6th Club

Sunday 15th June 2025

Club Founder
Dr. Mahmoud Bahgat

International Pharmacists Club

Compounding Pharmacy

صيدليات التركيبات في كندا

By Dr. Dalia Amr Hamdy
Pharmacist in Canada

9pm EGY 9pm KSA 11pm UAE

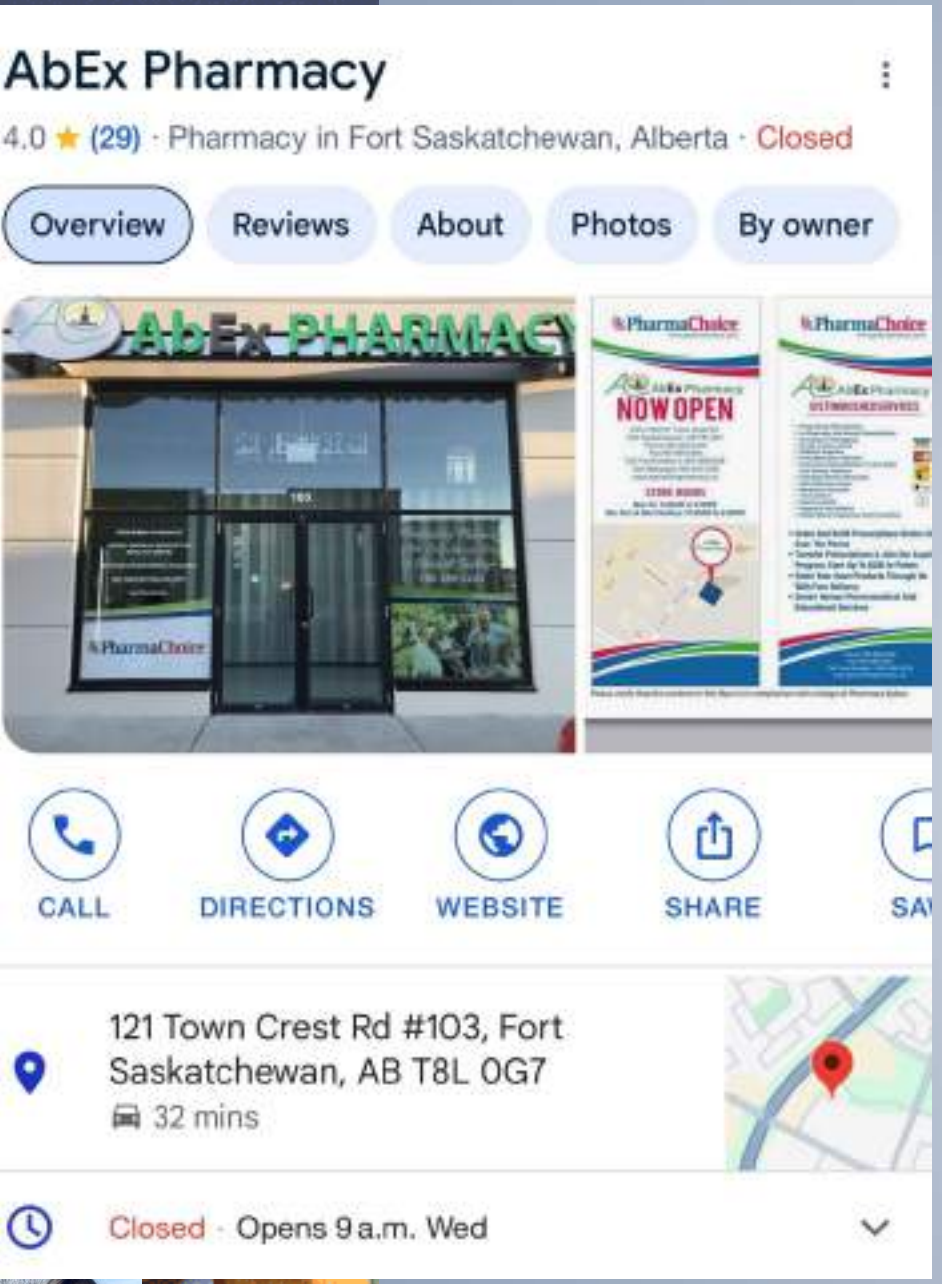
