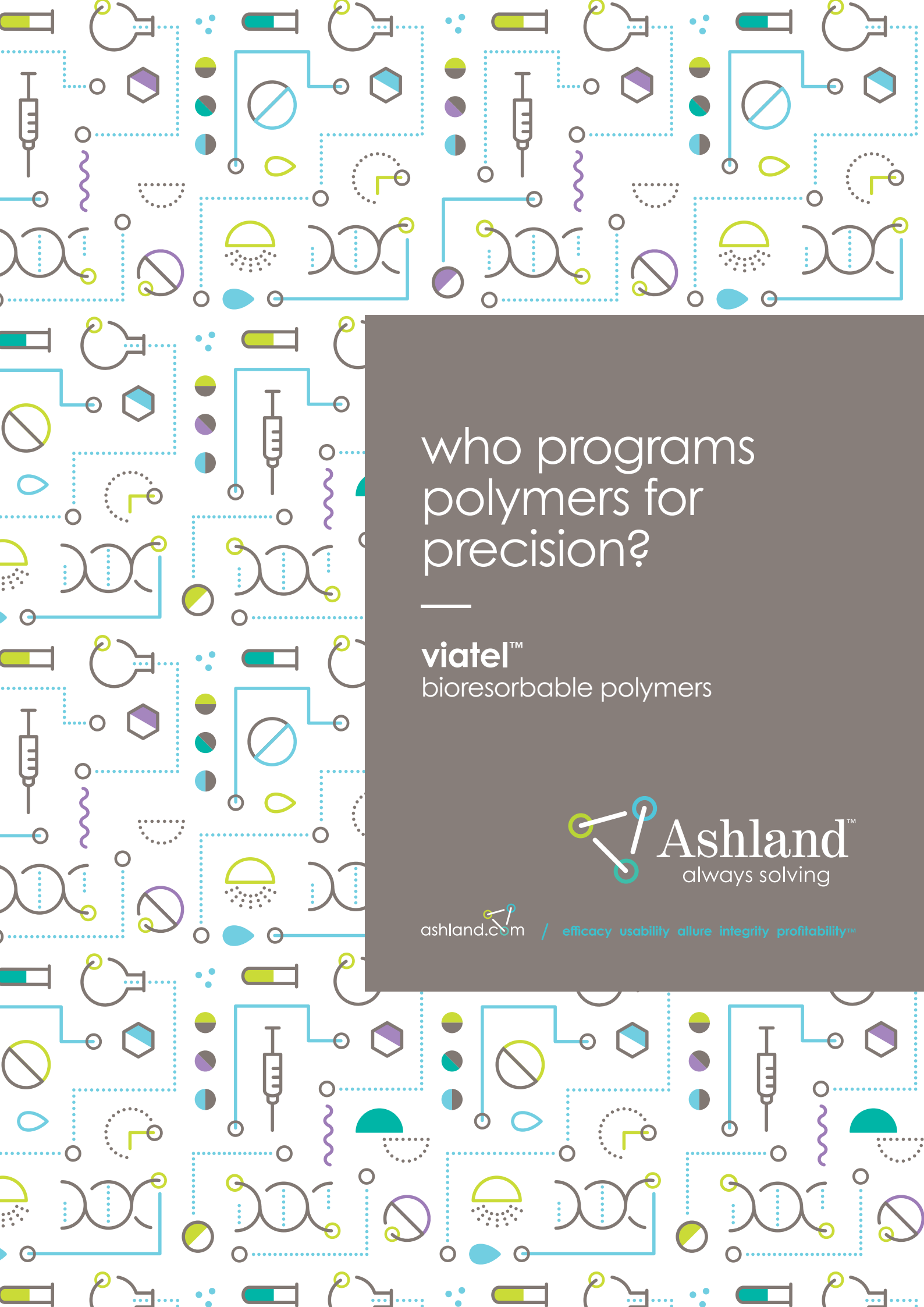

who programs polymers for precision?

viatel™
bioresorbable polymers

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Ashland Life Sciences is committed to responsibly solving for healthier lives everywhere. We offer the broadest range of excipients and raw materials to compose effective oral solid dosage (OSD), injectables, and medical devices.

