WHAT IS COMPOUNDING?
The art of pharmacy compounding is the method of preparing medications to meet the unique needs of patients and prescribers. Compounding pharmacies can prepare pharmaceutical products that are not commercially available or in different configurations that are not available commercially. Working with physicians, innovative compounding pharmacists at US Compounding continually provide unique solutions to medication dosing problems, meeting patients’ needs and providing improved patient care and quality of life.

PATIENT BENEFITS
- Customized Dosing
- Varying Strengths, Sizes and Shapes
- Dye Free, Preservative Free, Lactose Free Dosage Forms
- Provide Unavailable, Unformulated and Discontinued Items

PATIENT-SPECIFIC TRANSDERMAL COMPOUNDS
- Pain management
- Reduction of inflammation
- Delivery vehicles that increase patient comfort (LipodermTM)
- Delivery vehicles that increase patient compliance (Topi-ClickTM)
- Plus many more—if your patient has a unique need, we can help find a solution!

CLINIC USE SPECIALTY INJECTIONS
At US Compounding, we provide a wide range of solutions for sterile injectable products for orthopedic specialties, like corticosteroid injections.
- Dexamethasone Acetate
- Triamcinolone Acetate
QUALITY ASSURANCE
US Compounding has a documented, ongoing quality assurance program intended to ensure that compounded sterile drug products have the identity, strength, purity and quality that they are represented to possess. An independent lab tests every batch of sterile injectables compounded at our pharmacy. Each batch is sampled according to batch size and tested by Analytical Research Laboratories (www.arlok.com) of Oklahoma City, OK. ARL is a DEA and FDA registered lab.

US Compounding has Analytical Research Laboratories test each batch of compounded sterile injectables for sterility and the presence of fungus and endotoxins. The batch is then held in locked quarantine in identified storage areas until results are received and reviewed by the compounding pharmacist for release. No compounded injectable leaves our pharmacy before documented sterility is on file for that batch. This program exceeds all applicable federal, state and local laws and regulations.

Our quality assurance program also includes up-to-date policies and procedures for compounding sterile products focusing on stringent compliance with USP Guidelines on Pharmaceutical Compounding—Sterile Preparations.

Our sterile compounding is performed by qualified, licensed pharmacists and technicians who have undergone extensive training in the art of pharmacy compounding. All are trained to exceed ASHP guidelines for aseptic technique and are routinely validated for performance.

Products are prepared in a Class 100 environment using HEPA-filtration. Clean rooms and laminar airflow hoods are certified regularly for operational efficiency.

Bulk pharmaceuticals used to compound sterile products are purchased from Professional Compounding Centers of America (www.pccarx.com) located in Houston, TX. PCCA is the industry leader in providing pharmaceutical bulk chemicals and determines the products to be stable, compatible and appropriate for product preparation according to the USP guidelines.

OUR PLEDGE TO YOU
The team at US Compounding will work to improve your patients’ health and level of care while still providing personal, professional service and the highest quality compounds. Feel free to contact us to solve unique, patient-specific challenges.

OUR VALUES
Integrity
Quality
Leadership
Innovation
Teamwork
Patient Focus
Community
Respect for People

Eddie Glover, P.D.
Founder & CEO
### Keto-Flex Plus Back Pain USC #348

**Possible Applications:** Moderate back pain with/without sciatica.

**Description:** Keto-Flex Plus Back Pain has an additional NSAID (diclofenac) and a neuropathic NMDA receptor antagonist (gabapentin).

**Ingredients:** Ketoprofen 10%, Cyclobenzaprine 2%, Ketamine 10%, Lidocaine 5%, Diclofenac 2%, Gabapentin 5%, Baclofen 2%

### Diabetic Neuropathy and PHN Pain Cream USC #349

**Possible Applications:** Peripheral Diabetic Neuropathy and Pain Following Active Shingles

**Description:** Powerful blend of an NMDA antagonist, 2 NSAIDs, an anesthetic, 3 neuropathic pain medicines, and a calcium channel blocker for improved circulation.

**Ingredients:** Ketoprofen 20%, Ketamine 10%, Gabapentin 5%, Clonidine 0.2%, Nifedipine 5%, Lidocaine 5%, Diclofenac 2%, Baclofen 2%
Patient compliance is critical to clinical outcomes and patient satisfaction. We offer patients a variety of packaging options, and many patients prefer our dispensers because the ease of use, decreased waste and consistent dose. The pumps are most preferred because they travel well, protect the product from light, are much less messy than tubes or jars and can hold a large amount of medication. For smaller amounts of cream, the Topi-Click™ apparatus gives a measured dose in a deodorant-like container.

