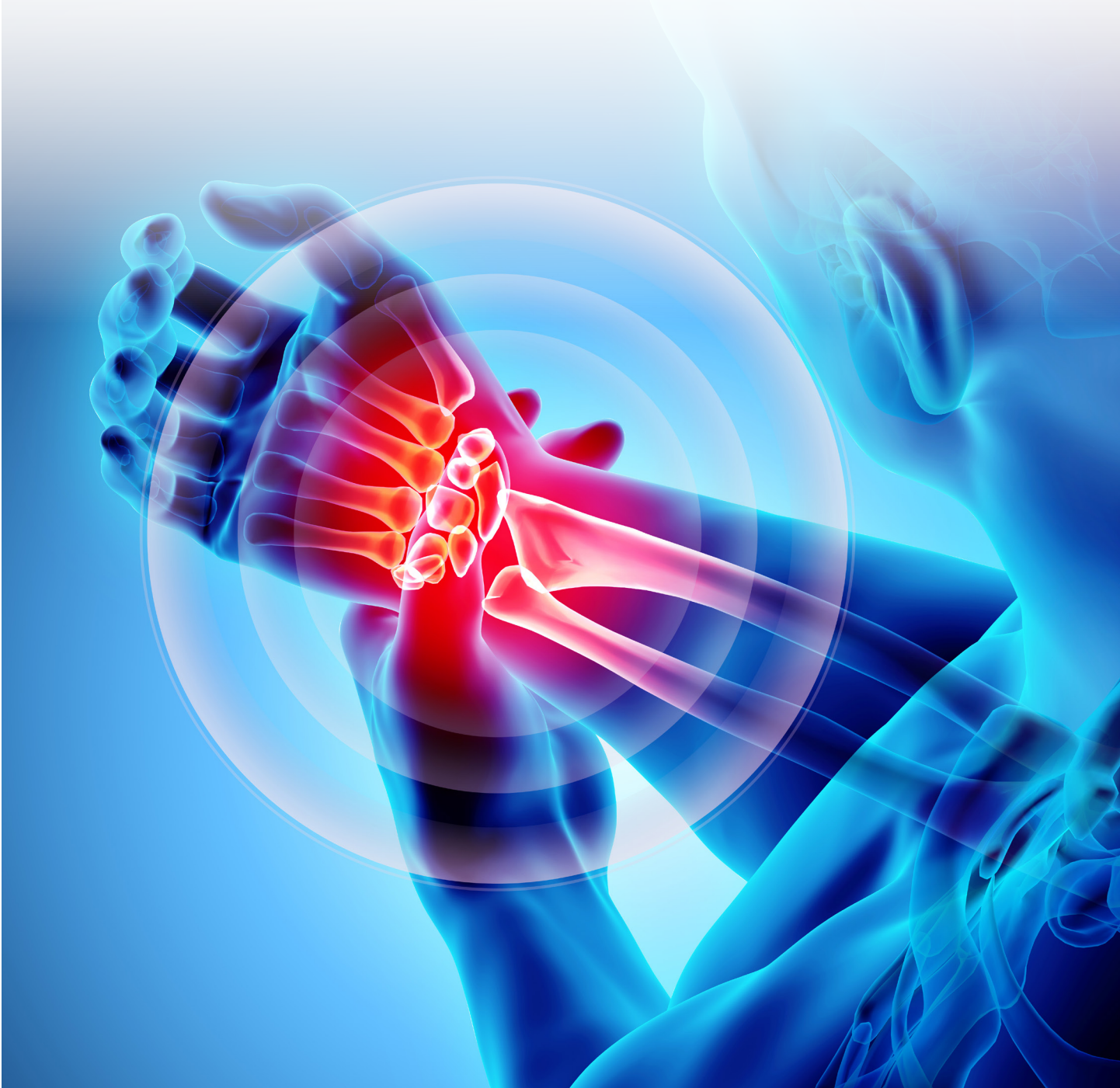
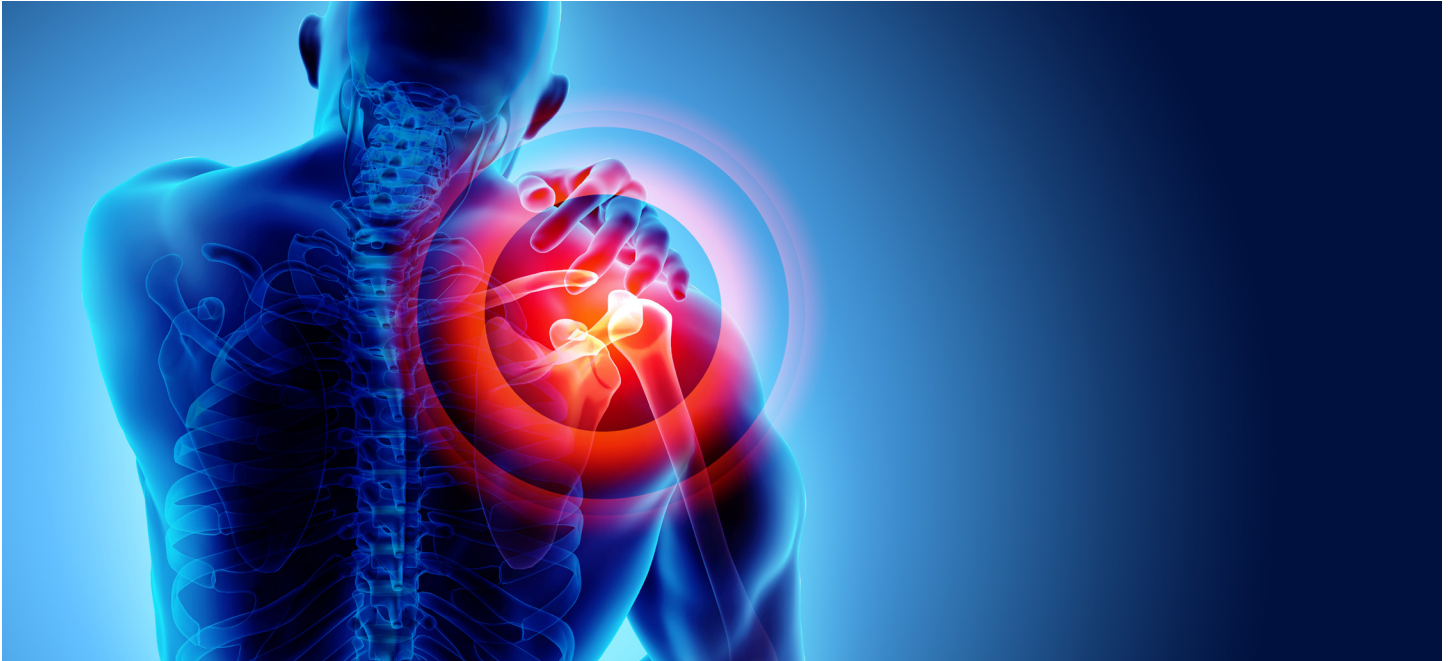