Bioresorbable polymer technology is part of Ashland's innovation platform. It is scalable and includes multiple market segments and potential applications including long acting injectables for chronic diseases and animal health; advanced drug delivery; and medical devices for dermal fillers, sutures, screws and more.

viatel™ bioresorbable polymers

a comprehensive platform

Viatel™ bioresorbable polymers are produced from lactide, glycolide, ε-caprolactone, and PEGylated chemistries.

For drug delivery applications, amorphous polymers Poly(D,L-lactide-co-glycolide) (PLGA) and Poly(D,L-lactide) (PDLLA) are the gold standard carrier in long-acting injectables and implants (LAII).

For medical device applications, we offer a range of semi-crystalline and amorphous polymers including Poly(L-lactide) (PLLA), Poly(ε-caprolactone) (PCL), Poly L-lactide-co-glycolide (PLLGA), and Poly(L-lactide-co-ε-caprolactone) (PLCL).

Viatel™ bioresorbable polymers are available as GMP grades in both standard and high-purity grades. Viatel™ Ultrapure polymers are specially purified for sensitive applications in which minute amounts of impurities can effect processing and performance.

chemistry, precision and raising the bar

Bioresorbable polymers break down via hydrolytic degradation into the monomer components lactic and glycolic acid, both of which are naturally resorbed or excreted by the body — this is their primary benefit. Starting from monomers derived from renewable resources, Ashland's scientists have developed a unique manufacturing and purification process that allows more precise control over polymer composition, chemical attributes, and purity. The outcome is production of high quality polymers that perform in a predictable manner for both drug delivery and medical device applications.

applications

drug delivery


microspheres and nanoparticles

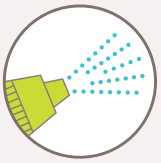

implants


in-situ depots

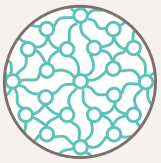

advanced drug delivery systems

medical devices and tissue engineering


degradable medical devices


device coatings


dermal fillers


scaffolds

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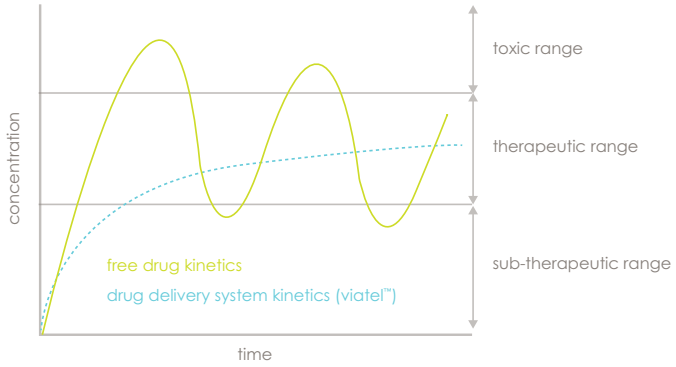
drug delivery

Bioresorbable polymers can be used to deliver many drugs, including small molecules, peptides, proteins, vaccines, and other biomolecules. These delivery systems can facilitate improved efficacy, fewer side effects, enhanced patient compliance, and ultimately better patient outcomes.

long-acting injectables and implants (LAII)

Lactide/glycolide chemistries are the gold standard polymer technology used to create LAII depots. Depots are formed by incorporating active pharmaceutical ingredients (API) into a polymer matrix in the form of microspheres, nanoparticles, in-situ forming depots, and solid implants to control drug release over days to months.



long-acting drug delivery systems control release over time using viatel™ polymers

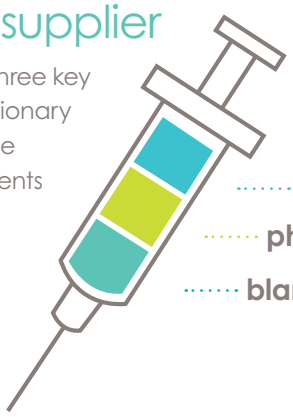
advancing drug delivery expanding methodologies

