

Effect of barrier integrity on topical/transdermal delivery of diclofenac sodium via iontophoresis

Amruta A.Dandekar¹, Madhura S. Kale¹, Mahadevabharath R. Somayaji², Harsha T. Garimella², Ajay K. Banga¹

¹ Center for Drug Delivery Research, Department of Pharmaceutical Sciences, College of Pharmacy, Mercer University, Atlanta, GA 30341

² CFD Research Corporation, 701 McMillian Way, Huntsville, AL 35806, USA

INTRODUCTION

Skin: barrier for diffusion of drugs

Various skin diseases lead to compromised skin barrier

Enhanced absorption of drugs: side-effects & toxicity

Increased risk in case of physical enhancement techniques

Importance of comparison between normal vs compromised skin

- Application of a drug product on compromised skin may result in altered drug delivery leading to potential systemic toxicity
- Here we used a model nonsteroidal anti-inflammatory drug-diclofenac to compare permeation from normal vs compromised skin
- We investigated the effect of barrier integrity on the topical and transdermal delivery of brand: generic pair of diclofenac sodium (model anti-inflammatory drug) via iontophoresis



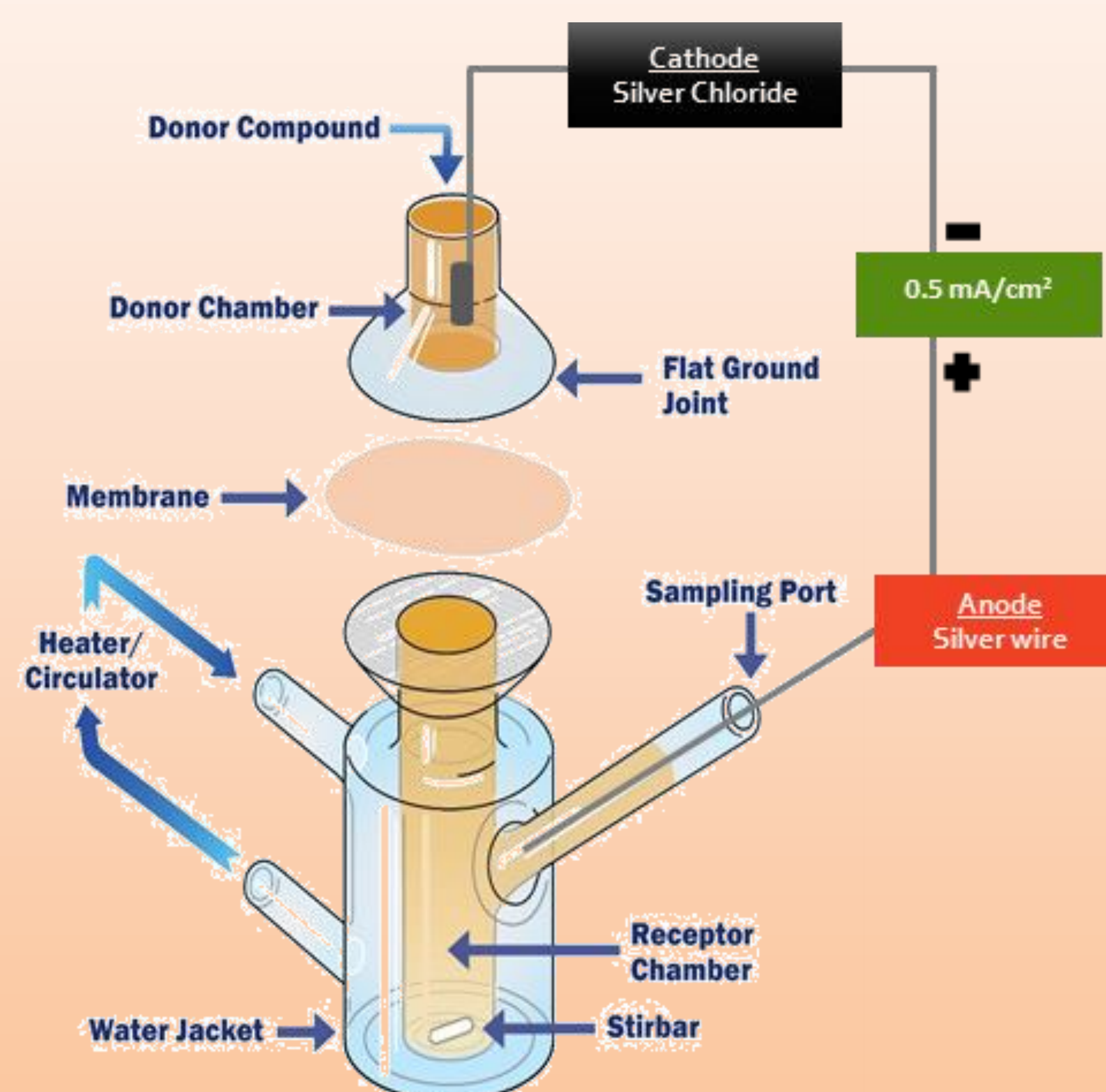
Marketed brand and generic formulations of diclofenac sodium (1% topical gel)

