

# PermE8<sup>®</sup> Anhydrous Gel

Patented Technology

An Anhydrous Permeation-Enhancing Topical Base With Prolonged BUDs\*

PCCA # 30-5038



For topical permeation-enhancing absorption with extended stability.

PermE8 Anhydrous Gel is a base from PCCA that uses next-generation technology to provide a better option than previous anhydrous permeation-enhancing bases.

Changes in the industry, along with the perennial need to maximize efficiency in the pharmacy, have lead compounders to look for vehicles that can extend beyond-use dates (BUDs) without having to spend thousands of dollars on stability testing. At the same time, they need bases that perform well and provide an elegant finished preparation for the patient.

PermE8 is the solution to these needs. It has water activity below 0.6 ( $A_w < 0.6$ ), classifying it as an anhydrous base. This allows extended default BUDs for preparations that do not have stability studies. Additionally, PermE8 can hold multiple drugs at once, including those in salt form.

Importantly, PermE8 delivers active ingredients exceptionally well. In independent testing, PermE8 delivered ketoprofen through human skin comparably to our industry-leading Lipoderm<sup>®</sup> (PCCA #30-3338), and it significantly outperformed Anhydrous Lipoderm (PCCA #30-4283).

Finally, it has a silky, smooth texture that provides better application for patients than other anhydrous permeation-enhancing bases, such as Anhydrous Lipoderm.

## BENEFITS FOR COMPOUNDERS

- **Lower operating costs:** PermE8 allows for prolonged default BUDs without having to spend thousands of dollars on stability testing, and it can increase operational efficiency for compounders making anticipatory batches
- **Higher performance:** In independent testing, PermE8 significantly outperformed Anhydrous Lipoderm in delivering ketoprofen through the skin.
- **Broader application:** It is a stable base that can accommodate multiple APIs in one preparation, including those in salt forms and those not stable in aqueous environments



## BENEFITS FOR PATIENTS

- **Convenience:** It's anhydrous, which allows for longer default BUDs and less-frequent prescription refills
- **Pleasant application:** PermE8 isn't tacky or oily, and spreads on the skin more easily than other anhydrous, topical permeation-enhancing vehicles, such as Anhydrous Lipoderm

## RELATED SPECIALTIES

- Family practice
- Sports medicine
- Surgery
- Hospice
- Palliative care
- Oncology
- Podiatry
- Pediatrics
- Veterinary medicine

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\* According to standards established in the latest version of USP General Chapter 795.

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# PermE8<sup>®</sup> Anhydrous Gel



## FORMULATED WITHOUT

- Preservatives
- Soy
- Petrolatum/mineral oil
- Gluten

## THE PROOF

The results of *in vitro* testing show that PermE8 performed comparably to Lipoderm and significantly outperformed Anhydrous Lipoderm. The results show that:

- PermE8 delivered a comparable amount of ketoprofen through the skin to Lipoderm
- PermE8 delivered four times as much ketoprofen through the skin as Anhydrous Lipoderm

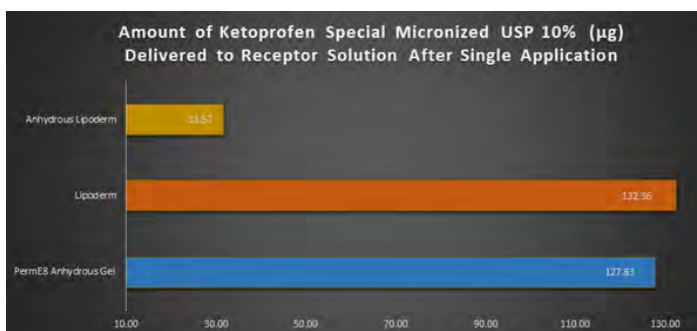


Figure 1: Amount of Ketoprofen Special Micronized USP 10% (µg) Delivered into and through *ex Vivo* Human Abdomen Skin over 40 Hours from a Single Application

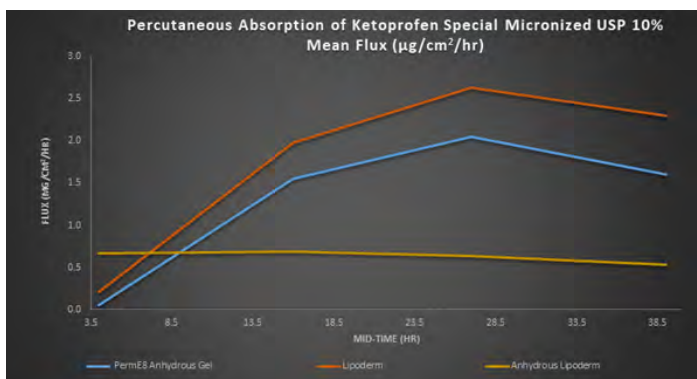


Figure 2: Mean Flux (µg/cm<sup>2</sup>/hr) Results: Percutaneous Absorption of Ketoprofen Special Micronized USP 10% through *ex Vivo* Human Abdomen Skin over 40 Hours from a Single Application

## PLEASE NOTE

Always make sure you have checked the PCCA formula database and are following the most up-to-date version of a formula, as changes are continually made to existing formulations to provide the highest quality. The formulas and/or statements listed are provided for educational purposes only. They are compounding ideas that have commonly been requested by physicians and have not been evaluated by the Food and Drug Administration. Formulas and/or material listed are not to be interpreted as a promise, guarantee, or claim of therapeutic efficacy or safety. The information contained herein is not intended to replace or substitute for conventional medical care or encourage its abandonment. Every patient is unique, and formulas should be adjusted to meet their individual needs.

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## FORMULATION EXAMPLES

- **PCCA Formula #13190**  
Ketoprofen 10%/Gabapentin 5%/Lidocaine 5%/Baclofen 2% Topical Gel (PermE8 Anhydrous)
- **PCCA Formula #13204**  
Diclofenac Sodium 10%/Gabapentin 5%/Lidocaine 5%/ Amitriptyline HCl 2% Topical Gel (PermE8 Anhydrous)
- **PCCA Formula #13198**  
Lorazepam 1 mg/mL/Diphenhydramine HCl 12.5 mg/mL Haloperidol 2 mg/mL Topical Gel (PermE8 Anhydrous)
- **PCCA Formula #13201**  
Verapamil HCl 15% Topical Gel (PermE8 Anhydrous)
- **PCCA Formula #13296**  
Promethazine HCl 125 mg/Gm Topical Gel (PermE8 Anhydrous)

## FREQUENTLY ASKED QUESTIONS

### Does PermE8 replace Lipoderm?

While this base does not replace Lipoderm, it is an anhydrous option to consider. Lipoderm is still the leading topical permeation-enhancing base. PermE8 is a great option when starting a new patient on a preparation that requires permeation enhancement in light of the delivery data and low water activity properties.

### Can I use PermE8 for topical permeation-enhancing veterinary medications?

Yes. PermE8 is safe for veterinary use.

### Sometimes I notice particles in the base. Will these affect the final preparation?

These should not affect the final preparation. Due to the characteristics of a vegetable-butter ingredient, a slight appearance of particles may occur in PermE8. However, these particles melt when rubbing into the skin, or they can be eliminated by mixing the preparation in an electronic mortar and pestle or milling according to the procedure stated in the formula.