Formulators are continually enhancing delivery technologies and use viatel™ bioresorbable polymer chemistries to create:

- nanoparticle delivery technologies, including both passive and active chemistries that are formulated to target/ permeate cells and specific tissues;
- long-acting orals (LAO's) that seek to translate long-acting performance into oral dosage forms emerging as a result of increased focus on patient compliance;
- transdermal drug delivery in which polymers are used to fabricate and coat microneedles that can be deposited in the skin to circumvent injections;
- inhalation therapies that utilize polymers to deliver active pharmaceutical ingredients (APIs) into the respiratory system.

key ingredients from one supplier

Ashland is the only excipient supplier offering three key ingredients used in formulation of these revolutionary LAII systems. In addition to viatel™ bioresorbable polymers, we offer two complementary excipients for LAII formulations: blanose™ sodium carboxymethylcellulose, a suspending agent for diluents used to carry microspheres, and pharmasolve™ n-methyl-2-pyrrolidone, a versatile solubilizer used to formulate in-situ depots.



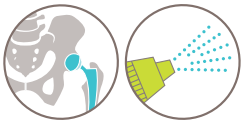
multiple LAI excipients from single source

- **viatel**™ bioresorbable polymers
- **pharmasolve**™ n-methyl-2-pyrrolidone (NMP)
- **blanose**™ sodium carboxymethylcellulose

medical devices and tissue engineering

Viatel™ bioresorbable polymers are used in the design and manufacture of degradable medical devices. These polymers are resorbed by the body, eliminating the need for surgical removal when the healing process is complete. New uses for bioresorbable polymers are being explored in the fields of 3D printing, regenerative medicine, and tissue engineering.

medical devices

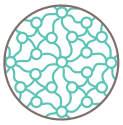


Viatel™ bioresorbable polymers are used to produce a wide range of medical devices that can degrade at varying rates and can also be engineered to elute antimicrobial and anti-inflammatory compounds to aid in a safe recovery process. Examples include:

- screws
- staples and sutures
- stents
- plates
- device coatings
- dental and ophthalmic implants

tissue engineering

Viatel™ bioresorbable polymers provide structural support and exceptional biocompatibility with cell, tissue, and organ regeneration to improve patient healing. They are typically processed via extrusion, injection molding, printing, and spinning. Examples include:

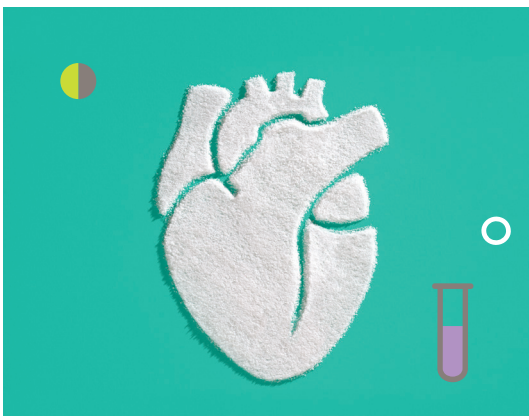


- bone regeneration scaffolds
- soft tissue regeneration scaffolds
- neural conduits
- hernia meshes

dermal fillers

Viatel™ bioresorbable polymers can also be used as an ingredient to produce dermal fillers. As the polymer naturally degrades, it stimulates endogenous collagen production, giving new structure to the site of a minimally invasive injection.

We are ready to help you solve your specific medical device needs. To expedite your development process, Ashland has experience with raw material grade selection, characterization, and polymer design as well as a technical knowledge base in extrusion, injection molding, 3D printing, emulsion formulation, spray coating, and laser cutting to fit your application. Viatel™ bioresorbable polymers are compatible with both melt- and solvent-based processing technologies.



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viatel™ ultrapure bioresorbable polymers

enhanced purity and flexibility

Viatel™ Ultrapure bioresorbable polymers are designed for sensitive applications. These polymers undergo additional purification via a solvent washing technology that removes residual monomers and pre-filters for enhanced purity. These grades are recommended for formulators working with sensitive APIs, melt-based applications such as hot melt extrusion or in-situ depots where residual monomers may cause variable performance.

benefits

- reduced acidity
- improved API stability
- improved shelf-life stability
- improved release consistency across all applications due to fewer variables
- extended release in hot melt extrusion and in-situ forming depot applications

milling capabilities and particle size optimization

Ashland has experience and offers support on form optimization via milling and refining technologies. Standard GMP grade viatel™ polymers are typically supplied in granule form.