METHODS

- In vitro permeation studies were performed using static Franz diffusion cells
- A compromised skin model was created using ten tape strips on dermatomed human skin
- Delivery of diclofenac into and across normal and compromised skin was compared using marketed brand (Voltaren®) and generic (Amneal) formulations

Parameters for in vitro permeation study

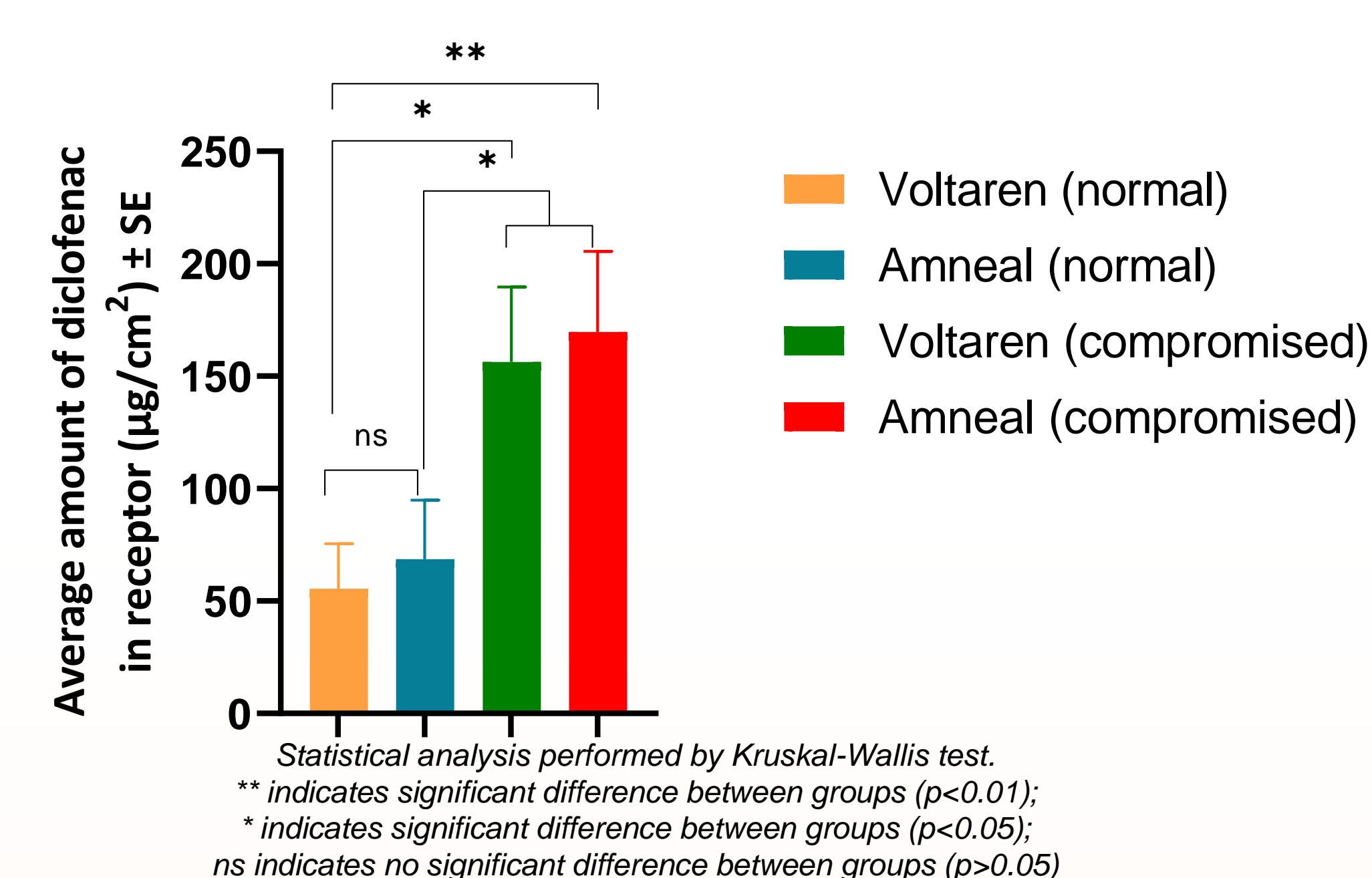
Cathodal iontophoresis	0.5 mA/cm ² ; 2h followed by passive delivery till 6h
Donor Solution	700 µL of marketed brand/generic formulation of diclofenac sodium
Receptor Solution	5 mL of 10mM PBS
Analysis	RP-HPLC method