# COMPOUNDING FOR **PAIN MANAGEMENT**





## Introduction

Chronic pain affects more than 1.5 billion people worldwide, including 115 million Americans. Pain affects more Americans than diabetes, heart disease and cancer combined, resulting in an annual cost of approximately 635 billion dollars in medical care and loss of workforce. Current treatment options for chronic pain are fraught with challenges such as serious systemic side effects affecting quality of life, increasing patient tolerance requiring higher doses and often, opioid addiction. According to the CDC, nearly 260 million opioid prescriptions were written in 2012, and in 2018, ER visits due to opioid overdose rose by 30%. As physicians are being pressured to reduce the number of opiates prescribed, non-traditional treatment options prepared by compounding pharmacists can ensure that patient-specific needs for effective pain management are being met, without adding to the burden currently being created by the opiate crisis in North America.

## Advantages of Compounding Topical and Transdermal Pain Preparations Include:

- Direct application to affected site
- Reduction in systemic side effects
- Reduction of drug concentration in bloodstream
- Reduction in first pass metabolism
- Painless administration
- Ability to combine multiple drugs into one preparation
- Ability to choose desired base
- Increased patient compliance
- Ability to continually customize and modify based on patients' changing needs
- Avoidance of opioid or narcotic dependency

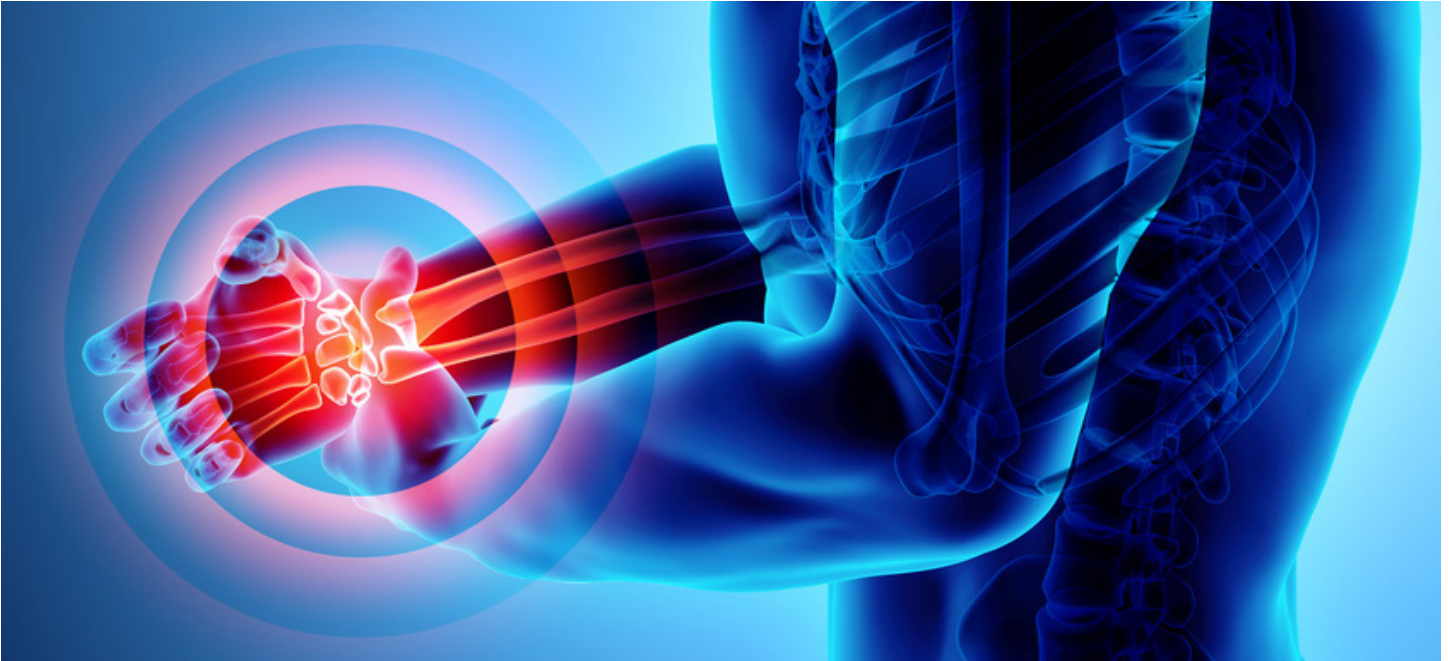
1. Institute of Medicine. (2011). Relieving pain in America: A blueprint for transforming prevention, care, education, and research. The National Academies Press, Washington, DC.