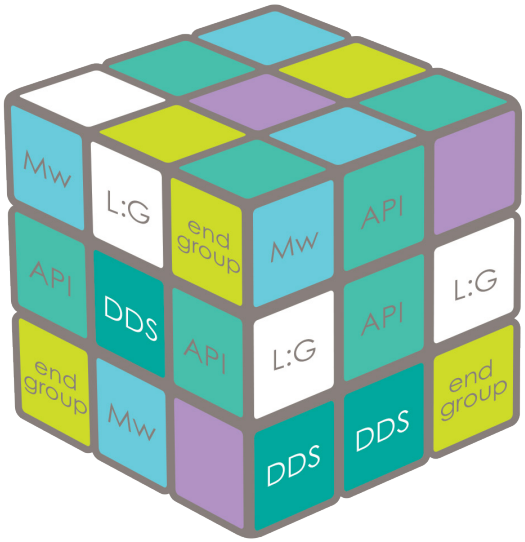
Ashland also can produce fine grind and powder formats on request.

custom polymers and new chemistries

Because one size does not fit all, we offer a custom polymer design service. Composition, structure, molar mass by molecular weight and IV, molar ratio, and functional end groups (acid, ester, polyethylene glycol or other) can be tailored to meet formulation requirements.

We would love to help you solve your most complex puzzle.