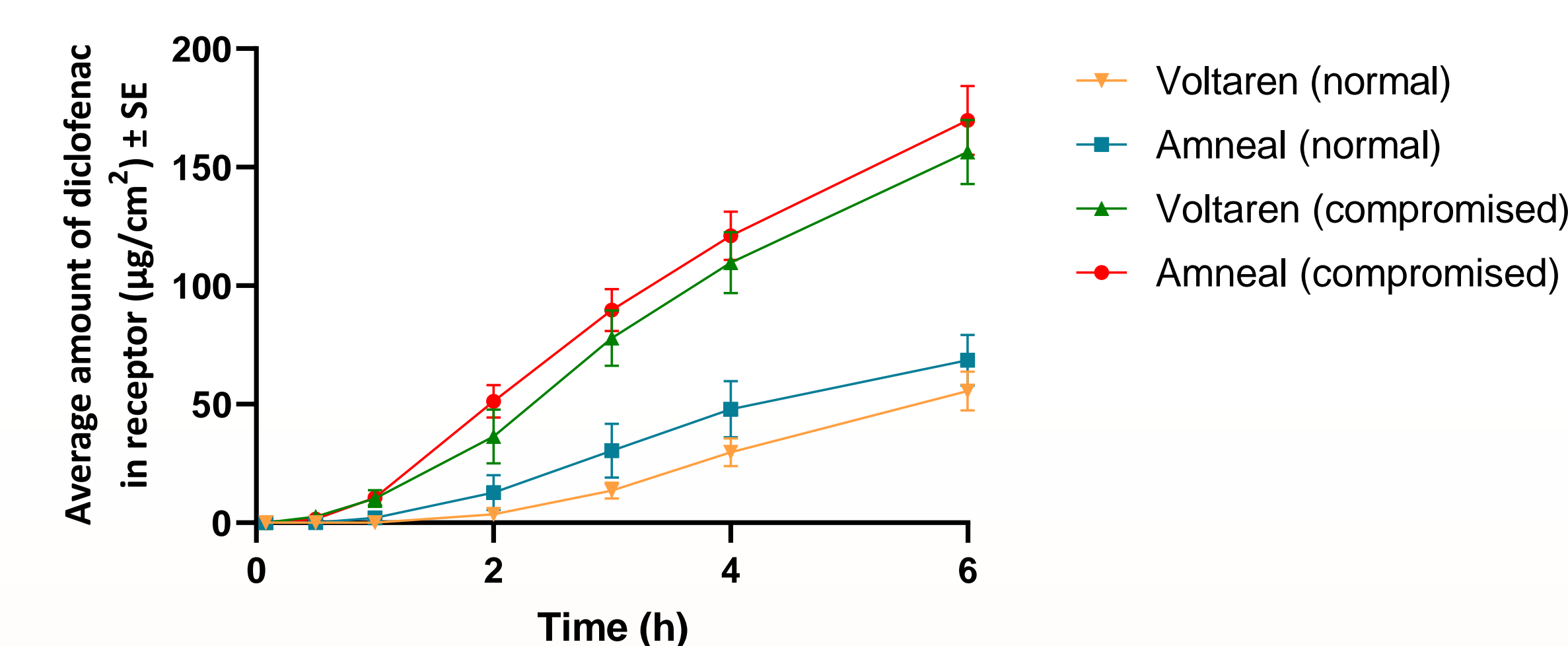
Cathodal iontophoresis

RESULTS

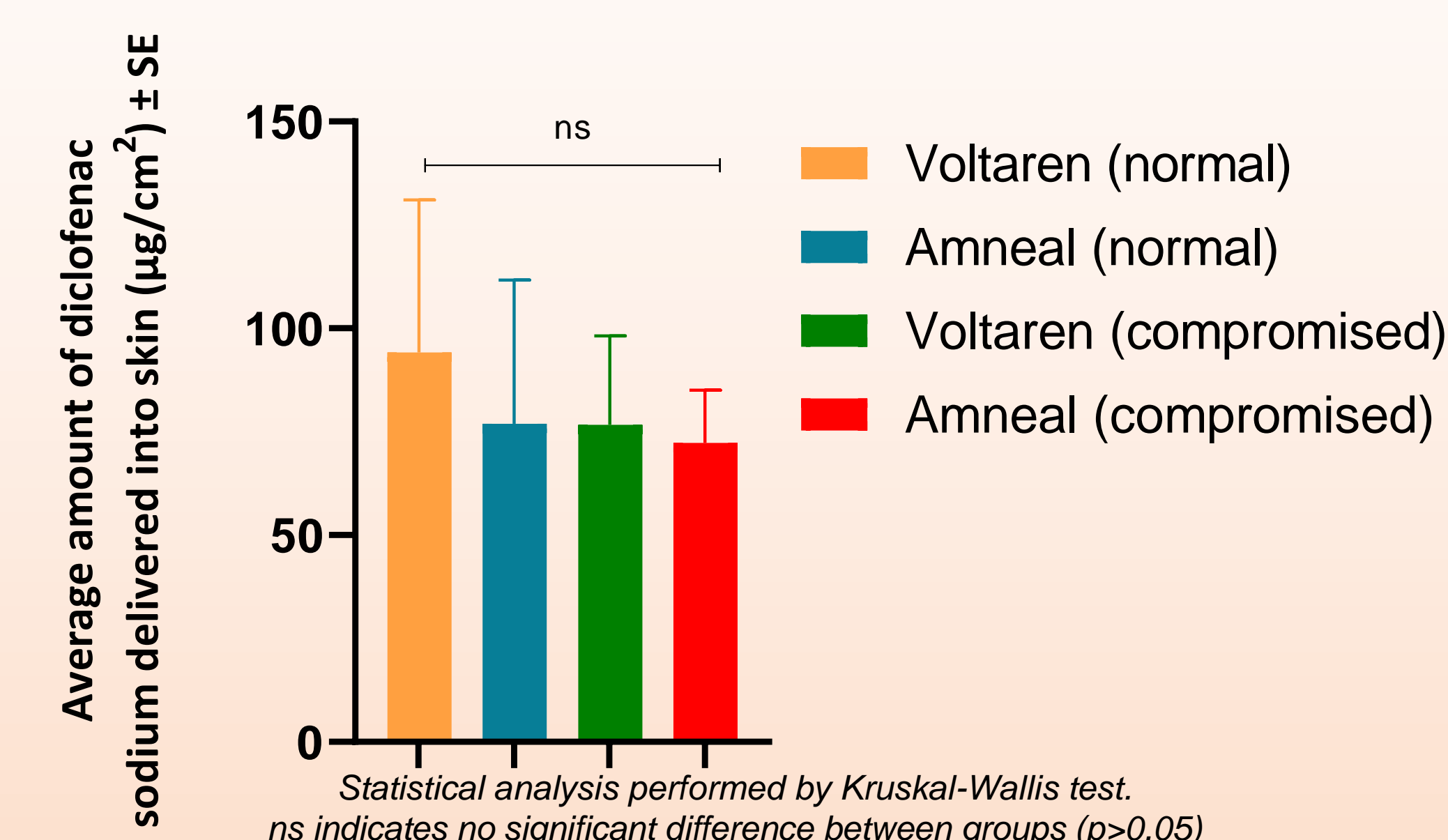
Average cumulative amount of diclofenac sodium delivered into receptor in 6 h



