DESCRIPTION FOR THE GENERAL PUBLIC

Capsules are popular oral drug forms. The so called hard (two-piece) and soft capsules (single-piece) are distinguished. The latter are produced in a single-stage process, in which capsules are formed from a soft gelatin ribbon, and, right after filling with active substances, closed by sticking together edges of two "halves" of the capsule. Similar to tablets, for certain active drug substances, that are labile in acidic environment or have irritating effect, it is appropriate to prepare so called enteric (gastro-resistant) capsules, from which the drug is released only in the intestine. This effect is achieved by e.g. coating of the tablets with polymers that are acid-insoluble, but dissolve rapidly at neutral pH (in the intestine). Unfortunately, in contrast to tablets and hard capsules, the technology of enteric soft capsules has not been developed yet.

The results of our preliminary studies show, that it is possible to obtain modified soft gelatin films, useful in the soft capsules production, that (in contrast to non-modified gelatin films) do not dissolve at pH below 5.0, but remain soluble at pH above 6.0.

In the proposed studies the desired solubility of gelatin films will be obtained by addition of modifying substances to gelatin. The modifiers will be most of all acid-insoluble synthetic polymers, that are already employed as enteric coating in tablets: e.g. semi-synthetic cellulose derivatives or methacrylic acid copolymers. The impact of other modifying agents will be also investigated, e.g. plasticisers, solvents, next to the variable temperature and various film drying methods. Functional properties of the obtained materials will be studied like dissolution in various fluids simulating gastrointestinal environment and active substances permeability. Also mechanical characteristics and adhesion – the properties crucial for capsule forming process – will be assessed. The most important objective of the project will be investigating the impact of applied modifications on a physical and chemical structure of gelatin films. For this purpose, microscopy and modern methods of physical and chemical analysis will be used. This will be e.g. thermal analysis (differential scanning calorimetry, DSC), NMR analysis, and spectral analyses (e.g. infrared spectroscopy).

Based on the data collected during realization of the proposed project, possible will be designing of "enteric" gelatin films with well-defined structure and properties, as a material non-toxic, physically stable, and useful in pharmaceutical technology.