MEDISCA®

YOUR TRUSTED PARTNER IN COMPOUNDING

IN VITRO SKIN STUDIES AND BUD RESULTS

Efficient.
Endurant.
Essential.

BASES

VERSAPRO™ GEL BASE

VersaPro™ Gel Base is MEDISCA's new addition to the VersaPro™ family. Much like its predecessor, VersaPro™ Cream Base, this product is a highly versatile pharmaceutical gel compatible with a wide range of actives. Stable at high temperatures, this clear, viscous gel is non-sticky, free of parabens and is intended for the preparation of gel-cream emulsions.

FEATURES & BENEFITS

SCIENTIFIC DATA	– Optimized delivery of Diclofenac Sodium to the target site (DPSI, March 2012) – Validated Beyond-Use-Dates (BUDs) available
APPEARANCE	Clear, viscous gel with faint odor
FUNCTION	Gel base for pharmaceutical compounding
INTENDED USE	– Highly versatile transdermal delivery vehicle which exhibits a high carrying capacity – Suitable when employing iontophoresis/phonophoresis techniques
API COMPATIBILITY	For lipophilic and hydrophilic drugs (hormones, analgesics, etc.)
TOLERANCE TO API BASE & SALT FORMS	Excellent
APPLICATION TO MUCOUS MEMBRANES	Yes - Vaginal/Rectal
HEAT SENSITIVITY	Stable at 45°C (113°F)
PRESERVATIVE EFFECTIVENESS	Passes USP microbial challenge test <51>

In vitro skin study : Optimized delivery of Diclofenac Sodium

TO THE TARGET SITE WITH MEDISCA'S VERSAPRO™ GEL BASE

INTRODUCTION

The greatest advantage of drug delivery through the skin is the optimization of drug concentrations at desirable sites, while reducing the chances of side effects. Prepared for either local or systemic purposes, the therapeutic efficacy of any topical formulation is greatly contingent upon the nature of the vehicle selected and its compatibility with the concentration and physiochemical properties of the selected drug[1]. It is therefore imperative to find a suitable vehicle that will not only provide means for the drug to permeate beyond the stratum corneum, but that will also allow the active ingredient to reach the target site.

MEDISCA, dedicated to developing and delivering innovative solutions to compounding pharmacists, demonstrated this concept by conducting an *in vitro* skin study which assessed the percutaneous absorption of Diclofenac Sodium from several vehicles, namely its newly designed **VersaPro™ Gel Base** and a comparator product. The aim of this study was to determine an appropriate transdermal vehicle for Diclofenac Sodium based on the percent deposition in the epidermis and dermis targeted sites. This was evaluated by comparing the skin permeation profile for Diclofenac Sodium from the two gel vehicles. Diclofenac Sodium was selected for this study because it is a potent member of non-steroidal anti-inflammatory drugs (NSAIDs) and also exhibits a low permeability through the skin[2].

METHODS

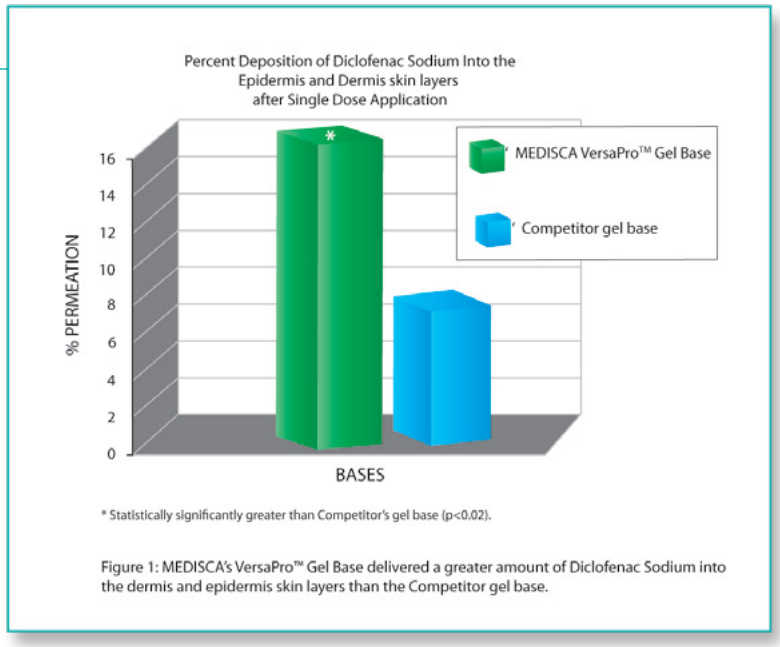
This *in vitro* percutaneous absorption study was conducted by Dow Pharmaceutical Sciences Inc. (DPSI). DPSI used the Bronaugh flow-through diffusion cell method and procedures adapted from the FDA and AAPS Report of the Workshop on Principles and Practices of *in vitro* Percutaneous Penetration Studies: Relevance to Bioavailability and Bioequivalence (Skelly et al., 1987). All evaluated formulations were prepared by incorporating 5% w/w Diclofenac Sodium, BP into formulation bases which were then spiked with radiolabeled (^{14}C)-Diclofenac Sodium at a nominal 1.0 µCi/3.2mg dose.

The clinically relevant dose of 5 mg/cm2 was applied to dermatomed human abdominal tissue from a single donor obtained following elective surgery thus reducing the potential for variability. The 54 flow-through diffusion cells were maintained at a constant temperature of 32°C by use of recirculating water baths and were left undisturbed for a 24-hour exposure period. Fresh receptor phase buffered solution was continuously pumped under the tissue at a flow rate of 1.0mL/hr and collected in 6-hour intervals.

Over the 24-hour period, liquid scintillation analyzing techniques were employed to quantify radioactivity thus determining tissue permeation and deposition results, while illustrating local delivery of Diclofenac Sodium.

RESULTS

Following a 24-hour period, MEDISCA's **VersaPro™ Gel Base** delivered significantly more Diclofenac Sodium to the epidermis and dermis skin layers relative to the competitor's gel base. This study demonstrates that **VersaPro™ Gel Base** is an appropriate delivery vehicle for Diclofenac Sodium as it enables the drug to reach the desired sites of action for local effect.



* Statistically significantly greater than Competitor's gel base ($p<0.02$).

Figure 1: MEDISCA's VersaPro™ Gel Base delivered a greater amount of Diclofenac Sodium into the dermis and epidermis skin layers than the Competitor gel base.

[1] Al-Suwayeh SA, Transdermal delivery of isradipine through excised rabbit skin : Effect of vehicle and drug concentration, Saudi. Pharm. J, 2003; 11(1-2):46-51.

[2] Parsaee S, Sarbolouki MN, Parnianpour M. *In vitro* release of diclofenac diethylammonium from lipid-based formulations. Int J Pharm. 2002;241:185Y190.

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