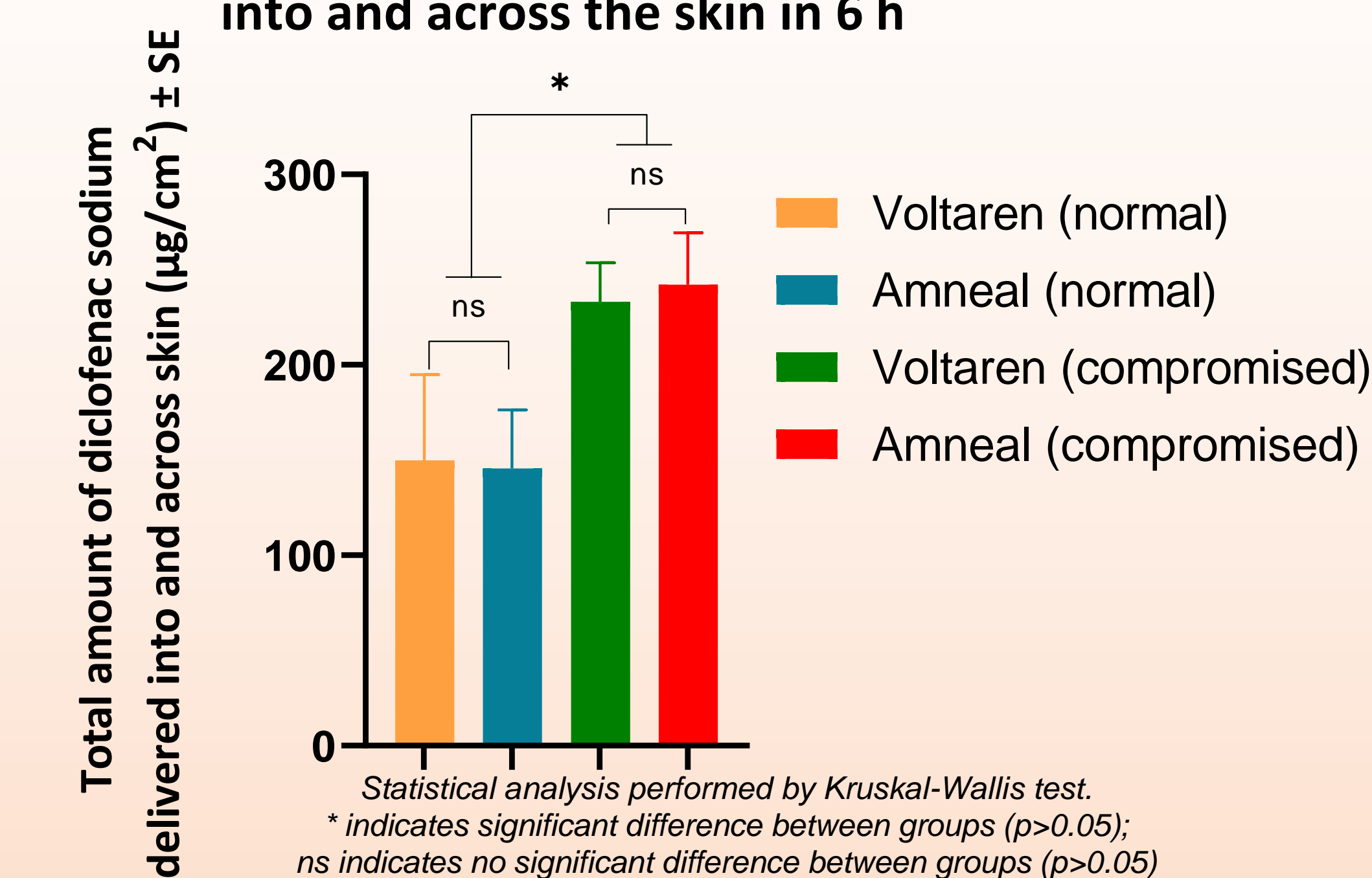
Permeation profile of diclofenac sodium across normal and compromised skin: Voltaren vs Amneal



Amount of diclofenac sodium delivered in skin after 6 h



Total amount of diclofenac sodium delivered into and across the skin in 6 h



CONCLUSION

- ✓ No significant difference observed between brand and generic formulations for delivery of diclofenac sodium via normal and compromised skin
- ✓ The total delivery of diclofenac was significantly higher for the brand-generic pair into and across compromised skin as compared to normal skin indicating the effect of barrier integrity on delivery of diclofenac sodium
- ✓ There was no significant difference in skin delivery of diclofenac sodium for normal and compromised skin

Acknowledgment

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