who puts the control in your release profile?

viatel™
bioresorbable polymers

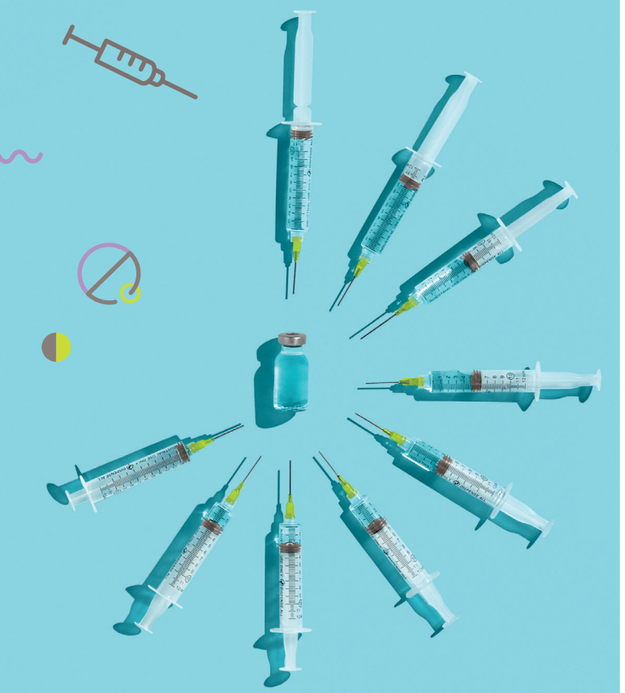
Ashland™
always solving

ashland.com / efficacy usability allure integrity profitability™

who releases over time?

—

we do.



Ashland™
always solving

polymers for parenteral controlled release drug delivery & medical devices

Ashland is a premier global specialty chemicals company serving customers in a wide range of consumer and industrial markets. We are passionate, tenacious solvers who thrive on developing practical, innovative and elegant solutions to complex problems for customers in more than 100 countries.

key ingredients from a single source

Bioresorbable polymers have been commercialized for more than 50 years, however, until now, no manufacturer has offered a single source of three key excipients used to formulate these revolutionary drug delivery systems that are designed to improve patients' lives. With the addition of Viatel™ bioresorbable polymers, Ashland provides a comprehensive line of products for parenteral, controlled release drug delivery. Complementary excipients include Aqualon™ CMC PH BET sodium carboxymethyl cellulose, a suspending agent for two-component systems; and Pharmasolve™ n-methyl-2-pyrrolidone, a versatile solubilizer for one-component systems.

Bioresorbable polymers are also the key ingredient in degradable medical devices, providing structural strength for load-bearing products such as sutures, stents, screws and plates.

bioresorbable polymers

Ashland offers five families of bioresorbable polymers for parenteral controlled release drug delivery systems and medical devices. For drug delivery, Ashland offers amorphous homopolymers and copolymers, including:

- Poly(D, L-lactide) (PDLLA) and
- Poly(D, L-lactide-co-glycolide) (PLGA).

For medical devices, Ashland offers semi-crystalline and amorphous homopolymers and copolymers including:

- Poly(L-lactide) (PLLA),
- Poly(ε-caprolactone) (PCL) and
- Poly(L-lactide-co-ε-caprolactone) (PLCL).

All Ashland Viatel™ bioresorbable polymers can be custom produced with defined chemical structures, molar masses (molecular weight or inherent viscosity) and selective terminal end groups.

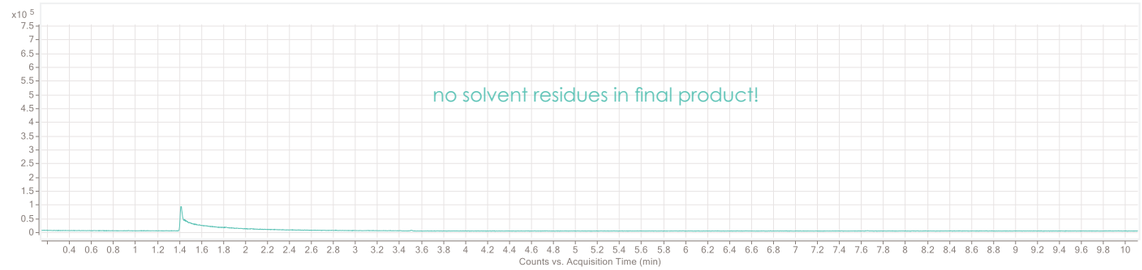
Whether they are in-stock or custom-designed to meet your drug delivery and medical device performance needs, Viatel™ bioresorbable polymers open the door for the formulation of unique and innovative medicines and medical devices.