**DELIVERY VEHICLE & APPLICATOR FOR TOPICAL COMPOUNDS**

A topical compound is only as good as the delivery vehicle used. At US Compounding, we use Lipoderm®, manufactured by PCCA. Lipoderm® delivers proven, superior results compared to PLO which most compounding pharmacies use. Lipoderm® is:

- Lipoderm® is proven to deliver micronized ketoprofen through the stratum corneum and epidermis 4.5 times better than PLO.
- Odorless
- Allergy Tested
- Hypo-allergenic
- Patients prefer Lipoderm® because it requires less volume and is rapidly absorbed.

**DISPENSERS**

At US Compounding we specialize in solving unique patient-specific challenges. Please let us help you provide those solutions.
1. US COMPOUNDING IS ACCREDITED AND TESTS 100% OF ALL BATCH INJECTABLES VIA AN FDA & DEA APPROVED LAB.

2. US COMPOUNDING CURRENTLY HAS OVER 7,000 ACTIVE ACCOUNTS.

3. US COMPOUNDING IS THE LARGEST PHARMACY IN THE US FOR CLINIC INJECTABLES.

CLINIC USE SPECIALTY INJECTIONS
At US Compounding, we provide a wide range of solutions for sterile injectable products for orthopedic specialties, like corticosteroid injections and viscosupplementation.

Corticosteroids:
- Dexamethasone Acetate
- Triamcinolone Diacetate
- Methylprednisolone with Lidocaine
- Betamethasone 7mg/ml.

Viscosupplementation:
- HA/lidocaine compounded in the USA and tested in FDA approved lab
- Non Avian HA
- Doses available in higher concentrations with less volume
- Doses with corticosteroid and viscosupplementation combination

Custom formulations are our specialty...what can we make for you?

As a CEO for a multimillion dollar orthopaedic physicians’ organization that has over 48,000 patient visits each year, the safety of our patients is our number one concern. US Compounding’s PCAB accreditation, reliability, outstanding customer service and value pricing are what make them stand out as a leader in the industry.

— Brian S. Bizub, Chief Executive Officer, Palm Beach Orthopaedic Institute, P.A.
As part of an ongoing effort to create the highest quality products, PCCA has aggressively studied the ability of Lipoderm® and PLO to deliver ketoprofen across human skin. PCCA teamed up with the highly regarded dermatologic laboratory PRACS Institute – Cetero Research to conduct this study. Using PCCA’s Special Micronized Ketoprofen USP, PCCA Lipoderm performed better than PLO.

Study
Evaluation of the Percutaneous Absorption of Ketoprofen, In Vitro, Using the Human Cadaver (Ex Vivo) Skin Model
The study was designed to evaluate the percutaneous absorption pharmacokinetics of PCCA’s Special Micronized Ketoprofen. Absorption was measured in human cadaver skin, in vitro, using the finite dose technique and Franz Diffusion Cells.

The products were tested on replicate sections from three different cadaver skin donors, for the percutaneous absorption of PCCA’s Special Micronized Ketoprofen over a 48-hour dose period. At pre-selected times after dose application, the dermal receptor solution was removed in its entirety, replaced with fresh receptor solution, and an aliquot saved for subsequent analysis. In addition, the epidermis and dermis were recovered and evaluated for drug content. The samples were analyzed for ketoprofen content by High Performance Liquid Chromatography (HPLC).

The in vitro human cadaver skin model has proven to be a valuable tool for the study of percutaneous absorption and the determination of the pharmacokinetics of topically applied drugs. The model uses human cadaver skin mounted in specially designed diffusion cells that allow the skin to be maintained at a temperature and humidity that match typical in vivo conditions. A finite dose of formulation is applied to the outer surface of the skin and drug absorption is measured by monitoring its rate of appearance in the receptor solution bathing the inner surface of the skin. Data defining total absorption, rate of absorption, as well as skin content can be accurately determined in this model. The method has historic precedent for accurately predicting in vivo percutaneous absorption kinetics.

Results
The data indicate that PCCA’s Special Micronized Ketoprofen did penetrate into and through human cadaver skin, in vitro, from the test formulations provided. The absorption profiles indicate a rapid penetration to a peak flux occurring at approximately 7-8 hours after dose application followed by a steady decline thereafter. PCCA Lipoderm performed significantly better than PLO at delivering PCCA’s Special Ketoprofen Transdermal Study
Ketoprofen in PCCA Lipoderm® Outperforms PLO in Transdermal Testing!

PCCA Lipoderm® now PROVEN to Deliver the NSAID Ketoprofen Through Human Skin In Vitro

Figure 1: PCCA Lipoderm® demonstrates a superior ability to deliver ketoprofen transdermally versus PLO.
Micronized Ketoprofen through human skin (see Figure 1). This formulation also delivered PCCA’s Special Micronized Ketoprofen more rapidly than all other formulations. Lipoderm with pentylene glycol as the wetting agent showed an even better total permeation result versus PLO, with the difference being statistically significant (p<0.01, see Figure 2). While this formulation delivered the most ketoprofen across the skin (total absorption), it was not as quick as the other Lipoderm formula.