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\*References continued on page 3.



### Most Common Ailments Benefiting from Personalized Prescribed Compounded Topical and Transdermal Pain Creams Include:

- **Arthritis:** Osteoarthritis, Rheumatoid, Gout
- **Back & Joint Pain**
- **Burns**
- **Fibromyalgia**
- **Headaches**
- **Hemorrhoids & Anal Fissures**
- **Multiple Sclerosis**
- **Neuralgia:** Diabetic, Neuropathy, Shingles
- **Sports Injury**

Adding to the struggle facing prescribers, pharmacists and patients coping with chronic pain, is the fact that many of these patients suffer from multiple co-morbid diseases which further complicates effective therapy. The gold standard in pain management has for many years, involved exclusively systemic or parenteral therapy leading to many undesirable effects. However, commercial transdermal patches and gels have recently become available, offering a much-needed alternative route of administration for patients. The clinical research that emerged supporting these alternative dosage forms has opened the door for prescribers and compounding pharmacists to use their pharmacology knowledge to offer topical and transdermal pain options, customized to the individual needs of each patient.

5. Stanos, S. P. (2007). Topical agents for the management of musculoskeletal pain. *Journal of pain and symptom management*, 33(3), 342-355.

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8. Jorge, L. L., Feres, C. C., & Teles, V. E. (2011). Topical preparations for pain relief: efficacy and patient adherence. *Journal of pain research*, 4, 11.



## Active Pharmaceutical Ingredients Used in Topical and Transdermal Pain Preparations

◆ = Controlled Substances (US) ◆ = Narcotics (CAN)

Drug Class	Proposed Mechanisms of Action When Used Topically	Examples
Anesthetics	Reduce ectopic discharges from superficial somatic nerves which temporarily produce loss of sensation at the application site.	Lidocaine, Tetracaine, Prilocaine, Benzocaine, Bupivacaine
Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	Inhibits prostaglandin synthesis which enables peripheral analgesic activity by decreasing sensitization of nerve endings.	Diclofenac, Flurbiprofen, Ketoprofen, Ketorolac, Indomethacin, Ibuprofen, Acetylsalicylic Acid, Salicylic Acid, Piroxicam, Meloxicam
Counterirritants	Provide analgesia by exciting and desensitizing nociceptive sensory neurons which inhibit pain perception.	Camphor, Capsaicin, Menthol, Methyl Salicylate (Oil of Wintergreen)
Muscle Relaxants	Decrease in excitatory neurotransmitter release resulting in muscle relaxation and anti-spasmodic activity.	Baclofen, Cyclobenzaprine, Orphenadrine, Tizanidine
Opioids	Produce immediate local analgesia directly on peripheral opioid receptors and indirectly decrease inflammatory processes.	Morphine ◆ ◆, Buprenorphine ◆ ◆, Tramadol (Synthetic opioid) ◆
Antidepressants	Theorized that antidepressants exert analgesic effect on peripheral pain receptors.	Imipramine, Amitriptyline, Doxepin
Nitrates	Activates potassium channels sensitive to ATP and exerts peripheral antinociception.	Nitroglycerin
α-Adrenoceptor Agonists	Presynaptic inhibition of noradrenaline release from sympathetic nerves and actions directly on primary afferent nerve terminals producing central and peripheral analgesic effects.	Clonidine
Corticosteroids	Modification in epidermal and dermal cell function involved in proliferative and inflammatory conditions through induction of phospholipase A2 inhibitory proteins.	Hydrocortisone, Dexamethasone, Betamethasone, Triamcinolone, Fluocinonide
Anti-Epileptics	Decreases polysynaptic responses and blockade of post-tetanic potentiation resulting in relief of neuralgia.	Gabapentin, Carbamazepine, Topiramate
Calcium Channel Blockers	Provides analgesia by increasing peripheral blood flow.	Nifedipine, Verapamil
NMDA Receptor Antagonists	Inhibition of NMDA receptors prevents pain transmission from periphery sensors to the brain.	Ketamine ◆ ◆, Amantadine
Antivirals	Specific inhibitor of herpes simplex virus DNA polymerase.	Acyclovir, Valacyclovir
Antihistamines	In addition to histamine receptor antagonism, provides anti-emetic properties and used in combination with analgesics in topical pain preparations.	Prochlorperazine, Promethazine, Metoclopramide



MEDISCA Network supports the operational needs of compounding pharmacists across North American, Australian, and other international markets, by offering services that include:

- Technical Support Services; online formula database, formula design & customization, and a customer service helpline
- Specialized Consultation Services
- Standard Operating Procedures (SOPs)

Our focus is improving patient care, all while fostering proactive networking between the practices of pharmacy and medicine.