raising the bar in quality and more

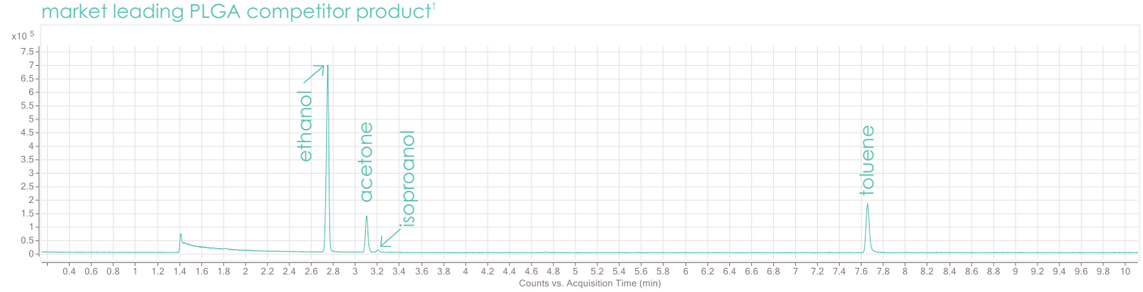
At Ashland, we are passionate about creating technologies and solutions to improve our customers' products and processes, reduce our environmental impact, preserve the world's natural resources and enhance the quality of life within our communities. Through good chemistry – our people, products, services, and close relationships with our stakeholders – Ashland continues to expand its offerings of renewable and sustainable solutions. Our bioresorbable polymers are designed with this approach in mind. Starting from monomers derived from renewable resources, Ashland's scientists have developed a unique manufacturing process designed to eliminate residual solvents from the final product.

The primary benefit of bioresorbable polymers is they break down via hydrolytic degradation into the monomer components lactic and glycolic acid– both of which are resorbed by the body. A key feature of Viatel™ bioresorbable polymers is that they contain no detectable residual solvents, reducing concern over potential inflammatory effects. Additionally, all Ashland Viatel™ bioresorbable polymers meet typical drug and device regulatory thresholds for tin catalyst levels established by health authorities. Furthermore, the Ashland process allows us to supply many of our Viatel™ bioresorbable polymers with significantly lower tin levels than regulatory requirements.

Viatel™ bioresorbable polymer†



market leading PLGA competitor product†



†Determined using solid-phase microextraction followed by gas chromatography-mass spectrometry (SPME-GC-MS)

By raising the bar with respect to product quality, Ashland Viatel™ bioresorbable polymers catapult parenteral controlled-release drug delivery technology and medical device manufacturing to a higher level. These polymers are ideal for designing medicines that breed patient compliance.