Speaker Biography
Dalia A. Hamdy

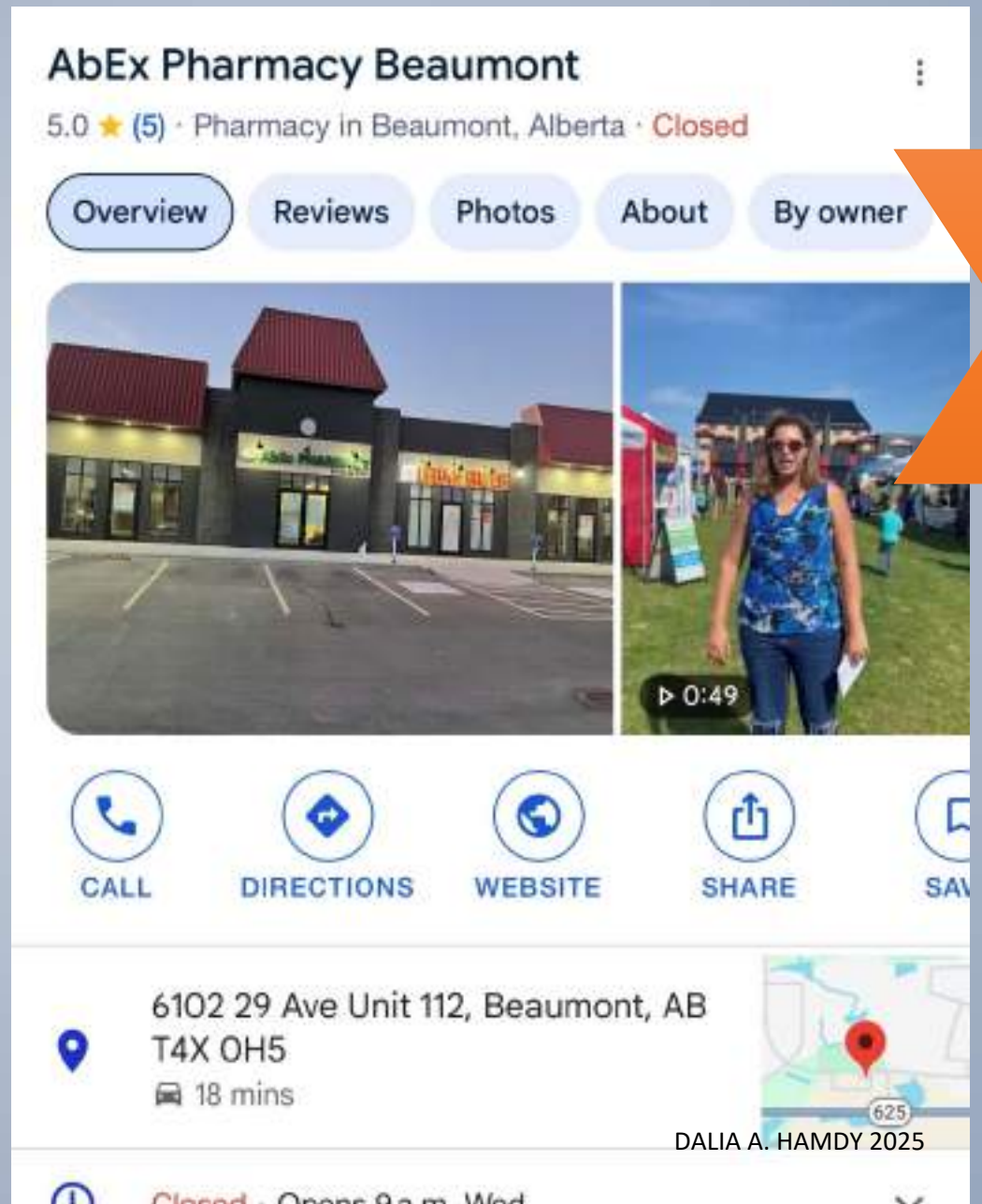
- BSc PharmSci, Alexandria University 2000
- MSc. Pharm Sci, Alexandria University 2004
- PhD PharmSci, University of Alberta 2010
- MBA, Eton University 2017