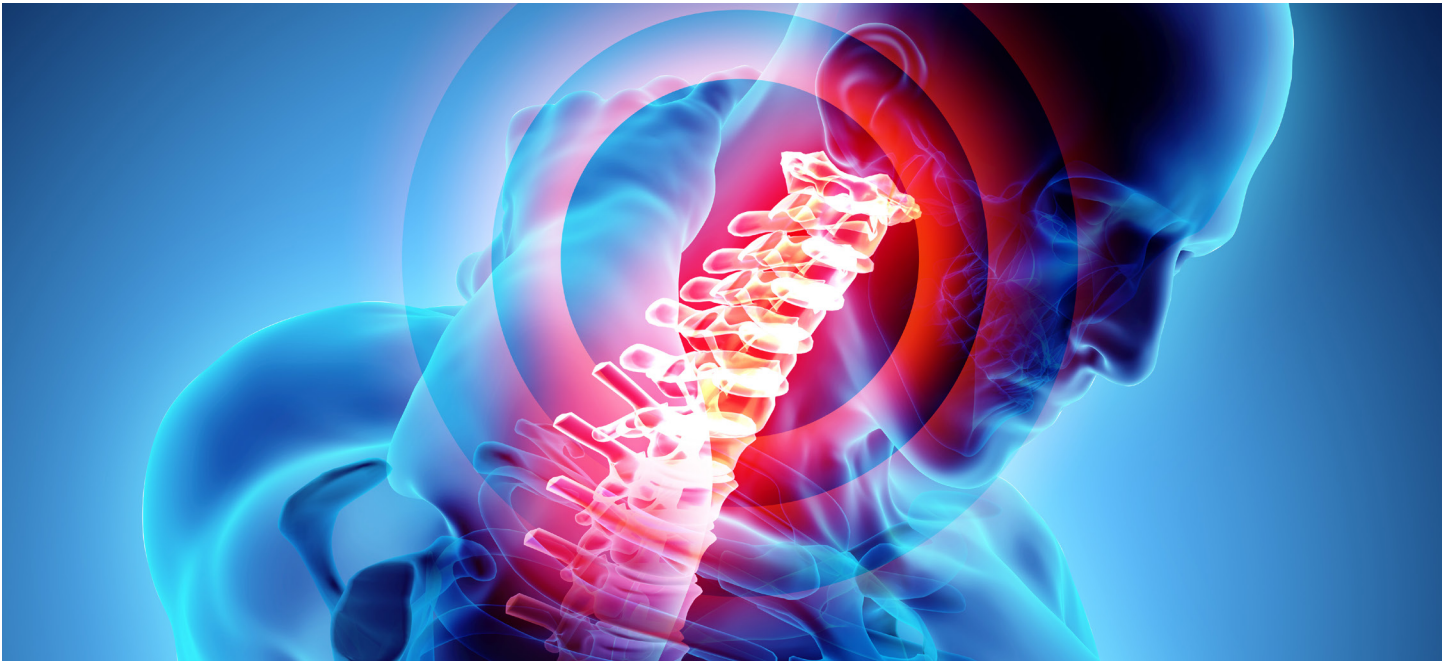
## Arthritis

Formula No.	Formula Title	Description	Base
F 005 977v2	Capsaicin 0.05% Topical Cream	Heat Producing Treatment to Soothe Joints Associated with Osteoarthritis	VersaPro™ Cream Base
F 005 978	Ketoprofen 10%, Piroxicam 1% Topical Cream	Provides Topical Analgesic and Anti-Inflammatory Properties to Application Site	VersaPro™ Cream Base
F 005 979	Ibuprofen 5%, Menthol 3% Topical Gel	Cooling, Anti-Inflammatory Gel Providing Relief from Arthritis Pain and Helping to Increase Mobility	VersaPro™ Gel Base
F 005 980	Acetaminophen 300 mg/g Topical Cream	Provides Topical Analgesia to Affected Areas in Individuals where NSAID Therapy is Contraindicated	VersaPro™ Cream Base
F 005 981	Glucosamine Hydrochloride 10%, Ketoprofen 15% Topical Cream	Anti-Inflammatory and Analgesic Relief for Pain Associated with Osteoarthritis	Transdermal Pain Base
F 005 465	Diclofenac Sodium 10% Topical Gel	Anti-Inflammatory and Analgesic Gel for the Treatment of Joint Pain Associated with Various Types of Arthritis	VersaPro™ Gel Base
F 005 982	Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 5%, Glucosamine Sulfate 10% Topical Cream	Anti-Inflammatory and Analgesic Relief for Pain Associated with Osteoarthritis	PenDerm™ Cream Base



## Sports Injury

Formula No.	Formula Title	Description	Base
F 006 583v2	Dextromethorphan Hydrobromide 3%, Guaifenesin 10% Topical Gel	Topical Muscle Relaxants for Muscle Spasms, Cramps and Low Back Pain	VersaPro™ Gel Base
F 004 036v3	Cyclobenzaprine Hydrochloride 1% Topical Cream	Treatment for Muscle Spasms Associated with Torn or Pulled Muscles and Ligaments	VersaPro™ Cream Base
F 006 220v2	Diclofenac Sodium 4%, Glucosamine Sulfate Potassium Chloride 8%, Magnesium Chloride 1.5% Topical Cream	Provides Treatment, Prevention and Inflammatory Relief from Joint Pain and Muscle Cramps Associated with sports Injuries	PenDerm™ Cream Base
F 005 984	Hydrocortisone 10% Phonophoresis Gel	Ultrasound Anti-Inflammatory Gel for use in Phonophoresis	VersaPro™ Gel Base
F 005 985v2	Dimethyl Sulfoxide 10%, Magnesium Chloride 20% Topical Lotion	Provides Deep Penetration of Magnesium into Muscle Tissue for Prevention or Treatment of Muscle Cramping Associated with Sports Performance	VersaPro™ Lotion Base
F 006 476	Lidocaine 3%, Phenytoin Sodium 5%, Sucralfate 20% Topical Ointment	General Burn Care	AlpaWash®
F 006 353	Betamethasone Valerate 0.12%, Tranilast 1% Topical Gel	Management and Treatment of Hypertrophic Scars	CopaSil®

