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Controlled release drug delivery systems

Controlled release drug delivery products are designed to release the active content in a predictable pattern in vivo over an extended time period albeit for some, faster release is desirable. The general design objective of a controlled release system is to fabricate a device capable of constant zero-order drug release over a prolonged time period. Besides the therapeutic advantages from less fluctuation in drug blood levels, reduced dosing frequency is a great benefit to patients. Thus, more and more oral products are being formulated and marketed as controlled release products as the technologies available for fabricating such products have matured considerably where many vendors are marketing excipients for controlled release purposes. The knowhow to develop controlled release oral products is relatively wellestablished. The main mechanisms to control drug release include complexation, matrix embedment and coated reservoir systems. Complexation may involve ion exchange resins or other adsorption agents. The use of long chain polymers or waxy lipids to embed drugs in is a popular option to design matrix-based controlled release products and is often presented as part of the multi-layered tablets or tablet-in-tablet designs. Coated reservoir systems are more commonly used in multi-particulate dosage forms where diffusion controlling membranes are used to seal the drug reservoir, controlling the drug release rate. In some cases, osmotic pump device may be created by a precisely punctured semi-permeable membrane coating which allows water ingression by osmosis and the build-up of osmotic pressure within causes a zero-order discharge via the laser-drilled hole or holes. Multi-particulate dosage forms are often marketed as pellets in capsules where the pellets are coated to confer different release profiles. Nowadays, there is a gradual shift for such products to be designed as pellets-in-tablet instead of filling into capsule, by compacting the pellets with cushioning excipients. There is also much interest to replace pellets with mini-tablets which can be manufactured more economically. Prolongation of gastric delivery or delay in gastrointestinal transit is attempted by the design of drug-containing flotation or muco-adhesive devices.

Controlled release products are also popular for drug delivery to body orifices, in particular, ocular products where requirements for delivery to the different parts of the eyes may differ. However, the direction is often to enhance absorption using nanoformulations. Prolonged ocular retention and release may be mediated by *in situ* gels, implants or nanocarrier systems. Thus, the ideal formulation should have high precorneal residence time with little non-specific drug tissue accumulation and deliver therapeutic drug levels to the ocular surface or into anterior and posterior ocular tissues, potentially able to replace the invasive drug administration by injections.

Parenteral drug delivery is often associated with rapid drug absorption but it would be advantageous to achieve the systemic drug levels within the therapeutically effective drug concentration over a more sustained period, and reduce the frequency of injections. This can be of particular importance for drugs with narrow therapeutic index or poor bioavailability. The development and formulation of parenteral controlled release systems as long-acting injectable preparations require special attention. Depot dosage forms based on polylactic acid and co-glycolic acid have good in vivo biodegradability. Often, details of in vivo release and degradation mechanisms should be clearly understood. There is also much interest in other chemosynthetic biodegradable and natural polymers for the fabrication of injectable microspheres but much more intensive research will be required to advance the method of formulation and availability of novel polymers for the wider commercial success of parenteral controlled release products. Implantable drug delivery systems can provide long-term therapy especially for the management of chronic conditions or hormonal treatments. In some cases, prolonged drug delivery may be via devices such as intrauterine devices, infusion pumps or transdermal patches.

The list may be inexhaustive as the search continues especially for biotechnology products. Many controlled release systems are already available for the delivery of most essential drugs that require it albeit innovative improvements are always being sought.

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