In Vivo Evaluation of Wound Healing by Phenytoin 2% and Misoprostol 0.0024% Topical Hydrogel (EctoSeal P2G) and Poloxamer Gel

Introduction:

Chronic wounds are a major clinical problem that leads to considerable morbidity and mortality worldwide. Newly developed products are subjected to both *in vitro* and *in vivo* studies to ensure safety and efficacy in wound management. A commonly used *in vivo* test is the diabetic mice wound healing model (BKS-db), including both control group and test group(s).

Methodology:

The *in vivo* evaluation test was conducted by GemPharmatech Co., Ltd, following ethics approval: certification number 511214900020707; animal protocol GPTAP20230810-4; project number PO-GJC052023078305-01. The test products Phenytoin 2% and Misoprostol 0.0024% Topical Hydrogel (EctoSeal P2G) (PCCA Formula 14811) (A), and Phenytoin 2% and Misoprostol 0.0024% in Poloxamer Gel (B) were provided by PCCA. C57BL/6J/BKS-db male diabetic mice (n=12) were divided in 3 groups (n=4) according to blood glucose and body weight: control group, test group A and test group B. All mice were anesthetized and the hair on their dorsal skin was shaved. Two full-thickness excisional skin wounds were made to the back of each mouse using an 8-mm biopsy punch. Subsequently, 300 mg of the test product A and B were applied daily on the skin wounds of the mice in the test groups A and B, respectively, for a total of 9 days. The photos below show the skin wounds on days 0, 3 and 9. The wound areas were measured, normalized as percentage of day 0 and expressed as mean ± standard deviation (mean ± SD). The statistical analysis was performed using a T-test in which $p < 0.05$ is considered statistically significant.

Results and Discussion:

The mice were successfully treated for 9 days in the test groups A and B, as shown in Figures 4-6 and 7-9, respectively. The mice in the control group (Figures 1-3) developed a slower wound healing response, in comparison to the treated mice. The test group A [Phenytoin and Misoprostol Topical Hydrogel (EctoSeal P2G)] – demonstrated a more effective treatment response in comparison to the test group B (Phenytoin and Misoprostol in Poloxamer Gel). Table 1 shows a lower mean percentage of relative wound area at day 9 for the test group A (49.67%), when compared to the test group B (71.54%) and the control group (75.44%). These mean percentage results obtained are consistent with Figures 1-9.

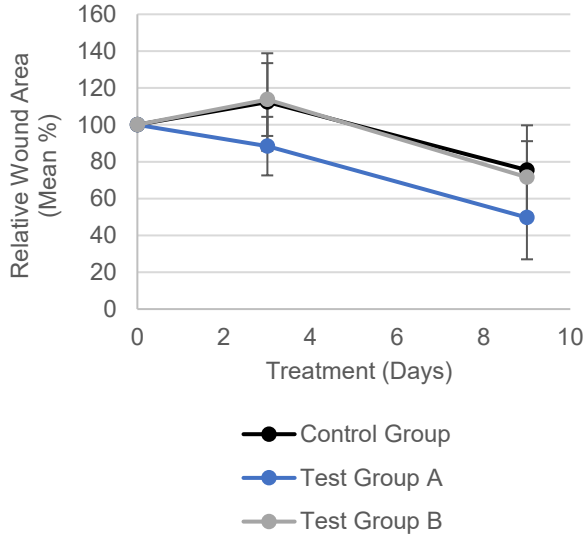
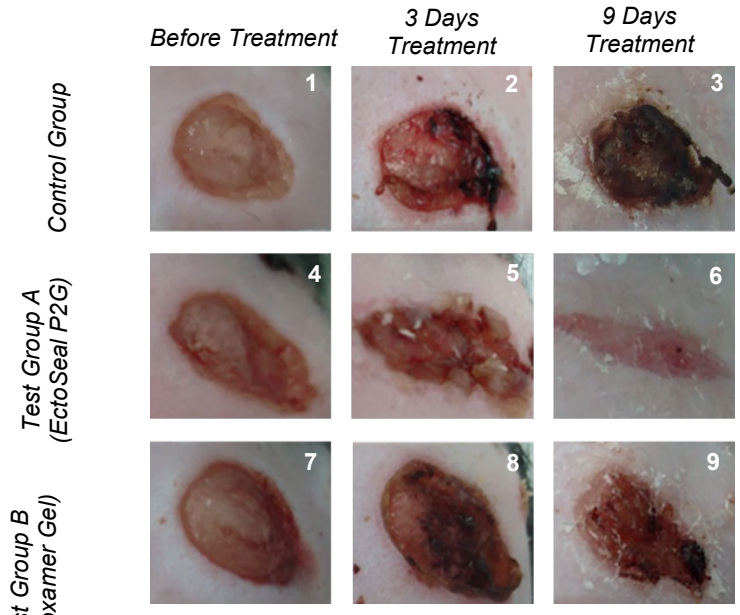


Table 1. *Mean percentage of relative wound area for the mice in the control group and test groups A and B, for a total of 9 days.*



Figures 1-9. *Digital photographs of the wound areas for selected mice in the control group and test groups A and B, at day 0 (before treatment) and days 3 and 9 of treatment.*

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