

# Permeation Study Ketoprofen in Medisca VersaPro™ Anhydrous Base



## Introduction

The skin is the largest organ of the human body, accounting for more than 10% of the total body mass. Skin offers an accessible and convenient site for drug administration. Advancement in topical drug delivery and formulation has allowed for improved bioavailability and increased the range of drugs which may be delivered via transdermal route.<sup>1,2</sup>

The purpose of this study is to evaluate *in vitro* skin permeation of Ketoprofen from an anhydrous transdermal gel, VersaPro Anhydrous Base and a comparable anhydrous gel, through excised human skin.

## Experimental / Methods

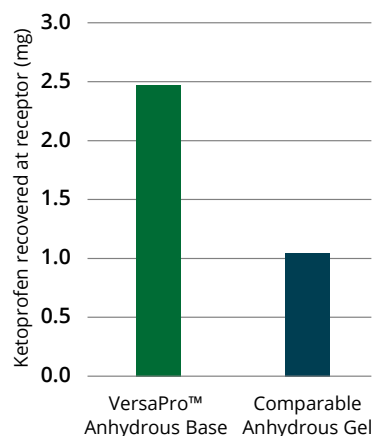
Both test preparations were made using proprietary compounding bases: VersaPro Anhydrous Base and a comparable anhydrous gel. Ketoprofen, USP (10 g) was accurately weighed and levigated with Ethoxy Diglycol (10 mL), then a sufficient amount of base was added for a final weight of 100 g.

An *in vitro* permeation experiment was conducted using a Logan Diffusion System, which is composed of 6 vertical Franz-style diffusion cells. Approximately 100 mg of each test preparation was in direct contact with the skin sample, obtained from a living human donor. Aliquots of receptor medium were taken at 0, 6, 12, 18 and 24 hours during the permeation experiment and assayed using a validated, HPLC method.

Statistical comparison of the data was performed using Student's T-test for paired means, and the significant difference was set at  $p \leq 0.05$ .

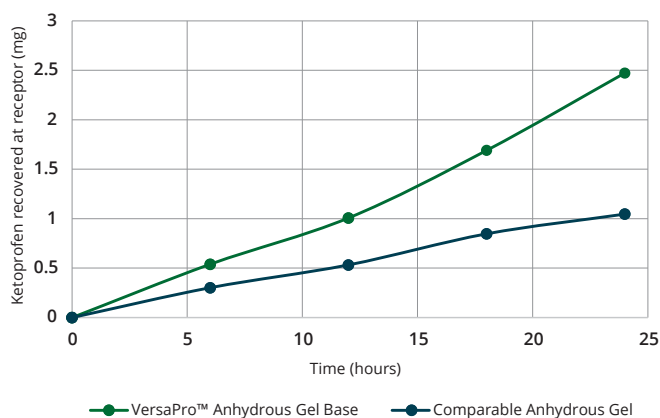
## Results & Discussion

Following a 24h hour period, VersaPro Anhydrous Base had the overall highest Ketoprofen permeation with 2.48 mg reaching the target site, versus the comparable anhydrous gel with 1.05 mg reaching the target site (*figure 1*). The difference in permeation between both vehicles was found to be statistically significant.



**Figure 1.** Overall cumulative Ketoprofen recovered at the receptor site after 24 hours (n = 6). There is a significant difference in Ketoprofen recovered between VersaPro Anhydrous Base and comparable anhydrous gel ( $p \leq 0.05$ ).

Diffusion flux is one of the principal parameters in percutaneous drug permeation that dictates the diffusion process of a drug molecule, as defined by the formula  $J_s = Q_t / At$ , where  $J_s$  is the steady-state flux,  $Q_t$  is the accumulated permeation amount in the receptor cell,  $A$  is the surface area of diffusion and  $t$  is the diffusion time. It is postulated that the flux of a mass diffusion across a given membrane is proportional to the concentration gradient across the membrane and the distance of diffusion.<sup>3</sup>



**Figure 2.** Comparative diffusion curves and cumulative amount of Ketoprofen at 6h, 12h, 18h and 24h (n = 6). VersaPro Anhydrous Base delivered significantly more Ketoprofen to the receptor ( $p \leq 0.05$ ).

The steady-state flux of Ketoprofen was calculated, where the drug concentration gradient across the membrane is viewed as a constant value and the equilibrium of diffusion has been reached. Among the preparations tested, the steady-state flux was highest for VersaPro Anhydrous Base at  $0.1610 \text{ mg/cm}^2\text{h}$ , while the comparable anhydrous gel was at  $0.0681 \text{ mg/cm}^2\text{h}$  (figure 2). This trend is consistent with that of overall Ketoprofen permeation. Statistical comparison indicates that Ketoprofen from VersaPro Anhydrous Base possesses significantly higher diffusion flux.

In conclusion, the *in vitro* permeation experiments were carried out to compare skin permeation of Ketoprofen from two transdermal anhydrous bases. VersaPro Anhydrous Base demonstrated enhanced permeation with overall highest amount of Ketoprofen reaching the target site, as well as highest Ketoprofen flux across the membrane. VersaPro Anhydrous Base is shown to be a promising vehicle to help promote absorption of certain APIs across human skin.

## References

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3. Brodin B, Steffansen B, Nielsen CU. Passive diffusion of drug substances: the concepts of flux and permeability. *Molecular Biopharmaceutics*. 2009. Chapter 3.2: 135-152.



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