Speaker Biography
Dalia A. Hamdy

- Community pharmacist –Alexandria ,EGYPT since 2000
- Teaching assistant, Alexandria University 2000-2005
- Teaching assistant, University of Alberta 2006-2009
- Community pharmacist –Alberta, Canada since 2010
- Assistant Professor, Qatar University 2010-2012
- Assistant Professor, Alexandria University 2012-2016
- Pharmacy Manager, Alberta, Canada 2016-2017
- Pharmacy Owner/Manager, Alberta Canada since 2017
- Assistant/Adjunct Professor, University of Alberta 2018-2025

August 2017





Tale of Three Cities
Dalia A. Hamdy
!!

March 2022


Compounding
Pharmacy In
Canada

Pharmacy Practicing to full potential (Scope)

Presentation Outline

- Pharmacy Compounding Facility requirements
- Personnel roles and training
- Documentation

Alberta College of Pharmacy

Guidance document for pharmacy compounding of non-sterile preparations

Companion to the Standards for pharmacy compounding of non-sterile preparations

Updated July 2018

Acknowledgements

The guidance in this document is based on the Model Standards for Pharmacy Compounding of Non-Sterile Preparations and its associated guidance document developed by the National Association of Pharmacy Regulatory Authori-ties (NAPRA) and modified for pharmacy professionals in Alberta. The modifications are in recognition of the scopes of practice available to pharmacists and pharmacy technicians in Alberta.

GUIDANCE DOCUMENT

FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS

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

NAPRA ANORP

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

Pharmacy Compounding Facility Requirements

- Level A
- Mixing and Reconstitution
- Not considered compounding in Canada
- Personel still encouraged to use compounding area and follow level A requirements

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

Pharmacy Compounding Facility Requirements

› Level B

- Compounding complex preparations or small quantities of products that require ventilation
- Require specific equipment, instruments and training

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

Pharmacy Compounding Facility Requirements

› Level B

- A dedicated room separate from the rest of pharmacy but still within the dispensary area-**uninterrupted workflow**
- The room should have

Powders

Cpding equipment

Ventilated contain-ment device (fume hood)

PPE

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

Pharmacy Compounding Facility Requirements

› Level B

- After performing the right risk assessment, level B facility can prepare very small quantities of compounds that require level C facility needs (hormones, hazardous cpds, etc)

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

Pharmacy Compounding Facility Requirements

› Level C

- Compounding any amount of any dosage form of hazardous drugs classified by

NIOSH as gp1

Or by

WHMIS as a health hazard

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

NIOSH: National Institute for Occupational Safety and Health
WHMIS:Workplace Hazardeous Material Information System

Pharmacy Compounding Facility Requirements

› Level C

- A dedicated room under negative pressure

separate from the rest of pharmacy but still within the dispensary area- **uninterrupted workflow**

- The room should have

Powders

Cpding equipment

Ventilated contain-ment device (fume hood)

