

BUCCOADHESIVE FILMS AS A NEW DOSAGE FORM FOR TRANSMUCOSAL DELIVERY OF ONDANSETRON

^{a,*}Trastullo R., ^bSaladini B., ^aAbruzzo A., ^aCerchiara T., ^aLuppi B., and ^aBigucci F.

^aUniversity of Bologna, Dept. Pharmacy and Biotechnology, Via San Donato, 19/2 - 40127 Bologna (Italy)

^bPolyCrystalLine srl, Via F.S. Fabri, 127/1 – 40059 Medicina (Italy)

[*ramona.trastullo2@unibo.it](mailto:ramona.trastullo2@unibo.it)

Purpose

The lack of appropriate pediatric formulations has been identified as a major obstacle for the study and use of drugs in children. In general, there is a need in pediatrics to develop flexible dosage forms able to allow minimal dosage and frequency, and characterized by minimal impact on lifestyle, and easy and reliable administration.

The aim of this study was the development of buccoadhesive polymeric films for transmucosal delivery of ondansetron hydrochloride (ODS), a serotonin 5-HT₃ receptor antagonist widely used in the management of nausea and vomiting.

Methods

An aqueous solution of hyaluronic acid (HA; MW 1800-2300 kDa), an aqueous solution of type B gelatine from bovine skin (GEL; MW 50 kDa) and an acid solution of chitosan (CH; MW 150 kDa) were separately added to an aqueous solution of hydroxypropylmethylcellulose (HPMC) at different weight ratios (10:0, 9:1, 7:3, 5:5, 0:10; HPMC:HA or HPMC:GEL or HPMC:CH). After addition of a child-appropriate dose of ODS, each mixture was stirred at room temperature for 24h, spreaded on a Petri-dish and dried at 50°C for 6h.

The films were characterized for their morphology (SEM), physical state (DSC, XRPD), mucoadhesion potential (residence time), water uptake ability (gravimetric method) and drug release (modified “paddle over disk” method). Moreover, *in vitro* permeation studies will carry out to evaluate drug permeation through biological membranes (Franz-type diffusion cell).

Results

All films exhibited a smooth surface and a dense and homogeneous cross-section. Characterization at the solid state indicated an amorphous molecular structure. The presence of HA, GEL and CH did not improve the mucoadhesive properties of HPMC film. The inclusion of GEL and CH in HPMC film enhanced *in vitro* drug release with respect to the inclusion of HA, although HPMC:HA films showed the highest water uptake. This behaviour could be attributed to the high viscosity of the HPMC:HA films in the gel state.

Conclusions

HPMC can be mixed with HA, GEL and CH to obtain buccal films for the administration of ODS in children. The selection of suitable polymeric mixture and appropriate weight ratio allowed the modulation of film functional properties, suggesting that these formulations could be used as a novel technological platform for pediatric medicines.