GUIDANCE DOCUMENT

FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS

COMPANION TO THE MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS

FILLABLE AND PRINTABLE FORMS

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

Contents

Disclaimer

These forms are drawn from NAPRA's *Guidance Document for Pharmacy Compounding of Non-sterile Preparations* and are intended as a tool to aid pharmacy professionals in meeting the requirements set out in the *Model Standards for Pharmacy Compounding of Non-sterile Preparations*. In the event of any inconsistency or conflict between the Model Standards and these forms, the Model Standards shall prevail. These documents are models that a pharmacy regulatory authority (PRA) may choose to implement as appropriate for their province or territory. Questions regarding compliance with the standards should be directed to the respective PRA.

Table 1
Elements to cover in training of compounding personnel

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Name: Position: ◉ Pharmacist (PH) ○ Technician (PT) ○ Non-regulated (NR) Date completed:

1.	For the compounding of non-sterile preparations	Required for the position	✓	X
1.1	Know the relevant federal/provincial/territorial legislation and regulations related to pharmacy compounding, as well as other governing standards, guides or guidelines.	●	☐	☐
1.2	Know and apply all policies and procedures related to the pharmacy compounding of non-sterile preparations, especially those related to hand hygiene, personal protective equipment, airflow principle, facilities, material, equipment, behaviour of personnel in compounding rooms, forms and logs to be completed, labelling, storage, distribution to patients, quality controls (sampling), and maintenance and cleaning of compounding areas.	●	☐	☐
1.3	Know physical and chemical properties, such as stability, physical–chemical compatibility and incompatibility, osmolality and osmolarity.	●	☐	☐
1.4	Know pharmaceutical and medical abbreviations.	●	☐	☐
1.5	Know and understand the importance of particulate and microbial contamination.	●	☐	☐
1.6	Perform pharmacy non-sterile compounding tasks meticulously, precisely and competently.	●	☐	☐
1.7	Know the operation and correct use of equipment, materials and automated instruments available for the non-sterile preparations to be compounded. Know how to calibrate the equipment and instruments used.	●	☐	☐
1.8	Be able to recognize errors in the compounding technique of compounding personnel.	●	☐	☐
1.9	Have a good command of the pharmaceutical calculations required to compound non-sterile preparations.	●	☐	☐
1.10	Understand the importance of and apply accurate measurements.	●	☐	☐
1.11	Apply cleaning measures for non-sterile preparation compounding rooms, facilities and materials.	●	☐	☐
1.12	Know the data to be monitored in controlled rooms (temperature, pressure) and document the data in the appropriate logs. Know and apply the corrective measures to be applied when irregularities are identified.	●	☐	☐
1.13	Know how the secondary ventilation system (heating, ventilation and air conditioning system) operates. Know, apply or enforce appropriate corrective measures when an irregularity is identified.	●	☐	☐
1.14	Know and apply quality assurance measures for the various compounded non-sterile preparations.	●	☐	☐
1.15	Know and follow the verification process.	●	☐	☐
1.16	Know and use the incident/accident documentation logs.	●	☐	☐
1.17	Know drug delivery systems.	●	☐	☐
1.18	Perform a risk assessment to determine level of risk.	●	☐	☐
1.19	Determine beyond-use date.	●	☐	☐
1.20	Develop Master Formula.	●	☐	☐
2.	**For the compounding of hazardous non-sterile preparations**	**Required for the position**	**✓**	**X**
2.1	Have the competency required to compound non-sterile preparations.	●	☐	☐
2.2	Identify hazardous products in the composition of non-sterile preparations.	●	☐	☐
2.3	Know and apply deactivation and decontamination measures.	●	☐	☐
2.4	Know and use the protection measures necessary to avoid exposure to hazardous products.	●	☐	☐
2.5	Know and use personal protective equipment specifically for handling hazardous products and preparations.	●	☐	☐
2.6	Safely handle (i.e., receive, unpack, store and deliver) hazardous products.	●	☐	☐
2.7	Know and use the emergency measures to be applied in the case of accidental exposure, accidents or spills.	●	☐	☐
2.8	Know how to safely destroy hazardous products and the materials used in their preparation.	●	☐	☐

Checklist 1

Skills assessment checklist for compounding process

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Name: Position: Date:

Compounding steps	Compliant	Non-compliant
1. Consider whether the compounded preparation prescribed is appropriate and safe for the patient, based on the therapeutic intention (pharmacist).	☐	☐
2. Determine whether a valid formula exists; if not, develop a Master Formula, in consultation with experts and/or reliable resources. Ensure that the Master Formula includes instructions for special handling considerations.	☐	☐
3. Calculate and verify the quantities of each ingredient required on the compounding record (pharmacist/pharmacist or pharmacist/pharmacy technician).	☐	☐
4. Ensure that personnel responsible for compounding are wearing the appropriate personal protective equipment (cap, mask, gloves) and a clean laboratory coat or disposable gown.	☐	☐
5. For preparations that contain hazardous products, ensure that personnel wear the appropriate personal protective equipment: cap, safety goggles, two pairs of gloves, an N95 mask and face protection, a gown and shoe covers, depending on the substance used.	☐	☐
6. Ensure that only one preparation is being compounded at a time.	☐	☐
7. Gather the ingredients and necessary equipment. Ensure that the equipment is ready for use (clean and in good repair).	☐	☐
8. Measure each ingredient using appropriate equipment in accordance with the compounding record.	☐	☐
9. Use an independent check to confirm each ingredient and its quantity with the compounding record, before the preparation is compounded.	☐	☐
10. Ensure that compounding of the preparation is in line with the Master Formulation Record and the prescription, as well as with good practice and pharmacy science (compounding pharmacist/pharmacy technician).	☐	☐
11. Verify that the labelling complies with requirements of the provincial/ territorial pharmacy regulatory authority:	☐	☐
a. All active ingredients and the concentration of each ingredient are identified on the label.	☐	☐
b. The beyond-use date is marked on the label.	☐	☐
c. The storage information has been added.	☐	☐
12. Approve, through an independent check, the appearance of the final preparation (clarity, odour, colour, consistency, pH, etc.) and sign the compounding record.	☐	☐
13. Ensure that the area and equipment are cleaned immediately after use, according to manufacturer's directions or standards, and dried.	☐	☐
14. Ensure that the products, ingredients and equipment are put away immediately after use for proper storage.	☐	☐

Table 2

Elements to cover in training of cleaning personnel

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Name:

Position: (●) Pharmacist ( ) Technician ( ) Non-regulated ( ) Other (specify)

Date completed:

1.	For cleaning and disinfecting the general area for compounding of non-sterile preparations	✓	X
1.1	Know all policies and procedures related to cleaning and decontaminating the equipment, furniture and facilities, notably those related to hygiene, personal protective equipment, and cleaning and disinfecting tasks.	☐	☐
1.2	Know and use personal protective equipment specifically for handling hazardous products.	☐	☐
1.3	Know and use the emergency measures to be applied in case of accidental exposure, accidents or spills.	☐	☐

Table 3
Examples of policies and procedures

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POLICIES AND PROCEDURES FOR NON-STERILE PREPARATIONS		
#	Topic	✓
A	**PERSONNEL AND FACILITIES**	
1	Obligations of personnel	
1.1	Attire and dress code (e.g., personal clothing, jewelry, hairstyles)	☐
1.2	Health conditions (reasons for temporary withdrawal from compounding activities)	☐
1.3	Expected behaviour in compounding areas (e.g., no drinking, eating or other activities not related to compounding; expectation that procedures will be followed; avoidance of unnecessary conversations)	☐
2	Training and assessment of personnel	
2.1	Initial training and assessment program	☐
2.2	Program to assess maintenance of competency	☐
2.3	Training and assessment of cleaning and disinfecting personnel	☐
2.4	Additional training in all aspects of handling and compounding complex or hazardous products	☐
3	Delegation and appropriate supervision of activities	
3.1	Delegation of technical activities to persons other than pharmacists or pharmacy technicians	☐
4	Facilities and equipment	
4.1	Access to controlled area or room	☐
4.2	Necessary facilities and equipment	☐
4.3	Maintenance of facilities and equipment (e.g., certification of rooms and instruments, calibration, maintenance of pre-filters and high-efficiency particulate air filters, verification of pressure)	☐
4.4	Cleaning activities for facilities and equipment	☐
B	**COMPOUNDED NON-STERILE PREPARATIONS**	
1	Determining beyond-use dates of products used in a preparation	☐
2	Determining beyond-use dates of final preparations	☐
3	Hand hygiene	☐
4	Personal protective equipment in compounding areas and for compounding	☐
5	Bringing equipment and products into the room	☐
6	Deactivation, decontamination and cleaning of the C-PEC (containment primary engineering control)	☐
7	Receipt, unpacking and storage of hazardous products	☐
8	Verification of the compounding process (including validation of calculations by a pharmacist) and of final preparations	☐
9	Labelling of final preparations	☐
10	Packaging of final preparations	☐
11	Storage of products used and final preparations	☐
12	Transport and delivery of final preparations (to the patient, to patient care units or to the dispensing pharmacist)	☐
13	Recording of preparations in the patient file	☐
14	Hazardous waste management (e.g., at the pharmacy, returns from patients or patient care units, instructions to patients)	☐
15	Action to be taken in case of accidental exposure of personnel to hazardous products (eyewash station, log)	☐
16	Spills and spill management	☐
17	Recall of products, ingredients or compounded non-sterile preparations	☐
C	**QUALITY ASSURANCE PROGRAM**	
1	Verification and maintenance of equipment, verification of appropriate storage of ingredients	☐
2	Environmental control of facilities and primary engineering control (e.g., pressure verification, air and surface sampling plan)	☐
3	Environmental monitoring of chemical contamination for hazardous products	☐
4	Quality assurance of compounded sterile preparations (e.g., existence of a protocol, compliance with prescription, documentation in logs)	☐