PPE appropriate for hazardous products

Sterile Facility

Non Sterile Facility

- Level A
- Level B
- Level C

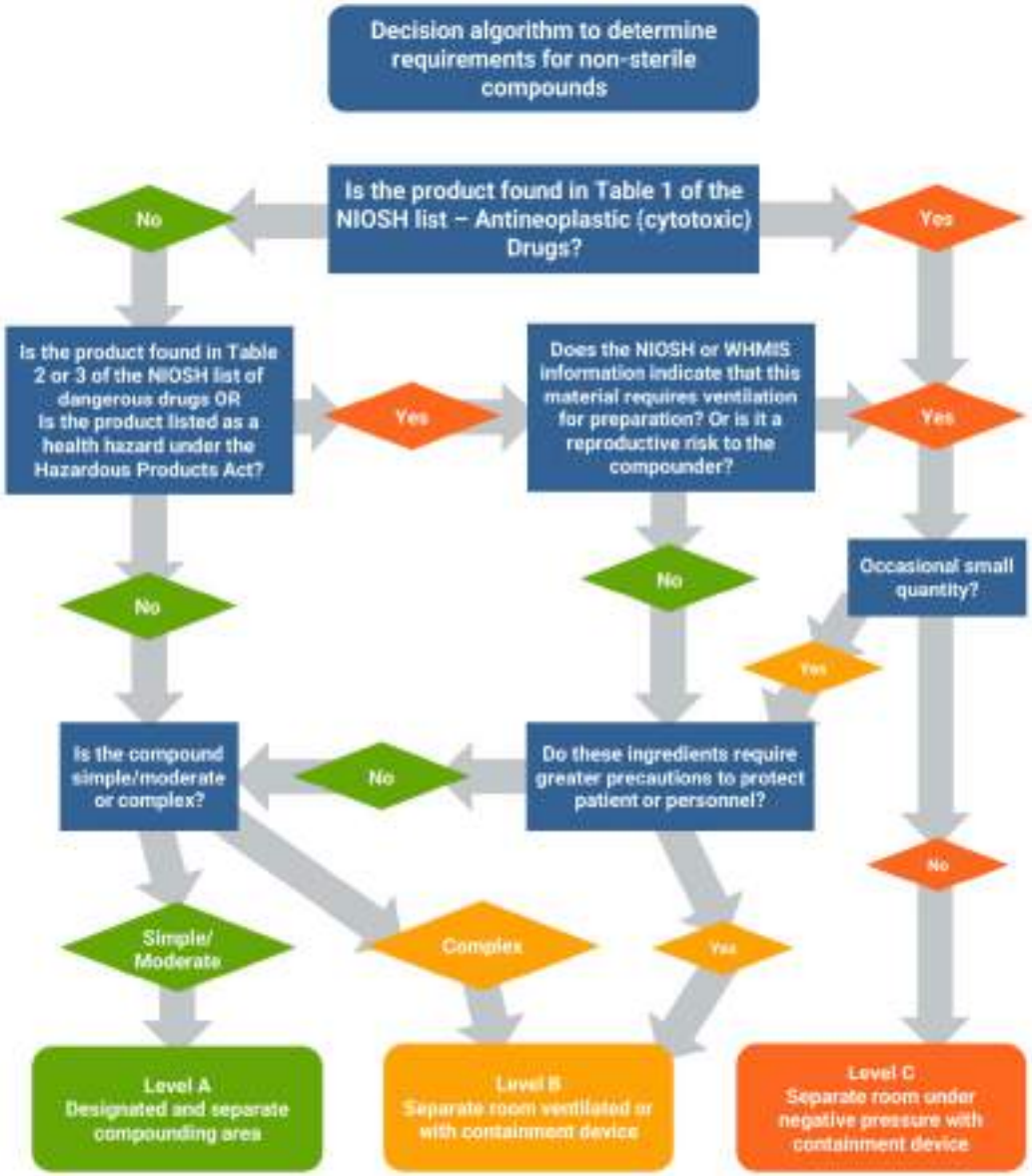
8.4 Summary of requirements for compounded non-sterile preparations

Table 7

Requirements		Level A	Level B	Level C
		Mandatory = ✓		
Personnel	**Section 7.1**			
Appoint a non-sterile compounding supervisor		✓	✓	✓
Training	**Section 7.2**			
Has received orientation and training during education or on the job concerning the preparations to be compounded and underwent a skills assessment at the time of hiring; training has included learning and assimilating workplace operating procedures		✓	✓	✓
Has been trained in techniques appropriate for the compounding of complex preparations and some hazardous products			✓	
Has received hazardous products training and has relevant training and experience in compounding all non-sterile dosage forms				✓
Participates in annual skills assessment program		✓	✓	✓
Facilities	**Section 7.3**			
Designated non-sterile compounding area		✓		
Dedicated room, entirely closed off, well ventilated or with a ventilated hood			✓	
Dedicated room under negative pressure to the pharmacy; containment device				✓