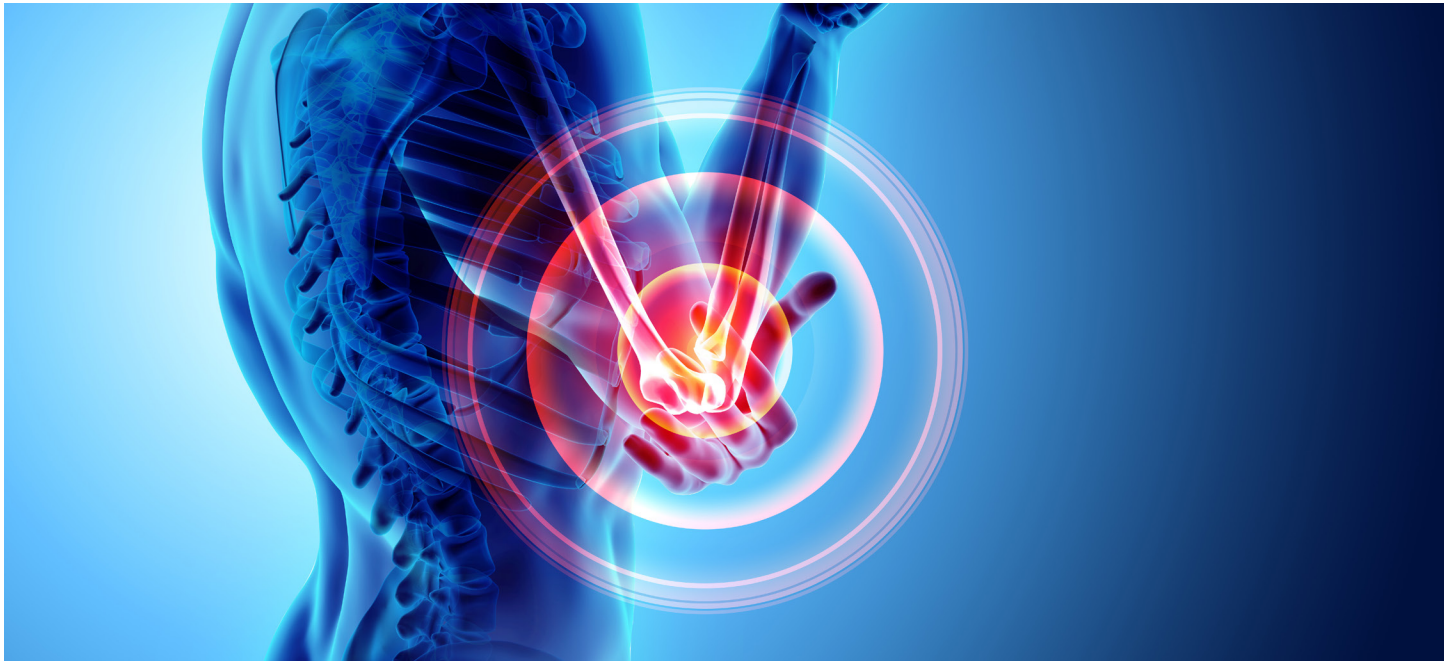


## Neuralgia

Ⓢ = Controlled Substances (US)   Ⓝ = Narcotics (CAN)

Formula No.	Formula Title	Description	Base
F 004 450v2	Diclofenac Sodium 2%, Gabapentin 6% Topical Cream	Provides Anti-Inflammation and Relief from Tingling and Burning Associated with Neuropathic Pain	VersaPro™ Cream Base
F 005 986	Acyclovir 5%, Lidocaine 2% Topical Gel	Treatment for Pain Associated with Active Shingles Outbreak	VersaPro™ Gel Base
F 005 987v2	Doxepin Hydrochloride 5%, Ketamine Hydrochloride 11.5% Ⓢ Ⓝ, Ketoprofen 5% Topical Cream	Provides Relief from Burning and Tingling Sensations, Analgesia and Anti-Inflammation for Severe Neuropathic Pain	VersaPro™ Cream Base
F 004 550v3	Gabapentin 6%, Ketamine Hydrochloride 9.2% Ⓢ Ⓝ, Ketoprofen 8% Topical Cream	Provides Relief from Burning and Tingling Sensations, Analgesia and Anti-Inflammation for Severe Neuropathic Pain	VersaPro™ Cream Base
F 005 990	Amitriptyline Hydrochloride 2%, Gabapentin 5% Topical Cream	Provides Relief from Burning and Tingling Sensations Associated with Neuropathic Pain	VersaPro™ Cream Base
F 005 988	Cyclobenzaprine Hydrochloride 2%, Gabapentin 6%, Lidocaine 10% Topical Cream	Provides Analgesia Through Numbing of the Affected Area and Relief from Burning, Tingling Sensations and Muscle Spasms Associated with Neuropathic Pain	Transdermal Pain Base