solving the "sustained release" puzzle



legend

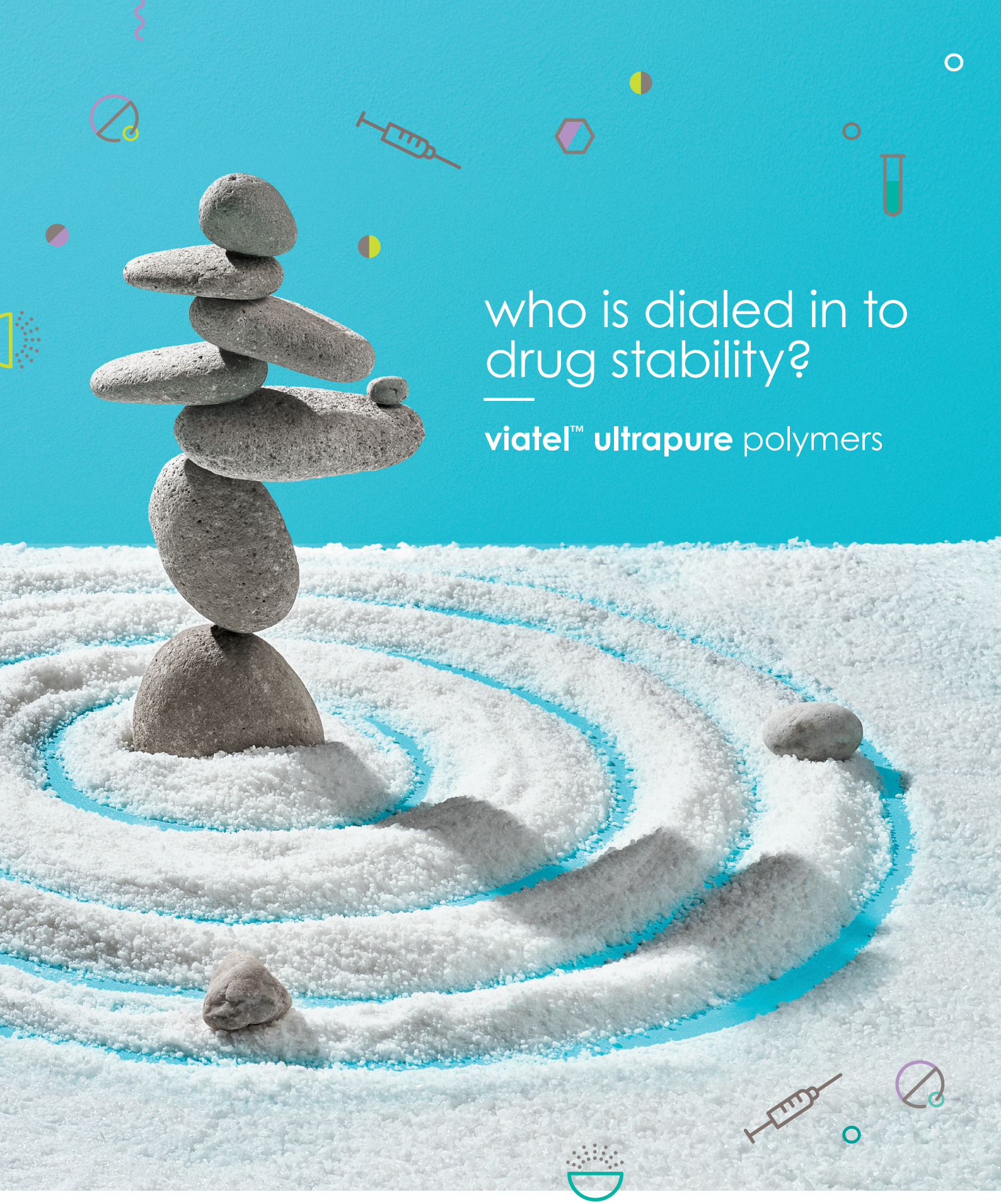
polymer characteristics

- composition and L:G molar ratio
- molecular weight / inherent viscosity
- structure, architecture and end-group

formulation characteristics

- depot / device type
- processing technology
- API* or additive form and concentration

*API : Active Pharmaceutical Ingredient



who is dialed in to drug stability?

viatel™ ultrapure polymers

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available grades

viatel™ ultrapure polymers for drug delivery

polymer	molar ratio (D,L LA : GA)*	inherent viscosity** range (dl/g)	weight average Mw (kDa) ***	end group options	product code
Poly(D,L-lactide-co-glycolide)	50:50	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 5002 A/E UP
		0.2 – 0.4	15 – 40		viatel™ DLG 5003 A/E UP
		0.4 – 0.6	40 – 65		viatel™ DLG 5005 A/E UP
	75:25	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 7502 A/E UP
		0.2 – 0.4	15 – 40		viatel™ DLG 7503 A/E UP
		0.4 – 0.6	40 – 65		viatel™ DLG 7505 A/E UP
		0.6 – 0.8	65 – 90		viatel™ DLG 7507 A/E UP
		0.8 – 1.0	90 – 120	ester	viatel™ DLG 7509 E UP
	80:20	0.2 – 0.4	15 – 40	acid	viatel™ DLG 8003 A UP
	85:15	0.2 – 0.4	15 – 40	acid or ester	viatel™ DLG 8503 A/E UP
Poly(D,L-lactide)	100:00	0.1 – 0.3	5 – 27	acid or ester	viatel™ DL 02 A/E UP
		0.2 – 0.4	15 – 40		viatel™ DL 07 A/E UP
		0.4 – 0.6	40 – 65	ester	viatel™ DL 09 E UP

viatel™ bioresorbable polymers for medical devices, dermal fillers, and tissue engineering

polymer	molar ratio (L:C)*	inherent viscosity** range (dl/g)	weight average Mw (kDa) ***	end group options	product code
Poly(L-lactide)	100:0	0.8 – 1.2	80 – 120	ester	viatel™ L 10 E
		1.2 – 1.6	120 – 160		viatel™ L 14 E
		1.6 – 2.0	160 – 200		viatel™ L 18 E
		2.0 – 2.7	200 – 270		viatel™ L 24 E
		2.7 – 3.5	270 – 350		viatel™ L 31 E
		3.5 – 4.4	350 – 500		viatel™ L 38 E
Poly(ε-caprolactone)	0:100	0.2 – 0.30	15 – 30	ester	viatel™ C 02 E
		0.35 – 0.50	35 – 50		viatel™ C 04 E
		0.6 – 1.0	60 – 95		viatel™ C 08 E
		1.0 – 1.4	95 – 140		viatel™ C 12 E
		1.6 – 2.0	160 – 230		viatel™ C 18 E
Poly(L-lactide-co-ε-caprolactone)	60:40	1.0 – 1.4	100 – 170	ester	viatel™ LC 6012 E
	70:30	1.0 – 1.4			viatel™ LC 7012 E
	80:20	1.0 – 1.4			viatel™ LC 8012 E