4.2 Decision algorithm for risk assessment

Diagram 1



Personnel roles and training

Pharmacy Manager

- Regulated Member
- Responsible for all compounding activities
- Can assign those responsibilities to another pharmacist/pharmacy tech. who will be assigned as a compounding supervisor

- Pharmacy Manager
- Non sterile compounding supervisor
- Compounding Pharmacists
- Pharmacy technician
- Pharmacy Assistant

Personnel roles and training

Non Sterile compounding Supervisor

- Regulated Member
- Pharmacists/pharmacy tech
- Responsible for all tasks retaled to non sterile compounding as assigned by manager
- Can assign some technical tasks to non regulated members depending on their training and competencies

- Pharmacy Manager
- Non sterile compounding supervisor
- Compounding Pharmacists
- Pharmacy technician
- Pharmacy Assistant

Responsibilities

The non-sterile compounding supervisor ensures that the following requirements are met:

- Measures are in place (i.e., personnel training and assessment program) to ensure that personnel are competent to perform compounding, which includes training for any specific populations (e.g., pediatric, geriatric, veterinary).
- Personnel know and fully comply with policies and procedures.
- The existing compounding process yields high-quality non-sterile preparations.
- A risk assessment is performed to determine appropriate requirements for each compounded preparation.
- Appropriate measures are taken to ensure the safety of personnel during each preparation.
- Procedures for incident/accident reporting and follow-up, as well as recall procedures, are in place.
- Policies and procedures covering all activities are developed, regularly reviewed and updated.
- The facilities and equipment used to compound non-sterile preparations meet requirements and are maintained, calibrated or certified according to manufacturers' specifications or standards, whichever are more stringent.
- The available, recognized scientific literature is used to determine stability and to establish the BUD for each non-sterile preparation.
- Master Formulation Records are developed, reviewed and updated.

Personnel roles and training

- An ongoing quality assurance program, designed to ensure that preparation activities are performed in accordance with standards of practice, scientific standards, existing data and relevant information, is implemented, followed, evaluated and updated as required.
- Current editions of mandatory and supplementary references, which should be in compliance with provincial/territorial requirements, are available. Safety data sheets are available and updated regularly, or are readily accessible in an electronic format.
- All records of decisions, activities or specifications required by the Model Standards are completed, and any changes are documented and traceable. The records are retained and readily available for audit and inspection purposes, as required by the provincial/territorial pharmacy regulatory authority.

Pharmacy Assistant

Personnel roles and training

Regulated Members

-Pharmacists

-Pharmacy technicians

Non Regulated Members

-Pharmacy Assistants

-Cleaning Personnel

- Pharmacy Manager
- Non sterile compounding supervisor
- Compounding Pharmacists
- Pharmacy technician
- Pharmacy Assistant

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Table 1

#	ELEMENTS TO COVER IN TRAINING OF COMPOUNDING PERSONNEL			
1.	FOR THE COMPOUNDING OF NON-STERILE PREPARATIONS	PH	PT	NR
1.1	Know the relevant federal/provincial/territorial legislation and regulations related to pharmacy compounding, as well as other governing standards, guides or guidelines.	X	X	
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.	X	X	X
1.3	Know physical and chemical properties, such as stability, physical–chemical compatibility and incompatibility, osmolality and osmolarity.	X		
1.4	Know pharmaceutical and medical abbreviations.	X	X	X
1.5	Know and understand the importance of particulate and microbial contamination.	X	X	X
1.6	Perform pharmacy non-sterile compounding tasks meticulously, precisely and competently.	X	X	X
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.	X	X	X
1.8	Be able to recognize errors in the compounding technique of compounding personnel.	X	X	
1.9	Have a good command of the pharmaceutical calculations required to compound non-sterile preparations.	X	X	X
1.10	Understand the importance of and apply accurate measurements.	X	X	X
1.11	Apply cleaning measures for non-sterile preparation compounding rooms, facilities and materials.	X	X	X
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.	X	X	X
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.	X	X	X
1.14	Know and apply quality assurance measures for the various compounded non-sterile preparations.	X	X	
1.15	Know and follow the verification process.	X	X	X
1.16	Know and use the incident/accident documentation logs.	X	X	X
1.17	Know drug delivery systems.	X	X	X
1.18	Perform a risk assessment to determine level of risk.	X	X	
1.19	Determine beyond-use date.	X	X	
1.20	Develop Master Formula.	X	X	

