Evonik Birmingham Laboratories

An integrated CDMO for advanced parenterals with a portfolio of delivery technologies, formulation development services and GMP manufacturing

EVONIK
POWER TO CREATE

Evonik Birmingham Laboratories

WE MAKE DRUGS SMARTER

Using our 40 years of experience, our state of the art facilities and our IP protected technologies, we leverage existing capabilities to create value for our pharmaceutical partners by providing a complete portfolio of integrated drug delivery services including product development and commercial manufacturing.

Meeting the parenteral drug delivery challenge

As promising drugs emerge from drug discovery laboratories, the challenge is to unfold their full potential. Our formulation technology can help to make drugs most effective by controlling, where and how long drugs are released in the body.

THE EVONIK EDGE IN POLYMER-BASED PARENTERAL FORMULATIONS

Evonik's broad range of delivery technologies, together with a deep problem-solving approach and advanced product development and manufacturing infrastructure, gives us a unique edge as a formulating partner. We can provide drug delivery solutions for virtually all therapeutic areas involving systemic and localized delivery.

TAKING EXTENDED RELEASE AND TARGETED RELEASE FURTHER – ADVANCED PARENTERALS

One of our many specialties is in the area of parenteral extended smart release. Our bioabsorbable, injectable microparticles, nanoparticles as well as bioabsorbable implants, fibers, films, meshes and devices have become proven scientific and practical references.

FROM SMALL MOLECULES TO BIOPHARMACEUTICALS – ALL BASES COVERED

Depending on the indication, route of administration and active pharmaceutical ingredient (API) properties, our products ensure that the drug is delivered at efficacious levels for days, weeks and months – following a single administration. Evonik microparticles, for instance, are a proven delivery system for small molecules, peptides, proteins and various other biological macromolecules.

ONE SOURCE FROM FORMULATION SERVICES TO GMP MANUFACTURING

We have integrated drug delivery services ranging from product development to clinical trial supply to commercial manufacturing, including our capability to handle high potency APIs (HPAPI).

Formulation development

The development of extended-release parenteral products that systemically or locally deliver active pharmaceutical ingredients for days to months is at the core of our activities.

We have a broad range of drug delivery technologies, solution solving approaches and product development infrastructures.

Depending on the indication and API properties, including potency and physical-chemical properties, our parenteral extended-release formulations can deliver API at efficacious levels for days, weeks and months following a single administration. To design the formulations we use our RESOMER® polymers and other bioabsorbable and non-bioabsorbable polymers.

EVONIK's CAPABILITIES TO FORMULATE COMPLEX PARENTERALS

Examples of our complex parenteral formulations include:

- microparticles
- nanoparticles
- liposomes
- implants
- fibers
- films
- meshes
- devices
- coatings

Evonik's bioabsorbable injectable microparticles and insertable implants are proven delivery systems for:

- small molecules
- peptides
- proteins
- nucleic acids
- vaccines
- high potency APIs
- controlled APIs

Our proprietary FormEZE® and NanoPCL technologies produce many advantages for parenteral microparticle formulations:

- smaller needles
- smaller injection volumes
- more microparticles injected (30-50 % microparticle solids)
- use of less potent drugs
- drugs delivered for longer durations
- easier injections
- easier self-administration

Microparticle development and GMP manufacturing

Injectable microparticles are complex, extended-release parenteral formulations. They consist of drug substances encapsulated in a spherical matrix of bioresorbable polymer, such as RESOMER® lactide/glycolide polymers.

Typically 100 micron or less in diameter, injectable microparticles can deliver peptides, small molecules, proteins and nucleic acids for days, weeks or months following a single parenteral administration. Drug delivery can be systemic or local, including in brains, joints, bones and eyes. Evonik's injectable microparticles made by proprietary FormEZE® processing can be injected with 27-G needles or smaller. Furthermore, up to five times more microencapsulated drug can be administered compared to marketed microparticle products, facilitating microencapsulation of less potent drug substances and delivering drug substances for longer periods.