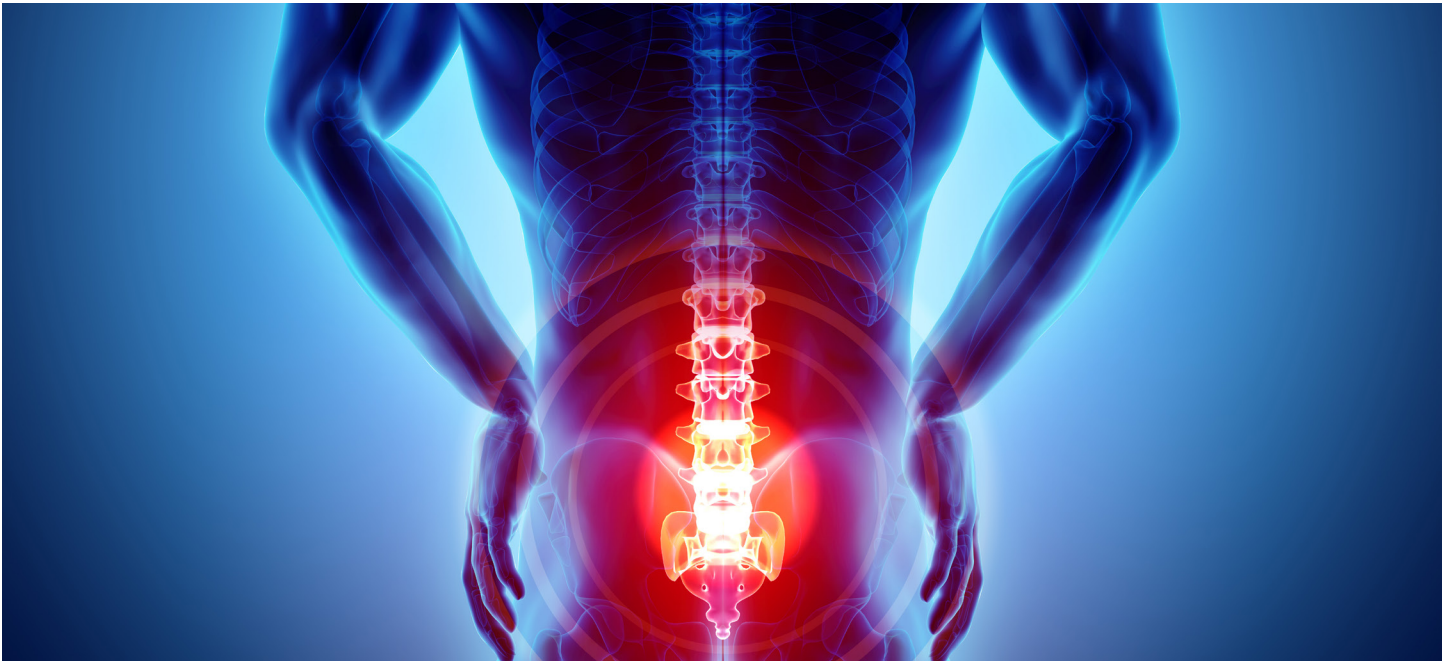


## Musculoskeletal

Ⓢ = Controlled Substances (US)   Ⓝ = Narcotics (CAN)

Formula No.	Formula Title	Description	Base
F 005 992	Diclofenac Sodium 3%, Flurbiprofen 6%, Gabapentin 6% Topical Cream	Provides Anti-Inflammation and Relief from Tingling and Burning Associated with Musculoskeletal Pain	Transdermal Pain Base
F 004 535v3	Ketoprofen 10%, Lidocaine 5% Topical Cream	Provides Numbing Analgesic Relief in Conjunction with Anti-Inflammatory Properties	VersaPro™ Cream Base
F 004 695v4	Ketamine Hydrochloride 8.625% Ⓢ Ⓝ Topical Cream	Analgesic Relief for Severe Pain	VersaPro™ Cream Base
F 004 828v2	Cyclobenzaprine Hydrochloride 5%, Lidocaine Hydrochloride 5% Topical Cream	Provides Numbing Analgesic, Muscle Relaxation and Muscle Spasm Relief	VersaPro™ Cream Base
F 005 060v2	Baclofen 2%, Diclofenac Sodium 3% Topical Cream	Provides Muscle Relaxation, Muscle Spasm, Analgesic and Anti-Inflammatory Relief	VersaPro™ Cream Base
F 005 997	Amantadine Hydrochloride 0.25%, Baclofen 0.25%, Ketoprofen 1% Topical Cream	Provides Muscle Relaxation, Muscle Spasm, Analgesic and Anti-Inflammatory Relief	VersaPro™ Cream Base





Miscellaneous

Formula No.	Formula Title	Description	Base
F 007 548	Lidocaine 1.5%, Nifedipine 0.3% Rectal Ointment	Treatment for Anal Fissures and Hemorrhoids	AlpaWash®
F 001 410v4	Guaifenesin 10%, Indomethacin 10%, Lidocaine Hydrochloride 2% Transdermal PLO Gel	Treatment for Pain and Inflammation Associated with Gout Attacks	PLO Gel MediFlo™ 30 (Pre-Mixed)
F 005 115v4	Diphenhydramine Hydrochloride 25 mg/g, Haloperidol 0.5 mg/g, Metoclopramide 10 mg/g Transdermal PLO Gel	Pain-Adjunct Treatment for Chemotherapy-Induced Nausea	PLO Gel MediFlo™ (Pre-Mixed)
F 001 386v4	Indomethacin 10% Transdermal PLO Gel	Transdermal Relief from Migraine Pain	PLO Gel MediFlo™ 30 (Pre-Mixed)
F 006 749v2	Benzocaine 20%, Lidocaine 6%, Tetracaine 4% Topical Paste	Topical Anesthetic used for Pain Prevention Prior to Medical and/or Cosmetic Procedures	OleaBase™ Plasticized
F 005 991	Ketoprofen 10%, Piroxicam 3% Topical Cream	Analgesic and Anti-Inflammatory Relief for Plantar Fasciitis	VersaPro™ Cream Base

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# BASE PORTFOLIO

MEDISCA offers a diverse line of compounding bases to cover all of your patients' unique needs. Based on the desired route of administration and the therapeutic intent, we can provide the optimal delivery system for any given formulation.