viatel™ bioresorbable polymers = no residual solvents

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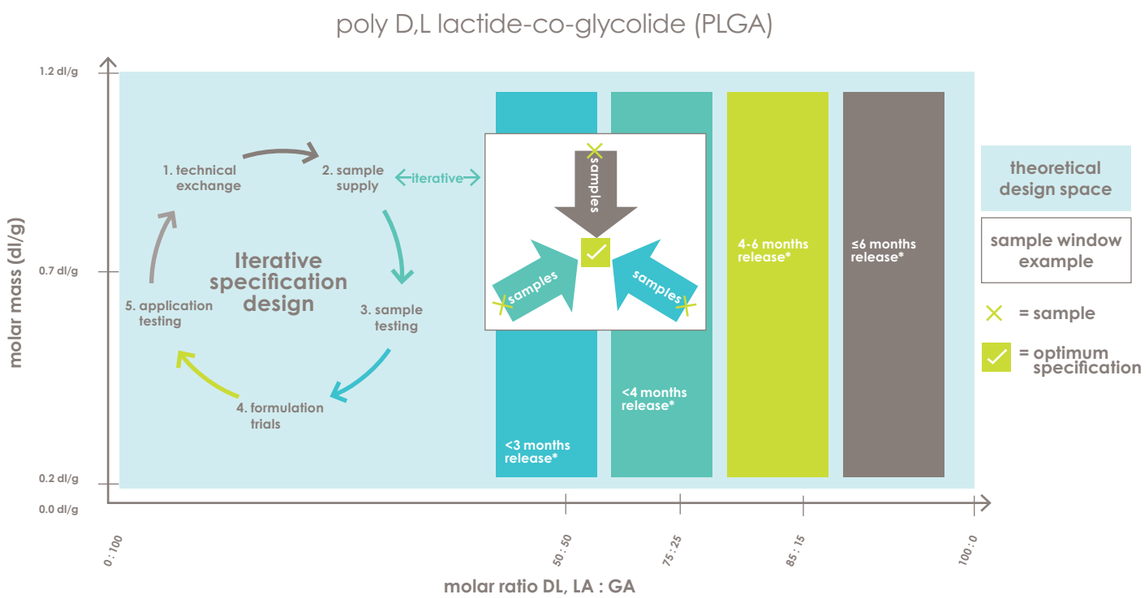
custom polymer design to meet your needs

One size does not fit all. We understand that active pharmaceutical ingredients (APIs) have their own unique characteristics and standard grades of bioresorbable polymers do not always fit. That is why Ashland offers a custom polymer design service that can provide just the right amount of drug release to meet patients' health and lifestyle requirements. Molecular weight, as measured by inherent viscosity; monomer selection and ratio; as well as the functional end groups (acid, ester, polyethylene glycol) impact bioresorbable polymer performance. Tuning these parameters results in a polymer that performs just right for your drug active and patients.

Ashland's passionate solvers have developed a bioresorbable polymer design space program to assist drug delivery teams as they accelerate formulation. Users can benefit from the program at any stage of development, whether they are first-time users reviewing injectable formulation options; in the process of polymer selection; or in later stage commercialization aiming to qualify a reliable supplier, refine process steps and achieve improved reproducibility.

Users of the program can achieve targeted drug release profiles, overcome formulation/delivery challenges, attain guidance on best practices for processing and assessment, effectively troubleshoot and, therefore, deliver improved products. Typical interactions begin with a technical exchange to identify needs, with the aim to move quickly into sampling. Years of drug delivery experience, intimate knowledge of bioresorbable polymers, extensive technical resources, existing literature and data generated on a case-by-case basis are relied upon to make informed decisions. Iterative sampling progresses quickly into application studies, with repeated technical exchanges between formulators and Ashland's design space panel. Ashland's bioresorbable polymer support program allows users to engage to their preferred level and quickly get the information and support needed to address their technical challenges.



*Timeframes will vary based on formulation parameters. Values shown are for indication purposes only and are based on a typical formulation. For more information, users are advised to consult Ashland for a technical exchange to discuss formulation parameters.

applications

Viatel™ bioresorbable polymers are used in medical applications across a diverse platform of controlled release parenteral drug delivery and medical devices in the following sectors:

- cardiovascular
- orthopedic
- dental
- ophthalmic
- neurologic regeneration
- wound care management
- advanced tissue engineering

Bioresorbable polymers give formulation scientists the opportunity to design better drug delivery systems, which can lead to improved efficacy, fewer side effects, higher compliance and ultimately better patient outcomes.

controlled release parenteral drug delivery

Bioresorbable polymers are used by formulators to create drug delivery systems that enhance the patient experience. Flexibility, convenience and better compliance can be addressed in the system design process to meet patients' needs. Viatel™ bioresorbable polymers are useful in the delivery of many drugs, including small molecules, peptides, proteins, vaccines, and other biomolecules. Scientists use Viatel™ polymers in formulation strategies to produce controlled release injectable depots, micro/nano particles and solid implants. API, polymer and solvent are injected through a standard syringe needle forming an in situ gel or solid state depot that provides sustained release of the drug, from days to months. Micro/nano particles are formed using chemical-based techniques, suspended in a diluent and administered by injection. Pre-formed drug loaded implants are prepared with API and polymers via melt extrusion and surgically implanted in the body or, if small enough, injected through standard-sized needles.