Implant development and GMP manufacturing

Insertable implants, typically cylindrical rods, consist of drug substances embedded in a polymer matrix of bioresorbable or non-resorbable material. For instance, the polymer matrix can be bioresorbable RESOMER® lactide/glycolide polymers or non-bioresorbable ethylene vinyl acetate.

Implants can have a rate-controlling membrane on their outside surface. These outer membranes can be made using coaxial extrusion or coating technologies.

Implants made by hot melt extrusion can be made to deliver small molecules and peptides for days, week or months following a single parenteral administration of one or more implants. Implants for local delivery can have various shapes, such as films, ribbons, fibers and meshes.

Benefit from our liposome experience

Evonik offers experience and GMP facilities to manufacture liposome suspensions and lyophilized liposomes for parenteral administration.

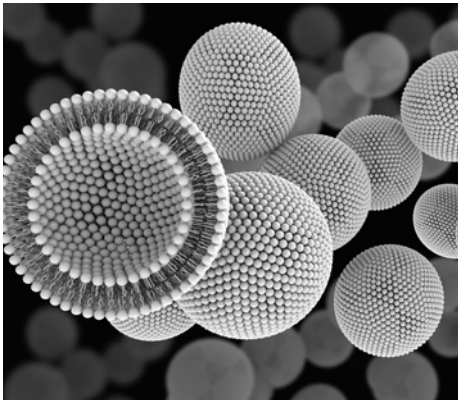
Liposomes are spherical structures having a single lipid bilayer or several lipid bilayers with drug substance located in the core. Lipids often used are phospholipids. Targeting moieties can be conjugated to the surface of liposomes. Liposomes are being used to reduce side effects by controlling biodistribution.

Nanomedicines

NOVEL, EMERGING MEDICAL PRODUCTS APPLYING NANOTECHNOLOGY

Nanomedicine applications involve the use of nanomaterials, devices, biosensors and diagnostics. Liposomes, polymeric nanoparticles, lipid nanoparticles, and polymeric micelles are examples of nanomedicines being developed in the field of drug delivery.

Through the nanoscale manipulation of materials, nanoscale drug delivery formulations can be designed to improve drug solubility, biodistribution, pharmacokinetics and reduce side effects. Because of their small size, nanoscale drug delivery formulations can also be designed to enter cells and release drug substance inside the cell. In addition to having the capability to develop nanomedicines, Evonik has the experience and world class GMP facilities to scale up and manufacture clinical and commercial nanomedicine materials.



Why not leave contract manufacturing to us?

Volume flexibility, consistent quality, reliable supply – batch for batch

Our idea of partnership is to be a natural extension of your own organization. At our facility in Birmingham, Alabama, USA, we manufacture a broad spectrum of complex parenteral dosage forms. Final presentation is available in a range of vial sizes, from 2 to 50 mL. Solids are available in the gram to kilogram range. The unique strength of Evonik is that our custom manufacturing capacity naturally follows through on our core competencies in drug substance development, functional excipients and formulation development.

In accordance with FDA, EU, Japan and other regulatory guidelines, we understand pharmaceutical processing, melt-extrusion processing, microparticle/powder technology, emulsion science, fluid dynamics, and various product isolation techniques. This expertise enables us to bring in client processes and analytical methods, and transfer them to our state of the art production facilities for clinical and commercial supply manufacture.

EVONIK BIRMINGHAM LABORATORIES – AT A GLANCE

- Programmed release profiles from days to months
- GMP manufacturing capabilities
- Microencapsulation of small molecules and biologicals
- Choice of Evonik´s bioabsorbalbe RESOMER® and RESOMER® Select polymers for microparticles and implants
- Choice of non-biodegradable polymers for removable implants
- Coaxial extrusion for implants
- Post-extrusion processing capabilities
- Multiple liposome formation technologies
- Lyophilization for liposomes
- Handling of high-potency drug substances

FOR FURTHER INFORMATION, PLEASE VISIT OUR WEBSITE: WWW. EVONIK. COM/PARENTERALS

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