Template 1
Template for developing a procedure

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Pharmacy/hospital pharmacy department:	Procedure #:
	Revised: Yes ☐ No ☐
	Approved by: Date:
	Effective date:
Procedure title:	
Aim and objective:	
Target personnel: ☐ Compounding supervisor ☐ Pharmacist ☐ Pharmacy technician ☐ Non-regulated personnel ☐ Cleaning and disinfecting personnel ☐ Other	
Required facilities, equipment and material:	
Procedures:	
List of logs and assessment of competencies required for this procedure:	
References:	
Procedure history: Procedure #:	
Drafted by:	Date:
Revised by: Revision: ☐ Full ☐ Partial Change made:	Date: Amended version: ☐ Yes ☐ No
Revised by: Revision: ☐ Full ☐ Partial Change made:	Date: Amended version: ☐ Yes ☐ No

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Name of compounded product:	Protocol number and version:
Concentration:	Effective date:
Pharmaceutical form:	Developed by:
Route of administration:	Verified by:

Formula

Ingredient	DIN/PIN (or other unique identifier such as CAS)	Manu-facturer	Quantity	Physical description	Additional information

Notes on calculations and measurements, expected yield:

Required equipment, instruments and materials:

Compounding method:

Quality controls	Expected specification

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Packaging:		
Stability and storage:		
	Beyond-use date:	Storage conditions:
Labelling:		
	Sample label(s):	
Training:		
References:		

Preparation data sheet history no.:	**Page** **of**
Revised date:	Change(s) made:
Revised by:	
Amended version #: ☐ Yes ☐ No	
Revised date:	Change(s) made:
Revised by:	
Amended version #: ☐ Yes ☐ No	

Template 3

Incident/accident reporting and follow-up form

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Pharmacy information:			
Incident/accident* reporting and follow-up			
Reporting an incident ◯ accident ◯			
General information			
Date and time of incident/accident:	Reported by:		
Name of patient affected, if applicable:	Full address:		
	Phone number:		
Pharmacy personnel involved:			
Information about incident/accident			
Disclosed to the patient concerned: ☐			
Name of pharmacist responsible for follow-up:			
Analysis of causes	Correction/change options:	Corrections/changes chosen:	
Action plan	Responsibility:	Deadline:	
			✓ ☐
Monitoring	Responsibility:		
			✓ ☐
Closing of the file		Date file closed:	
Pharmacist responsible for follow-up: License no.: Signature:			

*An accident is an action or situation in which the risk event occurs and has or could have an impact on the health status or well-being of the user(patient), personnel or a third party. An incident is an action or situation that has no impact on the health status or well-being of the user (patient),personnel or any third party, but that does have an unusual result that could, on other occasions, lead to adverse consequences.

Table 6
Example components of a quality assurance program

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QA	CONTROLS	FREQUENCY
FACILITIES	Verification of compounding area for Level A requirements (clean, orderly, good state of repair, appropriate storage, space reserved for compounding)	• At least every 6 months • When the compounding area is installed • When new equipment is installed • When area or equipment are repaired or maintained • When a contamination problem is identified
	Verification of compounding rooms for Level B or Level C requirements (appropriate ventilation, suitable materials storage, clean, orderly, good state of repair)	• At least every 6 months (more frequently at the start of the quality assurance program) • When the controlled room is installed • When new equipment is installed • When the controlled room or equipment is repaired or maintained (e.g., when HEPA filter is changed) • When a contamination problem is identified • When investigation of a contamination problem or non- compliance in the preparation process requires exclusion of malfunctioning facilities • According to an internal verification program
	Verification that daily temperature and humidity readings are documented in controlled areas	• Monthly
EQUIPMENT	Certification of C-PEC (Level B or Level C requirements)	• Before first use • Every 6 months • When a new C-PEC is installed • When the C-PEC is repaired or maintained • When a contamination problem is identified • When investigation of a contamination problem or non- compliance in the preparation process requires exclusion of malfunctioning equipment
	Temperature verification (e.g., refrigerator, freezer)	• Verify logs monthly (more often if problems are identified) • Calibrate temperature probes yearly
	Operational indicators of C-PEC and other instruments (e.g., for automated compounding)	• Verify logs monthly
PERSONNEL	Skills assessment (technique, following procedures, appropriate PPE, etc.)	• At initial qualification: theoretical and practical aspects • Periodically, to ensure compliance with policies and procedures • After extended leave • When assessing incidents and accidents • When a contamination problem is identified
FINAL PREPARATION	Verification of Master Formulation Records (usage and maintenance)	• Yearly or when new information becomes available
	Verification that preparation matches prescription; protocols have been followed; ingredients have been verified; preparation has been assessed for clarity, odour, colour and consistency; and labelling/ container are appropriate	• Quarterly review of documentation
	Verification that documentation of procedures, compounder's initials and entry in logs are being carried out	• Quarterly review of documentation
DOCUMENTATION	Policies and procedures are in place and updated regularly	• Every 3 years, or when new information becomes available
	Compounding records meet all regulatory requirements, and all logs are kept up to date	• Quarterly
	Current references and safety data sheets are available	• Yearly

HEPA = high efficiency particulate air; C-PEC = containment primary engineering control; PPE = personal protective equipment.