medical devices

Viatel™ bioresorbable polymers are valuable components in the design and manufacture of medical devices such as:

- screws
- plates and bone regeneration scaffolds
- staples and sutures
- neural conduits
- hernia meshes
- stents
- device coatings
- dental and ophthalmic treatments

Utilized for their structural characteristics, bioresorbable polymers are resorbed by the body, eliminating the need for surgical removal once the healing process is complete. And their potential doesn't stop there—every day new uses for bioresorbable polymers are being explored in the fields of 3D printing, regenerative medicine and tissue engineering.

Take advantage of Ashland's applications knowledge with raw material grade selection and polymer design to meet your specific medical device needs.

processing of Viatel™ bioresorbable polymers

Viatel™ bioresorbable polymers are compatible with melt and solvent based processing technologies. Tap into our knowledge base in extrusion, injection molding, 3D printing, emulsion formulation, spray coating, and laser cutting to expedite your development process.

manufacturing

Viatel™ bioresorbable polymers are produced in an ISO 14644-1 Class 8 cleanroom environment within an ISO 13485 LRQA Lloyds certified facility to meet medical device standards such as EN ISO13485:2016 medical devices, FDA 21 CFR part 820, and ASTM F2579-18; and to comply with USP/NF General Chapter <1078> Good Manufacturing Practices for Bulk Pharmaceutical Excipients and The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2017 as published under the auspices of the International Pharmaceutical Excipients Council for controlled-release drug delivery applications. Ashland hold a type IV excipient drug master file (DMF) with the FDA for Viatel PLGA's (DMF number 33847).

packaging, storage and stability

Ashland Viatel™ bioresorbable polymers are supplied as a milled granular powder in 100-gram and 1-kilogram units consisting of a primary polyethylene (PE) lined aluminum foil pouch and a secondary PE outer liner.

When stored in its original packaging at temperatures below -15°C, Viatel™ bioresorbable polymers will meet the ASI sales specifications up to 36 months. Ashland can provide shipping under cold conditions up to 120 hours

Ashland offers a fine grind or granule particulate option on all grades to meet your preferred form requirements

average particle diameter (µm)	maximum particle diameter (µm)	minimum particle diameter (µm)
351	1326	10.3

average particle diameter (µm)	maximum particle diameter (µm)	minimum particle diameter (µm)
2795	4230	2106

product range – controlled release applications

PLGA and PDLLA are the most commonly used bioresorbable polymers for parenteral, controlled-release drug delivery systems, due to their predictable degradation rate and amorphous polymer structure. Viatel™ bioresorbable polymers are available with inherent viscosities ranging from 0.2 to 1.0 dl/g. Typically white to light tan in color, Viatel™ bioresorbable polymers lend an aesthetic quality to finished products. Standard grades are supplied with molar ratios of D, L-lactide/glycolide of 50:50, 75:25, 85:15 and 100:0. Customized formulations are also available with ranging molar ratios, functional groups and molecular weights as desired by the customer.

product range – medical device applications

Due to the performance requirements in load-bearing applications and the need for local drug delivery at the site of implantation, Ashland offers R&D grades of PLLA, PCL and PLCL for medical device applications in a range of inherent viscosities from 0.2 to 2.0 dl/g. Customized, made-to-order GMP grade formulations are also available from the monomers D, L-lactide, L-lactide, ε-caprolactone and glycolide with ranging molar ratios, molar masses and functional end groups as desired by the customer.