## Transdermal Pain Base



- Smooth and thick PLO-base with no sticky residue
- Vehicle for lipophilic and hydrophilic APIs
- High carrying capacity allows for stable compounded pain formulations
- Fragrance-, alcohol-, mineral oil-, and petrolatum-free

## OleaBase™ Plasticized



- A soft, odorless anhydrous ointment base
- Exhibits oleaginous and emollient properties
- Intended for both dental and topical applications
- Ideal vehicle for occlusive preparations
- Paraben- petrolatum- and alcohol-free

## LiquiGel Complex™



- Off-white, opaque liquid
- Ready-to-use polymer blend
- Intended to thicken and stabilize any oil-in-water emulsion over a large pH range
- Handled at room temperature without the need for weighing or refrigerating



## AlpaWash®



- Unique PEG base that does not contain oleaginous components
- Completely water-washable and greaseless
- Contains natural extracts that have been thoroughly studied and can be beneficial in compounded medications prescribed for wound care
- Paraben-, Propylene Glycol-, Water-, Petrolatum- and Lanolin-free

## VersaPro™ Cream Base



- Scientifically proven moisturizer
- Versatile vehicle for lipophilic and hydrophilic drugs
- Oil-in-water emulsion that is non-greasy, non-irritant, and paraben-free
- High carrying capacity, pH stability and API compatibility
- Increased permeation of Progesterone through the skin (DPSI, January 2010)

## VersaPro™ Gel Base



- A highly versatile, clear, viscous gel
- Compatible with a wide range of active ingredients
- Proven target site delivery with Diclofenac Sodium\*
- Quick drying and non-greasy
- Acts as an ultrasound gel
- Petrolatum-, alcohol-, and paraben-free

\* In vitro Percutaneous Absorption of (14C)-Diclofenac Sodium from Prototype Formulations using Human Skin, conducted by Dow Pharmaceutical Sciences, Inc.

## VersaPro™ Lotion Base



- Smooth, fluid texture, non-greasy after feel
- Ideal for compounding higher concentrations of hormones
- Well suited for both cosmetic and dermatological applications
- Wide pH stability range
- Fragrance-, gluten-, mineral oils-, petrolatum-, and paraben-free

# EQUIPMENT & DEVICES

From a simple vial to sophisticated tools such as the MAZ™ mixer, MEDISCA offers over **600 types of equipment and devices** that meet the compounding needs of today's pharmaceutical industry. Our extensive line of products will provide you with everything needed to stay ahead of the curve as a leader among compounding pharmacies.

## MAZ™ Mixer

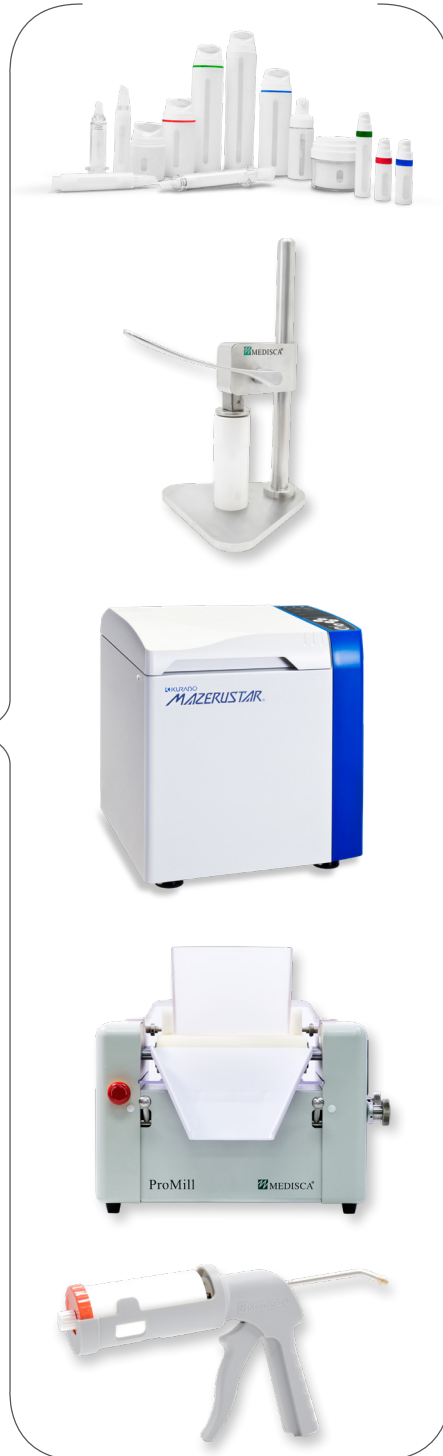


- Ideal for mixing creams, gels, ointments, and liquids
- Excellent for milling powders
- Ideal for melting gelatin gum base for troches
- Suitable for hazardous drug compounding due to closed system mixing; meets USP <800> requirements
- No mixing rods or blades; reduced risk for cross contamination
- Includes a vacuum-like feature to help remove air entrapment
- High speed mixing motion
- Ensures homogeneous formulations (< 4% RSD)
- Operates with redundant safety features
- Reusable and disposable containers allow for quick and easy clean-up
- Available in various model sizes: KK-300SS (310 g x 1 container), KK400W (400 g x 2 containers) KK-1000W (1 Kg x 2 containers), and KK-2000 (2 Kg x 2 containers)

