



# PCCA Lipoderm<sup>®</sup>

## A Validated Transdermal Vehicle With Superior Results Over PLO

### PCCA #30-3338

PCCA is dedicated to providing the very best products for your patients. PCCA is the only company that has a **PROVEN** transdermal delivery vehicle on the market today. Promethazine HCl in **PCCA Lipoderm<sup>®</sup>** base was successfully transported through human skin, *in vitro*, and performed better than PLO.

### Study Highlights

**EVALUATION OF THE PERCUTANEOUS ABSORPTION OF PROMETHAZINE HCl, *IN VITRO*, USING THE HUMAN CADAVER SKIN MODEL** (Study performed by PRACS Institute, Ltd., an independent contract research facility.)

The study was designed to evaluate the percutaneous absorption pharmacokinetics of Promethazine HCl in **PCCA Lipoderm<sup>®</sup>** versus PLO (Pluronic Lecithin Organogel). Absorption was measured in human cadaver skin, *in vitro*, using the finite dose technique and Franz Diffusion Cells.

The products were tested on a minimum of triplicate sections from three different cadaver skin donors, for the percutaneous absorption of Promethazine HCl 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 Promethazine HCl content by High Performance Liquid Chromatography (HPLC-UV-MS).

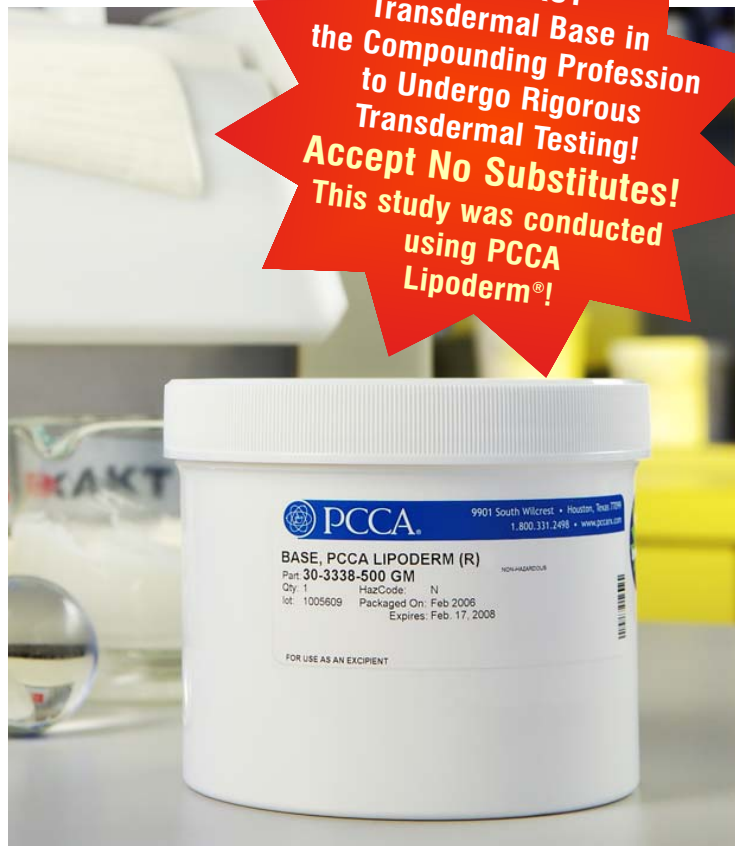
All samples contained Promethazine HCl 25mg/gm, 1.6% W/W Vitamin E Acetate, 0.2% BHT and 0.2% EDTA for stability purposes. 10% W/W Pentylene Glycol was used as a wetting agent/solvent for the Promethazine HCl. When PCCA studied the ability of **PCCA Lipoderm<sup>®</sup>** to transport drugs through the skin, a molecule was intentionally chosen that would have difficulty penetrating the skin. Promethazine HCl, due to its molecular weight and polarity, presents a challenge in delivery across the skin.

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 cryo-preservation, sealed in a water impermeable plastic bag, and stored at  $\leq -70^{\circ}\text{C}$  until the day of the experiment. Prior to use it was thawed in  $\sim 37^{\circ}\text{C}$  water, then rinsed in water to remove any adherent blood or other material from the surface.

