

fact sheet

MEDISORB® MICROSPHERES TECHNOLOGY

What is Medisorb®?

Medisorb is Alkermes' proprietary technology that enables novel formulations of pharmaceuticals by providing controlled, extended release of medication over time.

How does the Medisorb technology work?

In this technology, medication is encapsulated in microspheres made of a medical-grade polymer called polylactide co-glycolide (PLG). Each microsphere is about one-tenth of a millimeter in size, roughly equivalent to the diameter of a human hair.

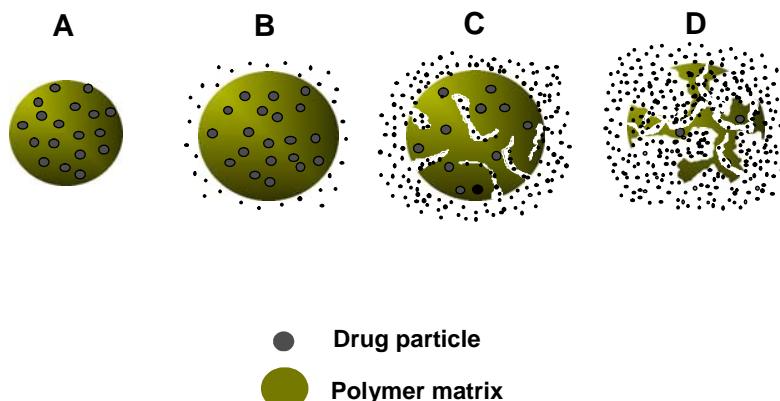
PLG is a common, biodegradable polymer with a history of safe human use in sutures, bone plates and extended-release pharmaceuticals.

Over time, the PLG polymer breaks down into lactic acid and glycolic acid, which are completely metabolized by the body and eliminated as carbon dioxide and water, thereby releasing the medication.

What happens when you inject into the body a long-acting medication using Medisorb technology?

Upon injection, the microspheres (A) begin to absorb water almost immediately, leading to a swelling of the microspheres (B). This process begins a phase in which a small amount of medication at or near the surface of the microspheres is released.

Over time water slowly breaks down the polymer structure allowing medication to release, resulting in a sustained supply of medication (C). The polymer matrix eventually breaks down and is eliminated from the body as carbon dioxide and water (D).



How does Alkermes use this injectable extended-release technology?

Alkermes' proprietary, injectable extended-release technology enables us to develop treatments that sustain effective levels of medication in the body over a prolonged time period. We have two commercial products based on this technology, RISPERDAL® CONSTA® and VIVITROL® and we are applying aspects of the technology to some of our development candidates, including exenatide once weekly.

Alkermes' extended-release technology is distinguished by:

- Clinically-proven extended-release of medication from microspheres in humans
- Demonstrated safety and tolerability in human clinical trials
- Potential to improve patient adherence to therapy, especially where extended-release dosage administration is an important factor for the selection of a medication for treatment
- Broad applicability to small molecules, peptides and proteins
- Demonstrated manufacturing capability at laboratory scale, pilot scale and commercial manufacturing scale, in compliance with cGMPs
- Ability to achieve a customized extended-release profile lasting from days to months