Alberta College of Pharmacy

The **Master Formulation Record (MFR)** for a non-sterile preparation includes all necessary information to compound the preparation. To ensure preparation quality and safety, the MFR should be current. All changes made in the MFR should include supporting rationale and references, and compounding personnel must be informed of the change. The development of a new MFR is based on scientific data and includes appropriate references.

MFRs **should be kept together**, in hard copy or electronic format, and be readily available.

The pharmacy must keep a **Compounding Record (CR)**, paper-based or computerized, for each individual prescription, as well as for non-sterile preparations made in batches. These records should be filed and retained for future reference as required by the provincial/territorial pharmacy regulatory authority.

The Master Formulation Record must include the	The Compounding Record must include the

• official or assigned name, strength, and dosage form of the preparation;
• expected yield;
• calculations needed to determine and verify quantities of ingredients and doses of APIs for quantity produced;
• description of all ingredients, along with their quantities, sources, and lot numbers (if applicable);
• compatibility and stability data, including references when available;
• references used to develop the formula and the consultation date, as appropriate;
• equipment needed to compound the preparation (and any special cleaning instructions);
• special precautions to be observed by compounding personnel, including personal protective equipment (PPE);
• source or origin of the formula;
• mixing instructions, which may include
  ○ order of mixing, mixing temperatures, or other environmental controls,
  ○ duration of mixing, and
  ○ other factors pertinent to replication of the preparation as compounded;
• sample labelling information, which should contain, in addition to legally required information the
  ○ generic name and quantity or concentration of each active ingredient,
  ○ assigned BUD,
  ○ storage conditions, and
  ○ prescription or control number, whichever is applicable;
• type of container used in dispensing;
• packaging and storage requirements;
• description of final preparation; and
• quality control procedures and expected results.
	• official or assigned name, strength, and dosage of the preparation;
	• reference to Master Formulation Record for the preparation;
	• names and quantities of all ingredients;
	• sources, lot numbers, and expiry dates of ingredients;
	• total quantity compounded;
	• name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the person who approved the preparation;
	• date of preparation;
	• assigned preparation batch number or prescription number;
	• assigned BUD;
	• results of quality control procedures as appropriate (e.g., weight range of filled capsules, pH of aqueous liquids); and
	• documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.