### DONOR DEMOGRAPHICS

DONOR ID	AGE	RACE	SEX	INTEGRITY TEST RESULT
RN****	63	Caucasian	Male	0.22 ± 0.07
LS****	71	Caucasian	Male	0.57 ± 0.14
FB****	65	Caucasian	Male	0.33 ± 0.07

**The FIRST Transdermal Base in the Compounding Profession to Undergo Rigorous Transdermal Testing! Accept No Substitutes! This study was conducted using PCCA Lipoderm<sup>®</sup>!**



compound with confidence<sup>®</sup>



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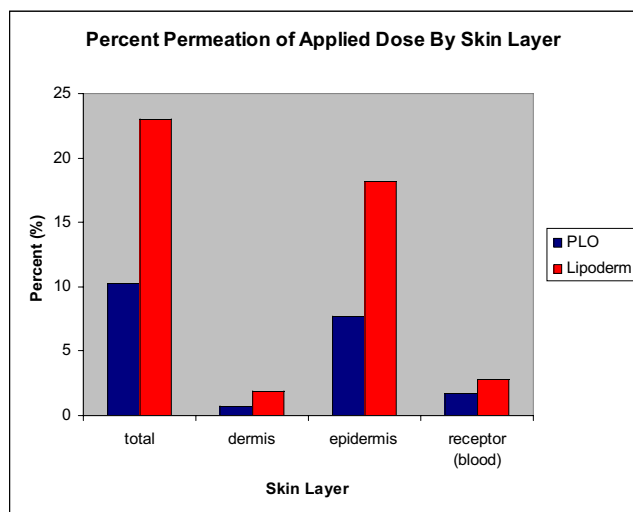
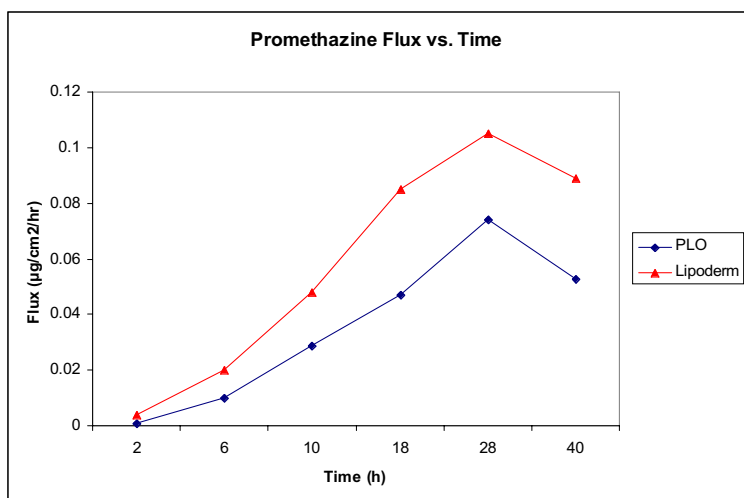
ALLERGY TESTED  
and  
HYPOALLERGENIC

Skin from a single donor was cut into multiple smaller sections large enough to fit on static 1.0 cm<sup>2</sup> Franz diffusion cells. 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° ± 1.0°C. To assure the integrity of each skin section, its permeability to tritiated water was determined before application of the test products.

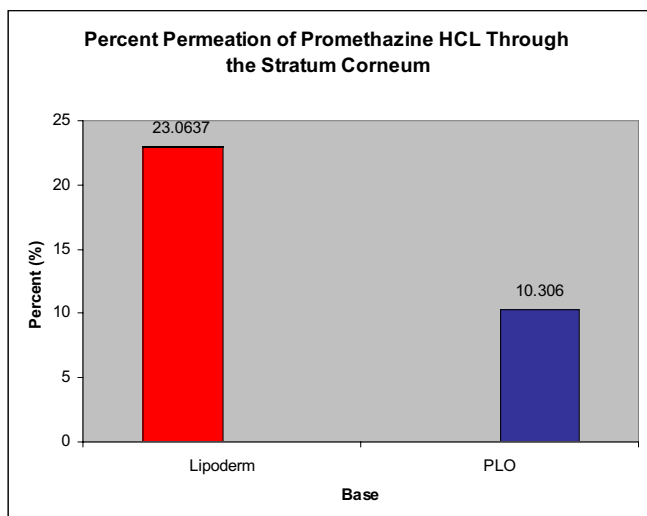
All formulations were then applied to the skin sections using a positive displacement pipette set to deliver 5 µL formulation/cm<sup>2</sup>. The dose was spread across the surface with the Teflon<sup>®</sup> tip of the pipette. At pre-selected times after dosing, (4, 8, 12, 24, 32 and 48 hours) the reservoir solution was removed in its entirety, replaced with fresh reservoir solution, and a predetermined volume aliquot saved for subsequent analysis.

## Results

The data indicate that Promethazine HCl does penetrate into and through human cadaver skin *in vitro*. Based on total penetration (through the skin into the reservoir solution), the data rank orders the test formulations as: **PCCA Lipoderm<sup>®</sup> > PLO**



Epidermal levels were found to be greater for **PCCA Lipoderm<sup>®</sup>** formulations (16.8 – 22.8 µg) than the other formulations (8.0 – 10.1 µg).



The percent of applied dose that penetrated past the Stratum Corneum with **PCCA Lipoderm<sup>®</sup>** was 2.24 times more than PLO.



PCCA

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