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2.	FOR THE COMPOUNDING OF HAZARDOUS NON-STERILE PREPARATIONS	PH	PT	NR
2.1	Have the competency required to compound non-sterile preparations.	X	X	X
2.2	Identify hazardous products in the composition of non-sterile preparations.	X	X	X
2.3	Know and apply deactivation and decontamination measures.	X	X	X
2.4	Know and use the protection measures necessary to avoid exposure to hazardous products.	X	X	X

2.5	Know and use personal protective equipment specifically for handling hazardous products and preparations.	X	X	X
2.6	Safely handle (i.e., receive, unpack, store and deliver) hazardous products.	X	X	
2.7	Know and use the emergency measures to be applied in the case of accidental exposure, accidents or spills.	X	X	X
2.8	Know how to safely destroy hazardous products and the materials used in their preparation.	X	X	
PH = pharmacist; PT = pharmacy technician, NR = non-regulated personnel.				

Personnel roles and training

Pharmacy Manager

#	ELEMENTS TO COVER IN TRAINING OF CLEANING PERSONNEL	PH/PT	NR	CP
1.	**FOR CLEANING AND DISINFECTING THE GENERAL AREA FOR COMPOUNDING OF NON-STERILE PREPARATIONS**			
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.	X	X	X
1.2	Know and use personal protective equipment specifically for handling hazardous products.	X	X	X
1.3	Know and use the emergency measures to be applied in case of accidental exposure, accidents or spills.	X	X	X

PH = pharmacist; PT = pharmacy technician; NR = non-regulated pharmacy personnel; CP = cleaning personnel.

follow each compounding step and sign off at appropriate intervals.

Checklist 1

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[16].		
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)		

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[16].		
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.		

16 Institute for Safe Medication Practices Canada (ISMP Canada). Death due to pharmacy compounding error reinforces need for safety focus. *ISMP Canada Safety Bulletin.* 2017; 17(5): 1-5. Available from: https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-05-Tryptophan.pdf

	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.		

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Documentation

- Policies and Procedures (SOP's)
- Safety Data Sheets (SDS)
- Master Formula
- Compounding record
- Compound risk assessment

Documentation

- Let us compound

10% Diclofenac Sodium cream

- Policies and Procedures (SOP's)
- Safety Data Sheets (SDS)
- Master Formula
- Compounding record
- Compound risk assessment

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TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Diclofenac Sodium 1% to 15% Topical Cream (Emulsion, 100 g)	FIN	F 008 9

SUGGESTED PREPARATION (for 100 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	
Diclofenac Sodium, USP §	TBD				
Ethoxy Diglycol, NF §	5.5	mL			
Medisca VersaPro™ Cream Base	TBD				

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction

1. **Ingredient quantification:**

A. Based on the desired strength of the Topical Cream, determine the required quantity of Diclofenac Sodium weigh for a 100 g batch, calculated as: $B = \frac{A \times BatchSize(g)}{100}$

Required concentration of Diclofenac Sodium (%) (A)	Diclofenac Sodium quantity to weigh for 100 g Batch Size (*without* processing error adjustments) (B)	Multiplied by the Processing error adjustments (C)	Diclofenac Sodium quan to weigh for 100 g Batc Size (*with* processing er adjustments) (D)
1.0	1.000 g	1.05 to 1.09	_____ g
_____	_____		_____ g
15.0	15.000 g		_____ g

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Suggested Formula	Diclofenac Sodium 1% to 15% Topical Cream (Emulsion, 100 g)	FIN	F 008 945v2

2. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Cream Base to weigh for the required Topical Cream, batch size (100.00 g):

Total Weight of the batch	100.00 g
MINUS	
The amount of Ethoxy Diglycol for levigation	5.43 g
MINUS	
The weight of Diclofenac Sodium(Step 1A Column B)	_____ g
EQUALS	
i. Quantity of VersaPro™ Cream Base needed for the batch	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of VersaPro™ Cream Base required *plus* processing error adjustments	_____ g

3. **Powder-Liquid preparation:**

A. Triturate the Diclofenac Sodium (amount determined from Step 1A Column D) to form a fine homogeneous powder.

B. Levigate the fine homogeneous powder (Step 3A) with the Ethoxy Diglycol.

End result: Homogeneous paste-like dispersion.