**Methods and Procedures**

Percutaneous absorption was measured using the in vitro cadaver skin finite dose technique. Human cadaver trunk skin without obvious signs of skin disease, obtained within ~24-48 hours of death, was used in this study. It was dermatomed, prepared for cryopreservation, sealed in a water impermeable plastic bag, and stored at <-70°C until the day of the experiment. Prior to use, it was thawed in ~37°C water, then rinsed in tap water to remove any adherent blood or other material from the surface.

Skin from a single donor was cut into multiple smaller sections large enough to fit on static 1.0 cm² Franz diffusion cells. The dermal chamber was filled to capacity with a reservoir solution of phosphate-buffered isotonic saline (PBS), pH 7.4 ± 0.1, and the epidermal cell (chimney) left open to ambient laboratory conditions. All cells were mounted in a diffusion apparatus in which the dermal bathing solution was stirred magnetically at approximately 600 RPM and the skin surface temperature maintained at 32.0°C ± 1.0°C.

To assure the integrity of each skin section, its permeability to tritiated water was determined before application of the test products. Following a brief (0.5-1 hour) equilibrium period, ³H₂O (NEN, Boston, MA, sp. Act. ~ 0.5 µCi/mL) was layered across the top of the skin by dropper so that the entire exposed surface was covered (approximately 200-500 µL). After 5 minutes, the ³H₂O aqueous layer was removed. At 30 minutes, the receptor solution was collected and analyzed for radioactive content by liquid scintillation counting. Skin specimens in which absorption of ³H₂O was less than 1.56 µL-equ/cm² were considered acceptable.

Just prior to dosing, the reservoir solution was replaced with a fresh solution of 1x PBS and an aliquot retained for subsequent analysis (pre-dose sample). The chimney was removed from the Franz Cell to allow full access to the epidermal surface of the skin. All formulations were then applied to the skin sections using a positive displacement pipette set to deliver 5 µL formulation/cm². The dose was spread across the surface with the Teflon® tip of the pipette. At pre-selected times after dosing (4, 8, 12, 24, 32, and 48 hours), the reservoir solution was removed in its entirety, replaced with fresh reservoir solution, and an aliquot saved for subsequent analysis.

In each study, if spare cells were available they were not dosed but used to evaluate for the appearance of substances diffusing out of the skin that might interfere with the analytic method.
After the last sample was collected, the skin surface was washed twice (0.5 mL volume each) with equal parts ethanol and water to collect un-absorbed formulation from the surface of the skin. Following the wash, the skin was removed from the chamber, split into epidermis and dermis, and were extracted overnight in equal parts ethanol and water.

Samples were either concentrated or diluted as necessary to fit within the standard curve range prior to analysis. Quantification of PCCA’s Special Micronized Ketoprofen was by High Performance Liquid Chromatography (HPLC/UV). Briefly, HPLC was conducted on a Hewlett-Packard 1100 Series HPLC system with an Agilent 1100 Series LC with a diode array detector.

**Formulas Tested**

**Lipoderm® Formula**
- Ketoprofen USP, PCCA Special Micronized: 10% W/W
- Diethylene Glycol Mono Ethyl Ether, NF: 2% W/W
- Propylene Glycol: 8% W/W
- PCCA Lipoderm®: q.s. to 100%

**PLO Formula**
- Ketoprofen USP, PCCA Special Micronized: 10% W/W
- Diethylene Glycol Mono Ethyl Ether, NF: 2% W/W
- Propylene Glycol: 8% W/W
- Lecithin Isopropyl Palmitate Solution: 22% W/W
- Poloxamer 407 20% Solution: q.s. to 100%

A third formula, using Pentylene Glycol as a wetting agent, also was evaluated:

**Lipoderm® Formula with Pentylene Glycol**
- Ketoprofen USP, PCCA Special Micronized: 10% W/W
- Pentylene Glycol: 10% W/W
- PCCA Lipoderm®: q.s. to 100%

**Figure 2:** The use of pentylene glycol 10% in PCCA Lipoderm® as wetting agent increases extent of percutaneous absorption, but is a little slower.

