Formulation Records are developed, reviewed regularly and updated as needed. When there are changes to the record, compounding personnel must be informed. The table below summarizes and compares the standards, guidance and content for these two types of records. Please remember this is only a summary and the Guidance Document must be read and interpreted as a whole.

STANDARDS AND GUIDANCE

MASTER FORMULATION RECORDS	COMPOUNDING RECORD
Must be kept (in hard copy or electronic format) and be readily available to compounding personnel	Must be kept (in paper-based or electronic form) for each individual prescription and for non-sterile preparations made in batches
Must be developed by regulated pharmacy personnel with adequate experience and broad scientific knowledge	These records should be filed and retained for future reference in accordance with the OCP Guidelines for Record Retention
Must include all necessary information to compound the non-sterile preparation	In cases where there is a marketed drug available, the rationale for compounding should be documented in the patient's file with the appropriate justification
Must be based on scientific data and contain supporting rationale and references	In cases where the preparation was compounded by another pharmacy in accordance with a Central Fill agreement, this should be recorded
Should be kept together	Allow for auditability and traceability, be able to track information related to preparations in the event of a recall
Must be current and reviewed yearly or when new information becomes available	As part of the quality assurance process, this should be reviewed quarterly

SUMMARY OF CONTENT

<table>
<tr><th>MASTER FORMULATION RECORD</th><th>COMPOUNDING RECORD</th></tr>
<tr><td colspan="2">Official or assigned name of the preparation</td></tr>
<tr><td colspan="2">Strength and dosage form of the preparation</td></tr>
<tr><td>Calculations needed to determine and verify quantities of ingredients for quantity produced</td><td>Names and quantities of ingredients used, and calculations performed (if applicable)</td></tr>
<tr><td>Description of ingredients, their quantities and sources (e.g., physical description, DIN, manufacturer, etc.)</td><td>Sources, lot numbers and expiry dates of ingredients</td></tr>
<tr><td>Expected yield</td><td>Total quantity compounded</td></tr>
<tr><td rowspan="2">Compatibility and stability data, including any supporting documentation and references used to determine the beyond-use date (BUD)</td><td>Assigned BUD</td></tr>
<tr><td>Assigned preparation batch number or prescription number</td></tr>
<tr><td rowspan="2">Source or origin of the formula*
• References used to develop the formula
• Date last reviewed and/or updated</td><td>Reference to Master Formulation Record (including any deviations)</td></tr>
<tr><td>Date of compounding the preparation</td></tr>
<tr><td>Special precautions to be observed
• Personal protective equipment (PPE)
• Any specialized training for a specific procedure</td><td>Name of the person who compounded the preparation
Name of the person who approved/verified the preparation</td></tr>
<tr><td>Description of final preparation</td><td rowspan="2">Results of quality control procedures
• Name of the person who performed the quality control procedures
• Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient</td></tr>
<tr><td>Quality control procedures and expected results (e.g., weight range of filled capsules, pH of aqueous liquids, etc.)</td></tr>
<tr><td>Equipment needed to compound the preparation (and any special cleaning instructions)</td><td rowspan="3">* There may be formulations for compounded preparations available in the public domain or for purchase. When considering the use of pre-existing formulations, the Non-Sterile Compounding Supervisor is responsible for ensuring that NAPRA standards for the Master Formulation Record are met and that they are suitable for the conditions and circumstances of the pharmacy's practice, by assessing, modifying, adapting and/or updating them as necessary.</td></tr>
<tr><td>Mixing instructions and methods, which may include:
• order of mixing
• mixing temperatures or other environmental controls
• duration of mixing
• other factors pertinent to consistent replication of the preparation</td></tr>
<tr><td>Packaging and storage requirements
• Type of container used in dispensing
•Sample label</td></tr>
</table>

Since there are similarities between the content of the Master Formulation Record and Compounding Record, some pharmacies may use a copy of the Master Formula as a basis for the Compounding Record. Also, a prescription's dispensing record created may also serve as an outline for the Compounding Record, if the information required by the *Drug and Pharmacies Regulations Act*, s156(1) is suitable for meeting what is required by NAPRA. The College is not directive in how the requirements of the Standards are met, and it is up to the pharmacy to develop policies and procedures taking into account the systems and technology they have in place.

ADDITIONAL REFERENCES

Printable and Fillable template for a Master Formulation Record (NAPRA)