Viatel™ bioresorbable polymers for drug delivery

product	polymer	*molar ratio (D,L LA: GA)	inherent viscosity range (dl/g)**	end group	product grade
PLGA	poly(D, L-lactide-co-glycolide)	50:50	0.1 – 0.3	acid / ester	Viatel™ DLG 5002 A/E
PLGA		50:50	0.2 – 0.4	acid / ester	Viatel™ DLG 5003 A/E
PLGA		50:50	0.4 – 0.6	acid / ester	Viatel™ DLG 5005 A/E
PLGA		50:50	0.6 – 0.8	acid / ester	Viatel™ DLG 5007 A/E
PLGA		50:50	0.8 – 1.0	acid / ester	Viatel™ DLG 5009 A/E
PLGA		50:50	1.0 – 1.2	acid / ester	Viatel™ DLG 5011 A/E
PLGA		50:50	1.2 – 1.4	acid / ester	Viatel™ DLG 5013 A/E
PLGA		55:45	0.2 – 0.4	acid / ester	Viatel™ DLG 5503 A/E
PLGA		55:45	0.4 – 0.6	acid / ester	Viatel™ DLG 5505 A/E
PLGA		65:35	0.2 – 0.4	acid / ester	Viatel™ DLG 6503 A/E
PLGA		75:25	0.1 – 0.3	acid / ester	Viatel™ DLG 7502 A/E
PLGA		75:25	0.2 – 0.4	acid / ester	Viatel™ DLG 7503 A/E
PLGA		75:25	0.4 – 0.6	acid / ester	Viatel™ DLG 7505 A/E
PLGA		75:25	0.6 – 0.8	acid / ester	Viatel™ DLG 7507 A/E
PLGA		75:25	0.8 – 1.0	acid / ester	Viatel™ DLG 7509 A/E
PLGA		75:25	1.0 – 1.2	acid / ester	Viatel™ DLG 7511 A/E
PLGA		75:25	1.2 – 1.4	acid / ester	Viatel™ DLG 7513 A/E
PLGA		85:15	0.1 – 0.3	acid / ester	Viatel™ DLG 8502 A/E
PLGA		85:15	0.2 – 0.4	acid / ester	Viatel™ DLG 8503 A/E
PLGA		85:15	0.4 – 0.6	acid / ester	Viatel™ DLG 8505 A/E
PLGA		85:15	0.6 – 0.8	acid / ester	Viatel™ DLG 8507 A/E
PLGA		85:15	0.8 – 1.0	acid / ester	Viatel™ DLG 8509 A/E
PLGA		85:15	1.0 – 1.2	acid / ester	Viatel™ DLG 8511 A/E
PLGA		85:15	1.2 – 1.4	acid / ester	Viatel™ DLG 8513 A/E
PDLLA	poly(D, L-lactide)	100:0	0.1 – 0.3	acid / ester	Viatel™ DL 02 A/E
PDLLA		100:0	0.2 – 0.4	acid / ester	Viatel™ DL 03 A/E
PDLLA		100:0	0.4 – 0.6	acid / ester	Viatel™ DL 05 A/E
PDLLA		100:0	0.6 – 0.8	acid / ester	Viatel™ DL 07 A/E
PDLLA		100:0	0.8 – 1.0	acid / ester	Viatel™ DL 09 A/E
PDLLA		100:0	1.0 – 1.2	acid / ester	Viatel™ DL 11 A/E
PDLLA		100:0	1.2 – 1.4	acid / ester	Viatel™ DL 13 A/E

**D, L-LA: D, L-lactide. GA: glycolide **inherent viscosity ranges per grade can be narrowed to meet customer requirements*

Viatel™ bioresorbable polymers for medical devices

product	polymer	*molar ratio (L: CL)	inherent viscosity range (dl/g)	end group	product grade
PLLA	Poly (L-lactide)	-	0.8 – 1.2	ester	Viatel™ L 10 E
PLLA		-	1.2 – 1.6	ester	Viatel™ L 14 E
PLLA		-	1.6 – 2.0	ester	Viatel™ L 18 E
PCL	Poly(ε-caprolactone)	-	1.0 – 1.4	ester	Viatel™ C 12 E
PCL		-	1.6 – 2.0	ester	Viatel™ C 18 E
PLCL	Poly(L-lactide-co-ε-caprolactone)	60:40	1.0 – 1.4	ester	Viatel™ LC 6012 E
PLCL		70:30	1.0 – 1.4	ester	Viatel™ LC 7012 E
PLCL		80:20	1.0 – 1.4	ester	Viatel™ LC 8012 E
PLCL		90:10	1.0 – 1.4	ester	Viatel™ LC 9012 E

** Molar ratio here only applies to PLCL copolymers: L: L-lactide, CL: ε-caprolactone*

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