INTRODUCTION

Wound healing is an intricate, modulated series of processes that maintain the integrity of the skin barrier. Diseases such as diabetes disrupt these processes involved in natural wound healing resulting in the development of a chronic wound.\(^1\) To date, REGRANEX® Gel (becaplermin) remains the only FDA approved topical treatment for chronic wounds in the form of diabetic foot ulcers and only available in the United States.\(^2\) Chronic wound healing remains an area of research interest and need for advancement. Our previous studies have demonstrated that digitoxigenin, a cardiacoid steroid, improved wound healing in a diabetic wound model by affecting many key events in a wound healing process, such as re-epithelialization and collagen deposition.\(^2\) The studies also suggested the importance of olive oil and alginate in the formulations. In efforts to improve the formulation, we used a unique bigel as a platform to be able to load drugs of different physicochemical properties.

BACKGROUND

As this research was to develop a formulation platform for drug delivery, digitoxigenin was not utilized in this project. Instead, we used benzocaine and diclofenac sodium as the model drugs of different physicochemical properties. Benzocaine is relatively hydrophobic and diclofenac sodium is relatively hydrophilic. Bigels contain a hydrophobic organogel phase and a hydrophilic hydrogel phase. In this study, the organogel phase was 15% Span 60 in olive oil to load the hydrophobic drug and the hydrogel phase was 2% alginate in phosphate buffered saline (PBS) to load the hydrophilic drug.

OBJECTIVES

To develop and characterize the formulations for stability and in vitro release of model drugs using Franz diffusion cells.

FORMULATION

The hydrogel phase (A) and the organogel phase (O) were mixed at different ratios using a mortar and pestle to prepare the bigels with trituration method. The bigels were stored at room temperature for physical stability testing.

IN VITRO RELEASE STUDY

The Franz diffusion cell has a donor compartment and a receptor compartment. A 0.45 µm filter membrane was assembled between the donor and the receptor as a physical support to the bigel formulation that was loaded to the donor. PBS was added to the receptor as a receptor solution, which was magnetically stirred and maintained at 32°C. Samples of 2 mL was taken from the sampling port at 1, 2, 3, and 4 hours. The same volume of fresh PBS was added to the receptor to keep the volume of the receptor solution constant. The samples from the receptor were assayed for drug concentration. The cumulative amount of drug at different time points was plotted against time to obtained the release profiles. As shown in Figure 3, both drugs showed linear release from the bigel formulation.

CONCLUSIONS

Based on the data, a bigel of both hydrophobic and hydrophilic properties can release a model drug at a constant rate.

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REFERENCES