4. **Powder-Liquid to Medium integration:**

A. Incrementally add the VersaPro™ Cream Base (amount determined from Step 2Aii) to the homogeneous paste-like dispersion (Step 3B).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous cream-like dispersion.

B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.

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Suggested Formula	Diclofenac Sodium 1% to 15% Topical Cream (Emulsion, 100 g)	FIN	F 008 945v2

5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		180 days at 25°C ± 2°C, based on available stability studies through Medisca*.	Packaging Requirements	Tightly closed, light-resistant container.	
		*This formula was studied as a bracketed concentration range of Diclofenac Sodium 1.0% to 15.0%. Any concentration compounded at or between these strengths may apply the suggested BUD based on the **exact** execution of the indicated ingredient list, procedures and quantities listed within this formulation. **Note:** ***This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.***		
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	7	Keep at controlled room temperature (25°C ± 2°C).
	3	For external use only.	8	Protect from light.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	9	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Cap tightly after use.	10	Keep in a dry place.
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions		Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

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Suggested Formula	Diclofenac Sodium 1% to 15% Topical Cream (Emulsion, 100 g)

REFERENCES

1. Ointments, Creams, and Pastes. In: Allen, LV, Jr. *The Art, Science, and Technology of … Fifth Edition*. American Pharmacists Association; 2016: 317.
2. Voltaren SR. In: Canadian Pharmacists Association. *Compendium of Pharmacists and S…*
3. Diclofenac Sodium. In: Brayfield, A., ed. *Martindale: The Complete Drug Reference, 3…* The Pharmaceutical Press; 2014: 48.
4. Diclofenac (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Sta… 2013: Monograph #3091.
5. Diclofenac Sodium. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th…* Pharmaceutical Association; 2012: 162.
6. Diclofenac Sodium (Monograph). *United States Pharmacopeia XLIII / National Formul…* Pharmacopeial Convention, Inc. 2020: 1347.
7. Diclofenac. Thomson Micromedex. *USP DI – Drug Information for the Health Care Pr…* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 415.
8. USP <795>. *United States Pharmacopeia XLIII / National Formulary 38*. Rockville, M… Convention, Inc. 2020: 7025.

Documentation

Finish the calculations

Download the safety data sheets of all ingredients

Start your risk assessment and finalize the documents

Make a compounding record

- Policies and Procedures (SOP's)
- Safety Data Sheets (SDS)
- Master Formula
- Compounding record
- Compound risk assessment

Mixture Instructions for Diclo 10% in VersaPro Cream

AbEx Pharmacy Beaumont, 112 - 6012 29 Ave, , Beaumont AB T4X 0H5
Phone: (780) 929-1810 Fax: (780) 929-1813

Mixture: Diclo 10% in VersaPro Cream
Date: 03-Feb-2022 Exp Date: 04-May-2022 Code:
Batch Qty: 100.000

Lot number: _____ Made By: _____ Verified by: _____
Schedule: 1 (Schedule 1 [F])

Estimated time to make:_____ Mix Fee: _____

Ingredients

Qty	Drug Name	DIN	Lot #	Expiration	Mfr
10	Diclofenac Powder USP	00999999			
6	ETHOXY DIGLYCOL	00999999			
84	VersaPro cream	00999999			

Instructions

Steps requiring second verification please initial

1. Pharmaceutical calculations _____
2. Weight of all ingredients _____
3. Final Product Verification _____

Please refer to risk assessment for this product for more information regarding personal protective equipment

Please refer to Master formula "Diclofenac Sodium 1%-15% Topical cream" for
-preparation instructions
-auxillary labels
-beyond use date

- Quality Assurance/Quality Control
- Forms
- Cleaning procedures

Questions?