*L-LA: L-lactide. CL: ε-caprolactone

**inherent viscosity ranges per grade can be narrowed to meet customer requirements

*** Mw data is an indicative range based on historical data. Ashland can support tailored Mw requests.

Ashland provides free samples upon request when appropriate at **ashland.com/viatel**

viatel™ polymers for drug delivery

polymer	molar ratio (L:G)*	inherent viscosity** range (dl/g)	weight average Mw (kDa) ***	end group options	product code
Poly(D,L-lactide-co-glycolide)	50:50	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 5002 A/E
		0.2 – 0.4	15 – 40		viatel™ DLG 5003 A/E
		0.4 – 0.6	40 – 65		viatel™ DLG 5005 A/E
		0.6 – 0.8	65 – 90		viatel™ DLG 5007 A/E
		0.8 – 1.0	90 – 120	ester	viatel™ DLG 5009 E
	55:45	0.2 – 0.4	15 – 40	acid or ester	viatel™ DLG 5503 A/E
		0.4 – 0.6	40 – 70		viatel™ DLG 5505 A/E
	65:35	0.2 – 0.4	15 – 40	acid or ester	viatel™ DLG 6503 A/E
	75:25	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 7502 A/E
		0.2 – 0.4	15 – 40		viatel™ DLG 7503 A/E
		0.4 – 0.6	40 – 65		viatel™ DLG 7505 A/E
		0.6 – 0.8	65 – 90		viatel™ DLG 7507 A/E
		0.8 – 1.0	90 – 120		viatel™ DLG 7509 A/E
		1.0 – 1.2	120 – 145	ester	viatel™ DLG 7511 E
		1.2 – 1.4	145 – 180	ester	viatel™ DLG 7513 E
	80:20	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 8002 A/E
		0.2 – 0.4	15 – 40		viatel™ DLG 8003 A/E
	85:15	0.1 – 0.3	5 – 27	acid or ester	viatel™ DLG 8502 A/E
		0.2 – 0.4	15 – 40		viatel™ DLG 8503 A/E
		0.4 – 0.6	40 – 65		viatel™ DLG 8505 A/E
		0.6 – 0.8	65 – 90		viatel™ DLG 8507 A/E
		0.8 – 1.0	90 – 120		viatel™ DLG 8509 A/E
		1.0 – 1.2	120 – 160		viatel™ DLG 8511 A/E
Poly(D,L-lactide)	100:00	0.1 – 0.3	5 – 27	acid or ester	viatel™ DL 02 A/E
		0.2 – 0.4	15 – 40		viatel™ DL 03 A/E
		0.4 – 0.6	40 – 65		viatel™ DL 05 A/E
		0.6 – 0.8	65 – 90		viatel™ DL 07 A/E
		0.8 – 1.0	90 – 130	ester	viatel™ DL 09 E
Poly(ethylene glycol) methyl ether-block-poly(D,L-lactide)		0.33 – 0.38 *	27 – 38	mPEG (Mn 5,000 Da)	viatel™ DL 03 PEG5K

*D,L-LA: D, L-lactide. GA: glycolide

**inherent viscosity ranges per grade can be narrowed to meet customer requirements

*** Mw data is an indicative range based on historical data. Ashland can support tailored Mw requests.

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dedicated to GMP manufacturing and quality

Viatel™ bioresorbable polymers are produced to meet pharmaceutical excipient and medical device manufacturing requirements.

