



# MicroSCOPE

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## What's new



### Compounding or Manufacturing?

To ensure that your pharmacy's compounding practice stays within the Health Canada defined practice of compounding and is not considered manufacturing, please review Health Canada's Policy 0051. Policy 0051 includes a list of eight questions to help you determine if your practice is considered compounding or manufacturing, which can also be found in the following links.

[Health Canada Policy 0051](#)  
[General Guidelines on Compounding Versus Manufacturing](#)

[Learn more](#)



### Compounding with Hormones

This article is to clarify confusion regarding the following statement from the October 24, 2019 CompEX Edition of MicroSCOPE: *"When reviewing the pharmacy's risk assessment, regularly preparing hormone preparations would identify **whether** the pharmacy falls into category of Level C non-sterile compounding."*

The intent of this statement was that when compounding supervisors review the risk assessment for hormone preparations, and when these compounds are prepared on a **regular basis**, that they determine whether the pharmacy must meet Level C requirements. However, if preparations are prepared within the pharmacy **infrequently**, then the compounding supervisor determines whether the pharmacy may be able to use a Level B facility and mitigate any exposure risks. Based on the risks associated with handling hormones, compounding hormones regularly would be defined as once a month or more.

In consultation with the other Provincial Regulatory Authorities, the determination is that on the infrequent basis of preparing any compound involving drugs with a higher exposure risk, there must be very specific, credible and evidence-based documentation of how the risks will be mitigated each time the compound is made (infrequently). This is to ensure staff safety in the volume and frequency that the pharmacy would be preparing the compound over a specific time-period within Level B requirements.

The processes and determination of compounding frequently versus compounding infrequently would have to validate that there is no risk of exposure to staff in the handling of these drugs. If satisfactory documentation cannot be provided by the pharmacy, then the pharmacy must defer to the higher standard. This would only be a consideration if hormones were to be compounded on a very infrequent basis of once a month or less.

Additionally, when reviewing risk assessments for any compound, the higher standard should be deferred to when there is uncertainty about quantity and frequency.



### Level B and C Compounding Room Requirements

If a risk assessment has determined that a pharmacy needs to be Level C compliant with the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Non-Sterile Compounding, the following question has been posed: "Do I need to have both a Level B and C room or can I compound non-hazardous non-sterile preparations within my Level C room?"

Ideally, the room should be dedicated to the compounding of non-sterile hazardous preparations (Level C) only, but if it is used for compounding of non-sterile non-hazardous preparations, the room must be meticulously cleaned to prevent cross contamination. Thorough cleaning procedures and risk mitigation procedures to prevent cross contamination must be documented, these documents must be readily available, and all staff must be educated on these procedures.

[Learn more](#)



### Compounding Consultations

To ensure a pharmacy is on the right track towards compliance with the [NAPRA Compounding Standards](#), pharmacy managers and compounding supervisors can contact the College's Compounding Inspector, Brittany Sharkey, with their compliance-related questions. The compounding supervisor can assess a pharmacy's proposed compounding area or room through either a scheduled Skype consultation, or by submitted photos of the proposed area or room. Feedback can be provided about any additional measures that may need to be taken for the pharmacy to meet compliance.

Brittany can be contacted via email at [Brittany.Sharkey@saskpharm.ca](mailto:Brittany.Sharkey@saskpharm.ca).



#### Continuing Education

RxFiles will be hosting a Webex on Insulin Therapy including the launch of Type 2 Diabetes 2nd Ed. Mini-book.

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#### Be in the Know

SCPP emails and newsletters are official methods of notification published by the Saskatchewan College of Pharmacy Professionals (SCPP) and is emailed to all active members of the College. As the newsletters include decisions on matters such as regulations, drug schedule changes, etc., SCPP expects all members are aware of these matters.

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