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New method for the production of gastroretentive dosage form

Background

Floating and gastroretentive dosage forms are a unique group among modified-release drug delivery systems. Drug release from these are sustained and targeted to a specific anatomic region. With their extended residence time, drug concentration in the stomach could be prolonged for a longer period, which is beneficial for the treatment of gastric disorders. Bioavailability of drugs with narrow absorption window, where the most dominant absorption of the medication is limited to a specific part of the gastrointestinal tract, can be increased with these formulations.

Technology

Researchers at the University of Debrecen have designed and developed a novel floating delivery system based on hot-melt technology, consisting of polyethylene-glycols, stearic acid, glycerin-distearate, glycerin-dipalmitostearate and solid fat. The carrier could be loaded with several active pharmaceutical ingredient (API) for instance furosemide, famotidine, ranitidine, captopril, levodopa, metronidazole, atenolol, metoprolol-succinate, verapamil, prazosine, diazepam, tramadol and baclofen or isradipine.
The in-house production starts with the melting of the components at high temperature, after complete melting the drug is dispersed into the molten material. When the viscous dispersion is homogenous, simultaneous cooling is started parallel with the dispersion of the air or other gases (nitrogen, argon or carbon-dioxide) or their mixture to foam the dispersion. The bulk product can be dispensed into various plastic or metal molds, even capsule filling is possible.
The single-pot melting and foaming device with the agitators are custom made and designed especially for this production.
The final product is a solid and single dosage form, with zero floating lag-time. The platform is solid and resistant at body temperature and could bear the shear forces of the gastric contractions compared to the so-far approved HBS (Hydrodynamically Balanced System) capsules. Components are miscible with water and the whole system is designed not to accumulate in the stomach.

Benefits

- Simple production
- Instant floating
- Resistance against gastric mixing and pumping motions
- Prolonged drug release
- Remain floating for 8 hours
- Water miscible excipients and designed disintegration

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Stage of development

Several compositions were tested in pharmacopoeial gastric juice to investigate floating properties and drug dissolution. Complete drug release were confirmed after up to 8 hours. To prove the designed disintegration of the platform, dissolution coupled texture analysis was performed.
Solid and resistant cores were found even after 5 hours, while at 8 hours, no dry parts were detected. This confirms potential gastric resistance.
To prove gastric retention, in vivo animal tests are designed and planned to be conducted in the future.

IP status

The Hungarian priority patent application has been filed in 2017.

Who we are looking for

Business partners interested in licensing and commercializing a unique gastroretentive formulation technology.