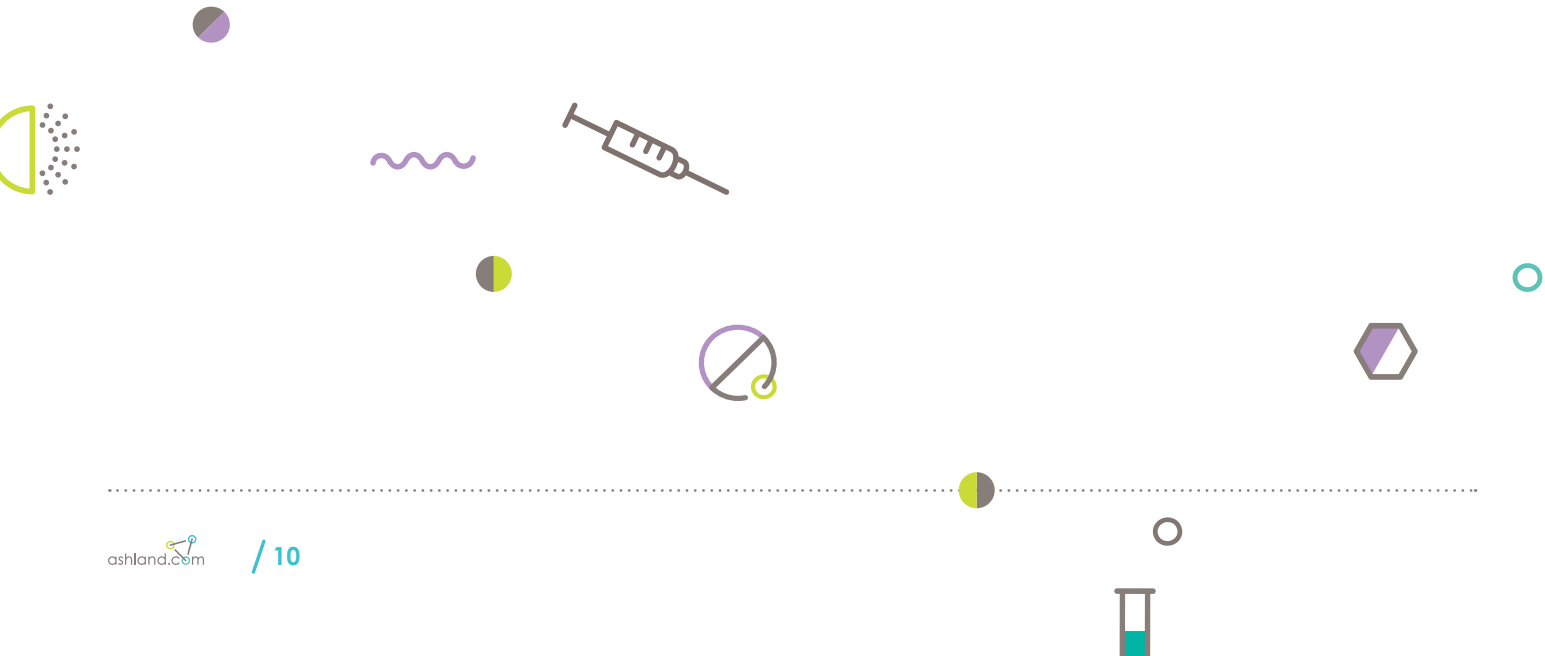
- ISO 13485:2016 certified facility within ISO 14644-1 Cleanroom environment
- Ashland holds a type IV excipient drug master file (DMF) with the FDA for Viatel™ PLGA's (DMF number 33847)
- Ashland also holds China Excipient DMF with National Medical Products Administration (NMPA) for PLGA 5050, PLGA 7525 and PLGA 8515.

packaging, storage, and stability

Viatel™ bioresorbable polymers commercial packaging consists of a triple layer system sealed under inert conditions.

Viatel™ bioresorbable polymers are supplied as granule or powder in 100-gram and 1-kilogram units and are shipped under controlled conditions to maintain 2 – 8°C for 120 hours or 5 days. The majority of viatel polymers offer a 5-year shelf life unless otherwise specified on new, unique or customized grades.

A stability statement containing summary of studies completed for viatel™ bioresorbable polymer portfolio is available on request.



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