PRINCE EDWARD ISLAND
COLLEGE OF PHARMACY
Member organization of National Association of Pharmacy Regulatory Authorities (NAPRA)

Non-Sterile Compounding FAQ

1. **As part of our risk assessment, which is more important: a) the WHIMIS list or the NIOSH list?[1]**

While both resources may be used as part of a risk assessment process in the pharmacy, each provides a different perspective to ingredient classification.

• WHMIS refers to products used in various workplaces, not just pharmacies, as outlined in Health Canada's Workplace Hazardous Materials Information System. WHMIS encompasses a far wider group of chemicals used in workplaces than NIOSH.

• NIOSH is an American reference from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), and refers to a list of ingredients more specific to health care materials: NIOSH List of Antineoplastic and Other Hazardous Drugs in Health care Settings 2016.

Practitioners may be familiar with the WHMIS Material Safety Data Sheets with regard to products used in the pharmacy for such things as cleaning supplies. The NIOSH list may be more useful for medications used during compounding. Ultimately, the standards reference both documents and, as such, both should be used while performing risk assessments of various ingredients used in making compounds.

2. **What if my pharmacy only makes very simple compounds, like 50:50 creams, or Magic Mouthwash—do I still have to go through this process?[2]**

The Standards are now the minimum requirements for all registrants of the College involved in non-sterile compounding. It is mandatory that pharmacies involved in non-sterile compounding be compliant with the Standards. While there will be less work for your pharmacy, particularly when it comes to preparation of Master Formulation Records, the Standards must still be met whenever a compound is prepared.

3. **Would current computer-generated compounding work sheets satisfy the requirements of Master Formulation Records and ongoing compounding records?[3]**

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[1] https://www.ocpinfo.com/wp-content/uploads/2019/09/Pharmacy-Connection-Summer-2019.pdf

[2] https://nbcp.in1touch.org/document/4723/FAQNAPRAModelStandardsforPharmacyCompoundingofNon-sterilePreparationsMay2019EN.pdf

[3] https://abpharmacy.ca/sites/default/files/Compounding_Non-sterile_FAQs.pdf

See section 5.2 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations for the requirements of a Master Formulation Record. The development of a new Master Formulation Record is based on scientific data and includes appropriate references. The Master Formulation Record for a non-sterile preparation includes all necessary information to compound the preparation. To ensure preparation quality and safety, the Master Formulation Record should be current. Changes made in the Master Formulation Record should include supporting rationale and references, and compounding personnel must be informed of the change. Computer-generated mixture instruction sheets may be used provided they meet documentation requirements as outlined in section 5.2.