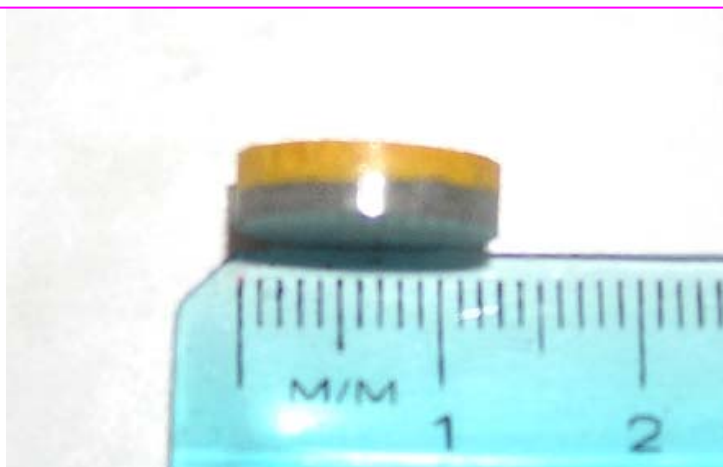


Bilayer-tablets for the oral controlled release of drugs to ruminants

Prof. Paolo Giunchedi – University of Sassari – Consorzio TEFARCO Innova

Rumen-stable devices ensure a protection of active ingredients against chemical degradation and bacterial fermentation processes that occur in the rumen. It is here described the preparation of new pharmaceutical dosage forms for veterinary use, bilayer-tablets as rumen-stable oral delivery system for the controlled release of active ingredients to ruminants. The tablets are designed to be rumen stable and to target a controlled release in the intestinal tract of the ruminant.



Bilayer – tablets for the oral controlled release of drugs to ruminants

1. Description of the product

The rumen-stable devices are constituted by tablets composed of two layers: layer A (“high density layer”) characterised by a sufficient density to avoid the effects of rumination; layer B (“release layer”), containing the active ingredient, designed to be rumen stable and to target a controlled release in the intestinal tract of the ruminant. Layer B can be designed with different compositions to achieve different release kinetics. The veterinary dosage form proposed here has a structure that can have a possible general use and broad application for the delivery of drugs or nutritional agents to ruminants.

2. Innovative aspect of the product

In recent years, veterinary controlled-release systems have been developed for the delivery of anthelmintics, antibiotics, antiparasitic drugs, vitamins, growth promotion, and nutritional agents. Controlled-release bilayer tablets based on poly (ϵ -caprolactone) or polymethylmethacrylates (Eudragit RS) containing folic acid are prepared in this study. As shown by *in vitro* tests, these systems displayed a good stability toward the rumen and the abomasal environments and provided a controlled release in the intestinal simulated conditions. The veterinary dosage forms proposed here have a structure (two layers, the first characterized by high density and the second designed to modulate the release) that can have a possible general use for the delivery of drugs or nutritional agents to ruminants. On the other hand, as these systems are composed of excipients [poly (ϵ -caprolactone) and polymethylmethacrylates], which allow the passage and the controlled release through the gastrointestinal tract, they may find a broader application both in veterinari and human fields.

3. Main advantages of the offer

Radiological preliminary tests show that these prepared bilayer tablets are able to be retained in the reticulum–rumen tract of the sheep. These systems permit a reduced frequency of dosing, with a consequent

decrease of animal stress, and they also can avoid exhausting procedures of administration. development of veterinary dosage forms.

4. Technology key words

Bilayer tablet; High-density layer; Release layer; Rumen-stable system; Poly (ε-caprolactone); Polymethylmethacrylates

5. Current Stage of Development

Development phase – laboratory tested ; Available for demonstration – field tested

6. Intellectual Property Rights

Product of the research is still not covered by patent

Technical and scientific publications

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CONTACT

info@biopharmanet.eu

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