



## ENTERAL FLEXIBLE FILMS FOR PREPARATION OF CAPSULES

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### Product description

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Modifying the release time of the active substance of the pharmaceutical is an important factor influencing the effectiveness and efficiency of the therapy. The use of gastro-resistant capsules allows protection of active substance against the action of gastric juice, release and absorption only in the intestines. In addition, this form of drug administration protects the gastric mucosa from the irritating action of the active substance. Gastro-resistant capsules are coated with a substance from insoluble polymer with an acidic pH, and soluble at pH greater than 6 gastric juice environment. Unlike tablets, this technology does not work in case of capsules which are technologically difficult to coat.

In response to the needs of the pharmaceutical market, we propose an innovative way of obtaining gelatinous mass, from which soft gelatine capsules can be made, that are characterized in gelatine casing being insoluble in the gastric juice and which releases the contents when dissolved in the gastric juice.

### Key words

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enteric capsules, soft capsules, gelatine films

### Legal status of the product

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– Polish Patent Office:

Patent application submitted (2016) – entity solely entitled to the invention – Medical University of Gdańsk

– European Patent Office:

European patent application submitted (2017) – entity solely entitled to the invention – Medical University of Gdańsk

### The aim of the offer

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The aim of the offer is an aqueous composition for making enteric films for manufacturing of soft capsules characterized by delayed release of active substances. In addition, the descriptions of the method of making the gelatine film for the capsule preparation are part of the invention.

### Foregoing funding of studies on the product

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The project was not funded by other sources.



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### *Analysis of competition on the market*

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IMS Health anticipates that in 2018 the value of the global market for medicines and dietary supplements, including gastro-resistant capsules, will increase significantly and reach 1.3 trillion US dollars. From the available reports it has been noted that from amongst solid forms of drugs more than half of consumers choose capsules.

No method has been invented to date for the preparation of gastro-resistant soft capsules that serve to close liquid or semi-solid fillings. Due to their considerable elasticity, the applied coating breaks. No attempts to date have succeeded to modify the composition of gelatine coating so that the soft capsule does not dissolve in the stomach and instead, dissolves in the intestines' environment.

### *Advantages of the product*

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In evaluating innovativeness and competitive advantage, it must be noted that it has not been previously reported in scientific publications how to produce soft, gastro-resistant capsules. Attempts to modify the gelatine casing ensuring its stability in the acidic environment have been made, however, they have not been successful or ended with such a change in the elasticity of the gelatine film that it could not be applied in the manufacturing of soft capsules.

The indicated improvement of physical and mechanical properties of the gelatine film combined with the easy way of manufacturing process makes the present solution useful and desirable for use in soft capsule manufacturing technology.