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New concepts in protein formulation for oral administration

Every year there are new therapeutic applications of proteins as carriers for bioactive agents or as active principles in treatment of various dysfunctions. Particular characteristics of proteins represent noteworthy cases of Molecular Self-Assembly in nature. Proteins drastically change their structure following various processing events such as heating, pH modification or action of ionic agents. These structural alterations can be useful for the utilisation of proteins as carriers (micro- and nano-spheres) for various bioactive agents or as biomedical materials (suture for surgery, skin grafts). However, these drastic alterations can be damaging for orally administered proteins susceptible to gastric acidity and proteolytic denaturation. New approaches in protein formulation are needed related to specific requirements for these biomolecules which can lose their activity due to processing temperature or to residual humidity remaining after coating. The proposed concepts are related to compacted pharmaceutical compositions containing one or more therapeutic enzymes designed for oral administration. The biopharmaceutical product could be under monolithic or multiparticulate forms and obtained without the application of an external polymer-based enteric coating. The self-assembled uncoated proteins are able to generate *in situ* an outer layer which will offer a gastro-protection and keep product availability. An example of excipient-free pancreatic enzyme will be discussed. The colonic delivery of an anti-inflammatory enzyme system based on a vegetal histaminase and on catalase will be also presented.

Biography

Mircea Alexandru Mateescu has a PhD from Bucharest Polytechnic University and is a receiver of a "Honorary Laurea" from Rome University "La Sapienza". He has been a full-time Professor at UQAM since 1994. His research relates to Multifunctional Proteins and to Drug Targeting. He is the Co-inventor of more than 30 patents covering therapeutic enzymes and new excipients for drug delivery. He has developed fruitful collaborations with pharmaceutical companies and was involved in several technological transfers. He published more than 130 papers in reputed journals, one book and 8 book-chapters. He is the holder of Bombardier Prize (1999) for Technological Innovation, of Venezia Prize (Italian Chamber of Commerce, 2012), and Research-Career Prize (UQAM, 2014).

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