

Pharmaceutical composition. This new patent protected technology describes the way for preparation of the new formulation of drugs. It is the system, which includes a few components, which will be incorporated in innovative "Pharmaceutical composition" for production of **new generation of medicines**. Components (the base and coatings) consist of substances approved for use in the pharmaceutical industry.

Problem. The main **problem** in therapy is uncontrolled administration of drugs (drug = **medicine**). Usage of existing drugs produces oscillation of concentration of drug in blood, bad treatments and insufficient therapy. After use, **high** concentration of drugs in blood causes side effects, and **low** concentration of drugs in blood is not effective. Periods so-called "on" and "off" phenomena have emerged as major problems in the long-term treatment of Parkinson's disease (PD).

Existing formulations. Several classes of drugs have been used in the treatment of PD with varying degrees of success. **Existing oral formulations** on the market (tablets and capsules) cause uncontrolled concentration of drugs in blood. **Existing parenteral formulation** (administration through opening / stoma from stomach to duodenum) ensures controlled administration of drug, but it is applicable only for 1% patients, it is expensive and administration is complicated, painful and uncomfortable (continuous, by stoma / opening through stomach directly in duodenum).

Solution is controlled administration of drugs. The new oral formulation of the drug contains a lot of **small particles** which will be placed in **capsules**. After administration, content from the capsule will be dispersed in the targeted place of the digestive tract. Small particles will be glued for a short time (thanks to the bioadhesive coating) and drugs will be controlled released from formulation (from particles) during the time.

Innovation. In one aspect the invention relates to an oral pharmaceutical composition comprising coated particles of a complex of at least one active agent with an ion-exchange resin, wherein said particles are coated with different coatings. **Controlled release (CR) of drug from formulation** is related to the **base and for the first** CR coating. Size of CR coating will define speed of release of drug from formulation.

Our added value (on the example of new better formulation of levodopa) is:

- controlled therapy - controlled release drug from formulation
- better absorption of in targeted place
- better bioavailability – only 5% levodopa comes to brain from existing formulations
- controlled level of drug in blood - avoid oscillations and peaks
- lower side effects – "low and slow" treatments
- lower single dose – 300 mg instead 600 mg
- lower number of single doses per day – 2-3 instead 8-10 times daily (each 2-3 hours)
- lower total dose per day - lower side effects
- reduced dyskinesia – up to 41,7% (1)
- reduced "on - off" phenomena – up to 29,2%
- decreased costs of treatments up to 10% per patient per year
- applicable for numerous therapies - The Platform
- better quality of life - health-related quality of life (HRQOL)
- **this new technology is THE PLATFOM – usable for all drugs containing nitrogen (N)**
- **it can ensure new generation of drugs** – new formulation – new price – new business opportunity

New innovative formulation of levodopa compared to existing product on the market will be:

- **effective** - be better compared to existing oral treatments
- **available** – without therapeutic limitations for patients
- **convenient for use** – simple oral administration.

During the project, we will conduct optimization of formulation and define final conditions of the new product (kind of resins as carrier of drug, kind and size of coatings) which will ensure the best conditions of the new product and which will ensure maximal exploitation of patent protection.

Future steps – we need support (grant, donation, loan, cooperation...) for our next steps.

Goal – development of a new better product (capsules of levodopa with controlled release of drug).