**Figure 3:** Percent of applied ketoprofen dose that was delivered completely through human skin in vitro was significantly better with PCCA Lipoderm® versus PLO.
# Microbiology Report

**CLIENT:** US Compounding-AR  
Rebecca Mitchell

**ARL #:** 160206-01  
**LOT #:** 1119103

**DESCRIPTION:** Methylpred Acet/Lido 40mg/1%/ml  
**DATE RECEIVED:** 10/20/2011  
**STORAGE:** 20°C to 25°C (68°F to 77°F)  
**CONTAINER:** Eight 10 mL amber vials in a clear bag

<table>
<thead>
<tr>
<th>ANALYSIS</th>
<th>Limits</th>
<th>Results</th>
<th>Test Method</th>
<th>Date Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterility (<em>Preliminary</em>)</td>
<td>Sterile / Not Sterile</td>
<td>Sterile</td>
<td>USP 71</td>
<td>10/20/2011</td>
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<td>Sterile / Not Sterile</td>
<td>Sterile</td>
<td>MBI-114</td>
<td>10/20/2011</td>
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</table>

**Sterility -** An Initial report will be issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

**Fungal -** An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

**Endotoxin -** To calculate the endotoxin limit use the following formulae:  
$$ EL = K/M $$  
where $K$ = tolerance limit (EU/kg) and $M$ = Maximum dose/kg/hour or Maximum dose/kg

- Parenteral: $K$ is 5 EU/kg for any route of administration /Intrathecal: $K$ is 0.2 EU/kg body weight)
- Radiopharmaceutical parenteral: $K$ is 175/V or Intrathecal radiopharmaceuticals: $K$ is 14/V, where $V$ is the maximum recommended dose in mL
- Dermal Application: $K/M$, where $K = 5$ EU/kg and $M$ is the (maximum dose/m2/hour $\times 1.80$ m$^2$)/70 Kg.

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Emily Shubnell - Microbiologist  
10/24/2011  
Date Reported

ARL Form QUF-078-V4 03/05/2010

*Results reported above relate only to the sample that was tested.*
Microbiology Report

CLIENT: US Compounding-AR
Rebecca Mitchell

ARL #: 159515-01
LOT #: 1107105
DESCRIPTION: Hyaluronic Acid/Lidocaine (2ml) 10mg/1%/ml
DATE RECEIVED: 10/11/2011
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Eighteen 3 mL syringes in sealed bags in a clear bag

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Sterility - An Initial report will be issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where $K$ = tolerance limit (EU/kg) and $M$ = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: $K$ is 5 EU/kg for any route of administration (Intrathecal: $K$ is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: $K$ is 175/V or Intrathecal radiopharmaceuticals: $K$ is 14/V, where $V$ is the maximum recommended dose in mL.

Dermal Application: $K/M$, where $K = 5$ EU/kg and $M$ is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Fungal - An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where $K$ = tolerance limit (EU/kg) and $M$ = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: $K$ is 5 EU/kg for any route of administration (Intrathecal: $K$ is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: $K$ is 175/V or Intrathecal radiopharmaceuticals: $K$ is 14/V, where $V$ is the maximum recommended dose in mL.

Dermal Application: $K/M$, where $K = 5$ EU/kg and $M$ is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Tiffany Hyde - Microbiologist
10/17/2011

DATE REPORTED
ARL FORM QUF-078-V4 03/05/2010
# Microbiology Report

**CLIENT:** US Compounding-AR  
Rebecca Mitchell

**ARL #:** 160126-01  
**LOT #:** 1118101

**DESCRIPTION:** Triamcinolone Diacetate 40MG/ML  
**DATE RECEIVED:** 10/19/2011  
**STORAGE:** 20°C to 25°C (68°F to 77°F)  
**CONTAINER:** Twelve 10 mL amber vials in a clear bag

<table>
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<tr>
<th>ANALYSIS</th>
<th>Limits</th>
<th>Results</th>
<th>Test Method</th>
<th>Date Tested</th>
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</table>

**Sterility - An Initial report will be issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.**

**Fungal - An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.**

**Endotoxin - To calculate the endotoxin limit use the following formulae: \( EL = K/M \) where \( K \) = tolerance limit (EU/kg) and \( M \) = Maximum dose/kg/hour or Maximum dose/kg.

- Parenteral: \( K \) is 5 EU/kg for any route of administration / Intrathecal: \( K \) is 0.2 EU/kg body weight
- Radiopharmaceutical parenteral: \( K \) is 175/V or Intrathecal radiopharmaceuticals: \( K \) is 14/V, where \( V \) is the maximum recommended dose in mL.
- Dermal Application: \( K/M \), where \( K \) = 5 EU/kg and \( M \) is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

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Emily Shubnell - Microbiologist  

10/24/2011  

Date Reported  

ARL Form QUF-078-V4 03/05/2010

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*Results reported above relate only to the sample that was tested.*
Certificate Of Analysis

CLIENT: US Compounding-AR  
Rebecca Mitchell

ARL #: 148923-01  
LOT #: 201121043

DESCRIPTION: Keto/Cyclo/Lido/Keta/Pirox/DMSO 20/2/5/10/2/5%

DATE RECEIVED: 04/22/2011

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: One topi click container in a clear bag

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<td>Ketoprofen</td>
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Date Reported: 05/03/2011

Russell Gotschall - Laboratory Director

Results reported above relate only to the sample that was tested.