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In Vitro Evaluation of the Filmogenic and Barrier Retention Capability of a 3D Cross-linked Formulation Based on a Novel Sodium Hyaluronate Lipoate Medical Device in Gel Form

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Abstract

Aphthous stomatitis (canker sore) is painful ulcerations of the oral mucosa that can affect the quality of life of affected people. The use of medical devices in gel form has become a valuable alternative to drug-based approaches in the treatment of aphthous stomatitis (canker sores). The presented study aimed to investigate the filmogenic capability and the barrier retention of a 3D cross-linked formulation based on a novel sodium hyaluronate lipoate medical device gel formulation, produced by BMG PHARMA. To investigate its efficacy in forming and retaining a barrier effect over time, an in vitro approach based on the well-established Franz cell system was applied. In particular, the BMG gel (BMG0725) product was compared with two commercial formulations available on the Italian market, Alovex® Gel and Tantum® Verde SOS Afte Gel. According to our results, the sodium hyaluronate-based gel of BMG products line showed a better barrier retention compared to the two commercial formulations: indeed, while the barrier efficacy for BMG gel medical device (BMG0725) was observed for up to 18 h, for the other two formulations the barrier efficacy lasted up to 6 h. All tested formulations readily form a barrier following application. Within the limitation of our experimental design, it can be concluded that the barrier forming sodium hyaluronate-based formulation of BMG line is effective in the treatment of aphthous stomatitis, since it protects the aphthae from the oral environment for a long period following application, limiting its application frequency while increasing the patient's compliance as a consequence.

Keywords: /

Introduction

Materials and Method

Formulation tested

Methods

Evaluation of the medical device lmogenic capability and barrier e ect retention:

Table 1: List of tested medical devices.

Formulation	Application Method
BMG Gel (BMG0725 Gel)	Gel
Alovex® Gel	
Tantum® Verde SOS Afte	

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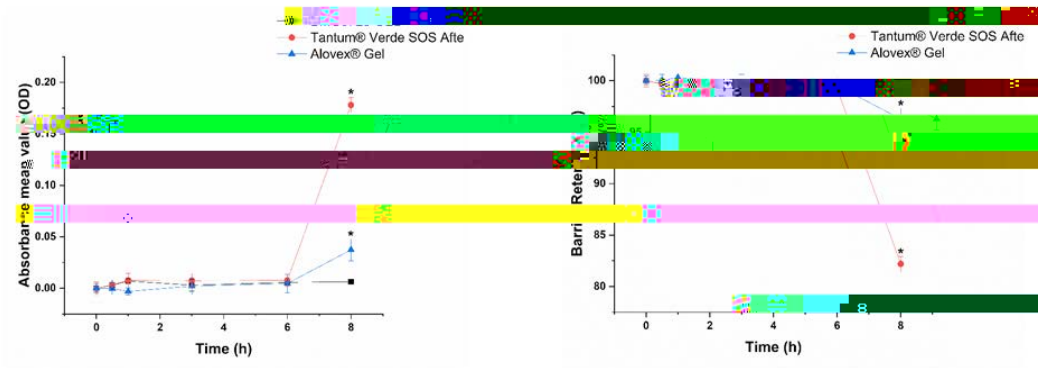
Statistical Analysis:

Results

BMG gel medical device (BMG0725) and commercial formulations lmogenic capability and barrier e ect retention

Figure 1, Table 2 and Table 3,



(A) (B)

Figure 1: Evaluation of the barrier e fect of tested gel medical devices. (A) Absorption kinetic of 0.5 % Trypan Blue solution permeated in the acceptor chamber through the fIm/barrier and (B) barrier retention over time of tested gel medical devices. BMG0725 GEL (Black Square and line), Tantum® Verde SOS Afte (red circle and line) and [illegible] blue triangle and line). * p < 0.05A Ď Min n ! * { Å Ď ж Ď Ə {

(Figure 1 and Table 2).

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