## MEDISCA ProMill™



- High volume throughput, up to 11 liters per hour
- Large hopper of 1.75 liters enables to process more material
- Digital control panel with variable speed control and counter time capabilities
- Solid and easy to clean aluminum oxide rollers for long term performance
- Self-calibrating gap distances
- Equipped with safety features: an emergency stop and engine overload protection



## MD® Dispensers



- Superior dosing accuracy
- Low standard deviation
- Pharmaceutically elegant design
- Unique UV-resistant view window
- Easy filling (top fill)
- Great versatility — sizes ranging from 5 mL to 240 mL in various dosage options
- New Actuator colors facilitate medication identification

## MD® CapSnapper



- Allows the compounder to easily snap on pump actuators with minimal force.
- Made of durable stainless steel
- Simple operation reduces snapping time
- Adjustable height to accommodate entire line of MD Dispensers, Top-Fill Mega Pumps or any other device requiring the cap to be snapped on
- Convenient grooves located at the base of Plate Stand for stable placement of dispensing device
- Balanced lever arm for easy operation – minimal downward force required!
- Works with right or left handed operators via switchable lever arm
- Easy to clean and wipe down

## EAZY-Fill™ Topical Transfer Gun



- For efficient filling and transferring of creams, gels or ointments into a variety of devices or dispensers
- Lightweight construction for maximum mobility
- Ergonomic handle provides a comfortable grip with low trigger actuation force required
- Detachable cradle system enables compatibility with multiple EMP jar sizes (100 mL, 200 mL, 300 mL and 500 mL)
- Multi-mode plunger advancement system provides better control with accurate transfers



## ON-DEMAND WEBINARS



### COMPOUNDING OPPORTUNITIES IN TRANSDERMAL DELIVERY

With personalized pharmacotherapy on the rise, innovations in drug delivery systems are taking place at an exponential rate. Now, more than ever before, patients are seeking customized pharmaceutical dosages that are better tailored to their individual needs. Given the prevailing limitations and side effects associated with conventional oral routes of administration (e.g., difficulty swallowing, distaste for certain flavors, gastrointestinal irritations, and metabolic constraints among others), transdermal modes of delivery are gaining increasing recognition.

In this webinar, participants will learn about the benefits of transdermal delivery and the opportunity for transdermal compounding within niche therapeutic areas (i.e., hormone replacement therapy, pain management, and veterinary care). Participants will also gain an appropriate understanding of the challenges associated with the delivery of drugs across the epidermal layers (i.e., bioavailability and skin permeation), and how to circumvent these challenges with innovations in pharmaceutical technology and formulation chemistry.

### IONTOPHORESIS AND PHONOPHORESIS FOR TARGETED TRANSDERMAL DRUG DELIVERY

Iontophoresis and phonophoresis for targeted transdermal drug delivery systems have been widely used and are well-accepted physical therapy modalities. The mechanisms and techniques used to deliver drugs to the soft tissues of the musculoskeletal system must be well understood to ensure efficacious and safe treatment. Not all drug agents can be used in conjunction with these technologies – the use of certain drug agents would not result in adequate permeation across the stratum corneum in quantities sufficient to bring about a positive therapeutic outcome. Furthermore, the differential diagnosis and causative factors at a physiological level must be taken into account to ensure correct drug selection.

In recent years, the diagnostic use of ultrasound has proven instrumental in understanding the effects of drug agents on soft tissue. Ultrasound-guided treatment has also improved the efficacy of invasive therapeutic interventions. The correct technology settings and conductive properties of the carrier and transport systems must be properly matched to the physicochemical properties of the drug agent such that appropriate drug penetration, partitioning, diffusion, and permeation is achieved. The use of drug-free microneedle systems, figuratively and literally, paves the way for the enhancement of targeted transdermal drug delivery.

## LEARN MORE!

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## LIVE TRAININGS



### ESSENTIAL ELEMENTS OF PERSONALIZED ANALGESIC MEDICATIONS

Living with chronic pain is an ever-growing reality for many people, both young and old. Among those suffering, many are inadequately treated with commercial pharmaceutical remedies that may be unsuitable for the individual patient's needs including, improper dosage form and strength, the presence of irritating inactive ingredients, among much more. Although these options may help reduce pain for the average person, the adverse reactions that can be associated with these standard one-size-fits-all commercial products is becoming of increasing concern. Moreover, given the complexity and unique experience of each individual's pain, personalized treatment options are increasingly warranted. With healthcare moving towards a more personalized approach and with advancements being made in pharmaceutical customization, these individuals can now receive medications that are tailored to their own unique needs and pain experience. Taking advantage of the numerous customization options available today including creams, gels, ointments, sprays, capsules, and others, painful conditions can be managed in a fashion oriented to the individual needs of each patient.

### ANALGESIC COMPOUNDING – LABORATORY TRAINING

As it stands today, first-line treatments for pain management are often associated with adverse systemic effects, including gastrointestinal erosions, constipation, central nervous system depression, addiction, and tolerance. Moreover, many currently available commercial analgesics are limited in therapeutic efficacy, rendering many pain symptoms left untreated or inadequately managed. With compounded topical creams and gels, patients are better able to target the site of action through local application to affected regions, limiting systemic reactions and in many cases, improving therapeutic outcome. In addition, compounders can develop low-dose multi-drug formulations that reach multiple nociceptive pathways, further optimizing targeted effect and ultimately therapeutic payoff.

The objective of this laboratory training is to expose pharmacists and technicians to the hands-on experience of compounding dosage forms common to the niche market of analgesic therapy, notably creams, gels, and pastes. Participants will learn how to optimize the efficiency and quality of their compounding process by practicing novel compounding techniques and implementing innovative technologies and equipment.

## LEARN MORE!

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