

Biocompatible polymer films for the vaginal delivery of biologically active compounds

Prof. Giovanni Puglisi – University of Catania – Consorzio TEFARCO Innova

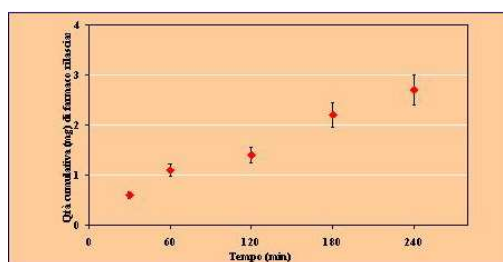
Drug delivery films are obtained using mucoadhesive, biodegradable polymers, like mixtures of PVA and hyaluronic acid. The systems can be loaded with drugs or other biologically active compounds, for the local treatment of vaginal affections or intravaginal administration of systemically active drugs.

Formulation	1	2a	2b	3	4	5	6
<i>Ingredients</i>							
PVA	1%	1% 30%	1% 50%	0.1%	0.1%		
HA		1% 70%	1% 50%	0.1%		1%	
HPMC							2.5%
PEG400				17%	17%		
Distid. water	q.b.	q.b.	q.b.	q.b.	q.b.	q.b.	q.b.

Percent composition (w/v) of the studied films

FORMULATION	Bioerosion times	Swelling degree after 1 h at pH 5.01
1	quick (< 1h)	Disciolto
2a	4 h	2.13
2b	2 h	2.6
5	quick (< 1 h)	dissolved
6	quick (< 1 h)	dissolved

Swelling and bioerosion times of the prepared films



Metronidazole release time course from the film # 2a in simulated vaginal fluid (pH 4.5; 37°C)

1. Description of the product

Intravaginal administration is particularly appropriate for active substances, associated to female vaginal pathologies such as infections, but it can be used also for systemic administration, i.e. for peptide and vaccine delivery.

The advantages of intravaginal way are:

- provides an accessible and not invasive site
- consists of highly perfused tissues
- avoid the hepatic first-pass
- is very permeable with enhancers with appropriate chemical and physical characteristics.

This project consists in the realisation of polymeric films based on a mixed composition of PVA and hyaluronic acid (HA). Both are biocompatible and biodegradable materials, used in lots of biomedical applications.

Hyaluronic acid gives to system the mucoadhesivity necessary to grant permanence in situ after the application. In this way drug and active substances loaded in the films can be better released.

2. Innovative aspect of the product

The transmucosal release of drugs represents one of the most innovative and promising areas for the non parenteral administration of drugs as proteins and peptides of biological derivation. In this area the

intravaginal administration captured the attention of researchers for the favourable characteristics of this tissue.

The result of this project could be both a local application for the care of pathologic affections (i.e. mycotic and bacterial infections or inflammatory states), para-physiological states of vaginal area and a systemic administration of active agents through a not invasive way (a very vascularized and permeable way, favourable to the stability of drugs).

This research can interest not only the pharmaceutical industry – for its therapeutic, topic and systemic applications – but also that deals with medical devices, destined to prevention and treatment of typical female diseases (for example vaginal dryness, irritative states associated to menstrual cycle, etc

3. Main advantages of the offer

The advantages expected from this approach, compared to actual systems, are:

- Simple and economic preparing procedure
- Modulation of release of active substances. The composition, the productive procedure and rheologic and physico-chemical properties can be easily adapted to the used drugs.
- Low environmental impact because the preparation is made in aqueous media.

The industrial application of the project can improve the efficacy of existing therapeutic treatments.

4. Technology key words

Polymeric films, PVA, hyaluronic acid.

5. Current Stage of Development

Developed phase - Tested in laboratory.

6. Intellectual Property Rights

The product of the research is still uncovered by patent

Technical and scientific publications

C. Giannavola, C. Bucolo, A. Maltese, D. Paolino, M. A. Vandelli, G. Puglisi, V. H. L. Lee, M. Fresta.

Influence of preparation conditions on acyclovir-loaded poly-D,L-lactic acid nanospheres and effect of PEG coating on ocular drug bioavailability. Pharm. Res. 20, 584-590, 2003

CONTACT

info@biopharmanet.eu

Tel.: +39 0521 905073 Fax: +39 0521 905006