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Short communication

Preliminary evaluation of alginate/pectin buccal films with posaconazole prepared by solvent casting technique

Marta Szekalska, Katarzyna Olechno*, Katarzyna Winnicka

Medical University of Bialystok, Department of Pharmaceutical Technology, Mickiewicza 2c, 15-222 Białystok, Poland

Introduction

Mucoadhesive buccal films (MBFs) represent a modern, solid drug dosage form appearing as polymeric strips intended to be placed in the oral cavity. Being designed for maintaining both local or systemic drug effects, MBFs seem to be a promising alternative to conventional oral formulations (Shipp et al., 2022). Posaconazole (POS) is a new triazole antifungal agent with broad spectrum of antifungal activity against commonly encountered fungal species (Chen et al., 2020). Sodium alginate (ALG) possesses antioxidant, anti-inflammatory and antimicrobial properties, which enhance the activity of antifungal drugs (Cattelan et al., 2020). Pectins (PEC) are natural ionic polysaccharides found in the cell wall of terrestrial plants (Freitas et al., 2021). Both, ALG and PEC, are characterized by non-toxicity, is biocompatibility, gelling, swelling and mucoadhesive properties. ALG-based MBFs are characterized by low flexibility and poor mechanical properties (Szekalska et al., 2019). Therefore, the aim of this study was to evaluate impact of PEC addition on ALG MBFs characteristics**.**

Materials and methods

Films preparation: MBFs were obtained by the solvent casting method. The ALG/PEC mixtures with POS (with content 2 mg/cm^2) were poured into plexiglass molds and dried in the oven at 40 °C for 24 h, then cut into pieces of 2 x 2 cm. Composition of designed MBFs is presented in Table 1.

Measurement of film weight, thickness and moisture content: Weight uniformity was calculated using analytical balance (Mettler Toledo, Switzerland), thickness was measured using thickness gauge (Mitutoyo, Japan), and the moisture content - with using moisture analyzer balance (Radwag WSP 50SX, Poland).

Table 1. Composition of designed MBFs.

Formu-lation	ALG (g)	PEC (g)	Glyce-rol (g)	POS (g)*	Purifi-ed water (up to)
P1	2	–	1	–	100.0
P2	1.5	0.5	1	–	100.0
P3	1	1	1	–	100.0
P4	0.5	1.5	1	–	100.0
F1	2	–	1	0.649*	100.0
F2	1.5	0.5	1	0.649*	100.0
F3	1	1	1	0.649*	100.0
F4	0.5	1.5	1	0.649*	100.0

*to provide 2 mg POS/cm^2

Drug content uniformity: POS content uniformity was evaluated spectrophotometrically using Genesys 10S UV-Vis spectrophotometer (Thermo Scientific, USA) (Szekalska et al. 2019) at the wavelength of 260 nm.

Mechanical properties: Mechanical properties were examined using Texture Analyzer TA.XT.Plus (Stable Microsystems, UK) and expressed by three different parameters: percent of elongation (E%), tensile strength (TS) and Young's modulus (E) (Szekalska et al.)

Mucoadhesive properties: Evaluation of mucoadhesiveness was performed using TA.XT.Plus Texture Analyzer (Stable Micro Systems, UK) and expressed as the maximum detachment force (Fmax) and the work of mucoadhesion (Wad) (Szekalska et al. 2019).

*katarzyna.olechno@umb.edu.pl

Statistical analysis: Data were assessed by Statistica 10.0 (StatSoft, Tulsa, OK, USA) using one-way analysis of variance (ANOVA) or a Kruskal-Wallis test.

Results and discussion

The study proved that ALG/PEC MBFs obtained by the solvent casting technique were characterized by uniformity of weight, size, thickness and drug content. Moisture content below 10% in all formulations was reported. Mechanical properties, expressed as tensile strength (TS), percent of elongation (E%), and Young's modulus (E) are presented in Table 2. After PEC addition, reduced hardness and increased flexibility of ALG MBFs were observed.

Table 2. Mechanical properties of MBFs.

Formulation	TS (MPa)	E% (%)	E (MPa)
P1	37.7±7.8	5.8±1.9	8.7±1.0
P2	33.2±1.7	10.0±2.4	9.8±1.4
P3	21.7±2.0	2.0±1.8	4.1±1.5
P4	16.0±2.1	15.5±1.5	3.9±0.7
F1	18.7±4.3	16.3±2.0	4.3±1.4
F2	17.6±5.0	9.0±2.5	3.8±0.8
F3	13.0±3.3	12.3±3.8	3.0±0.4
F4	11.3±0.6	15±0.9	2.0±0.8

The presence of PEC had only little effect on the mucoadhesiveness in case of placebo formulations, but in POS-loaded formulations, according to the obtained statistical data, significantly lower ($p < 0.05$) values of Fmax and Wad were observed (Figure 1).

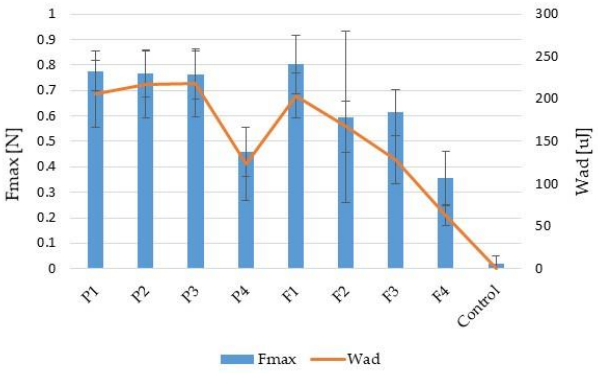

Fig. 1. Mucoadhesive properties of MBFs.

Conclusion

It was proved that PEC addition reduced hardness, increased flexibility of ALG MBFs and decreased mucoadhesiveness of POS-loaded formulations.

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