viatel™ ultrapure
bioresorbable polymers

high-purity controlled release polymer

Viatel™ Ultrapure polymers are high-purity, controlled-release polymers that provide improved release consistency and extended-release durations; they are better suited for sensitive drug compounds in long-acting injectables and implants (LAII). Removing residual monomer reduces acidic equivalents and results in a more consistent rate of water uptake and degradation kinetics. This means more reproducible performance while also creating a more neutral pH environment. Viatel™ Ultrapure polymers leverage a proprietary purification process that reduces total residual monomer content specifications to below 0.5% with typical batch results of approximately 0.1%. Furthermore, these polymers are pre-filtered during the purification process to ensure exceptional quality.

These low-monomer products are available as GMP grades across the Viatel™ platform and provide formulators greater versatility when solving challenging formulation problems.

Viatel™ Ultrapure polymers are the result of Ashland's commitment to continuous improvement in response to customer needs.

key features

- lowered residual monomer content: ≤ 0.5% total, typical batch results of 0.1%
- reduced tin content (catalyst) is available upon request
- pre-filtered polymer to remove risk of impurities or foreign particles

benefits

- reduced acidity leading to improved stability of sensitive drug compounds
- improved release consistency across all applications due to fewer variables
- extended release with hot melt extrusion applications
- faster solubilization in organic solvents

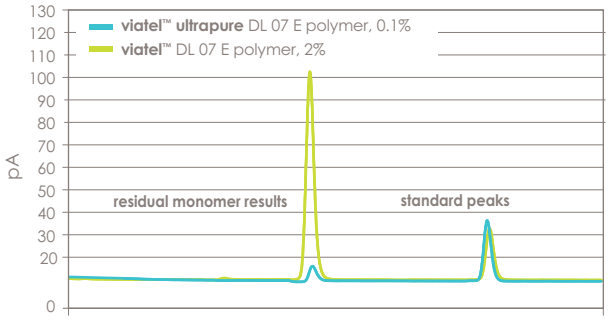
applications

- LAII products, such as microspheres, in-situ depots, implants, and nanoparticles

low residual monomer

Figure 1 displays the gas chromatography comparison for Viatel™ Ultrapure polymer grades versus Viatel™ standard grades and shows significantly lower residual monomer content.

figure 1: viatel™ polymers



reduced acidity

Figures 2 and 3 show change in pH over time to a phosphate buffer saline (PBS) solution containing Viatel™ polymers or their Viatel™ Ultrapure polymer equivalents. Viatel™ Ultrapure polymers exhibit less acidity over time compared to their standard counterparts.

figure 2: viatel™ acidification of PBS — viatel™ Poly D,L-lactide, ester terminated, DL 07 E polymer versus viatel™ ultrapure DL 07 E polymer

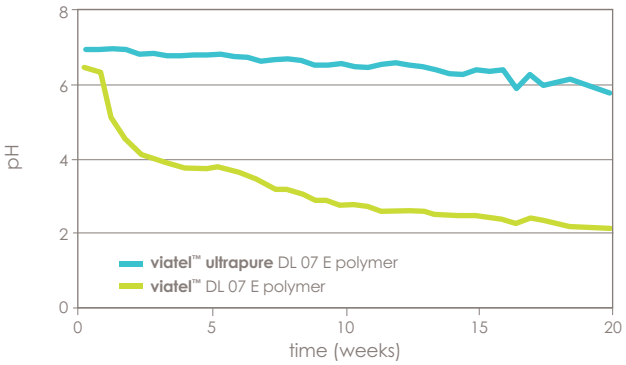
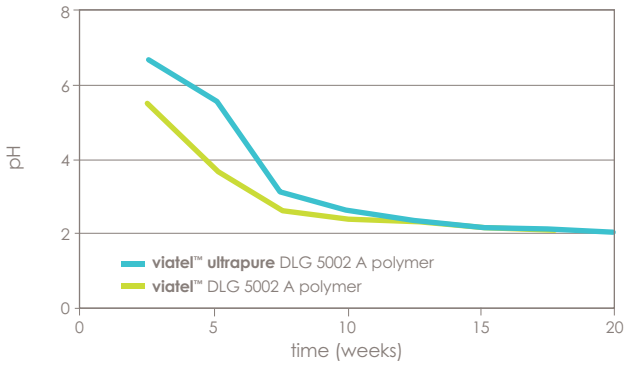


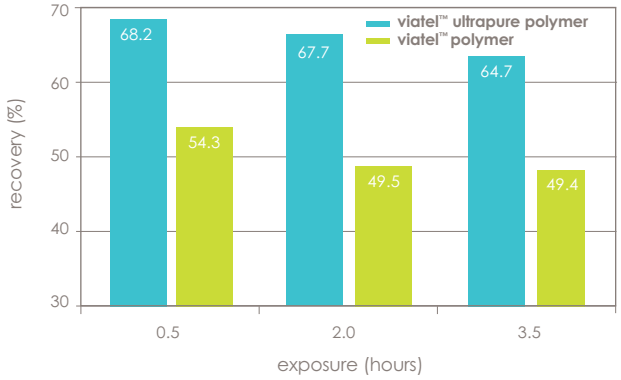
figure 3: viatel™ acidification of PBS — viatel™ Poly D,L-lactide-co-glycolide 50:50 acid terminated, DLG 5002 A polymer versus viatel™ ultrapure DLG 5002 A polymer



improved stability

Reduced acidity can preserve sensitive APIs, as demonstrated in figure 4. Omeprazole was dissolved in N-Methyl-2-pyrrolidone (NMP) and exposed to Viatel™ polymer or the equivalent Viatel™ Ultrapure polymer. Viatel™ Ultrapure polymer demonstrated reduced degradation to the API.

figure 4: omeprazole stability during exposure to residual monomer



extended release using viatel™ ultrapure polymer

Hot melt extrusion was utilized to fabricate two implants consisting of metformin (10% drug load) and either Viatel™ DLG 7509 E polymer or Viatel™ Ultrapure DLG 7509 E polymer. These implants were exposed to phosphate buffered saline at 37 °C for 5 weeks, sampling at various timepoints to assay for molecular weight and drug released. Figure 5 shows Viatel™ standard grade polymer experienced a greater loss of molecular weight due to acid catalyzed hydrolysis of the polymer. This resulted in a faster release profile compared to Viatel™ Ultrapure polymer, as shown in figure 6.

figure 5: molecular weight degradation during *in-vitro* release

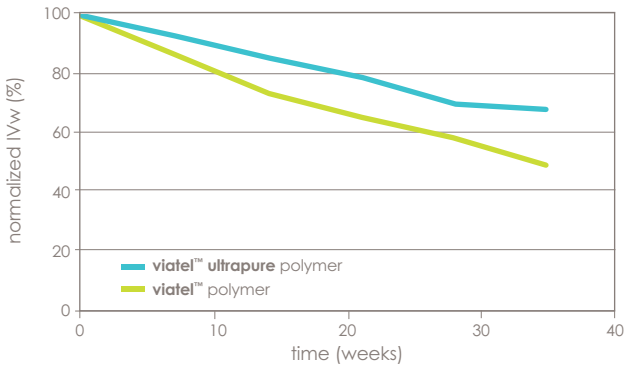
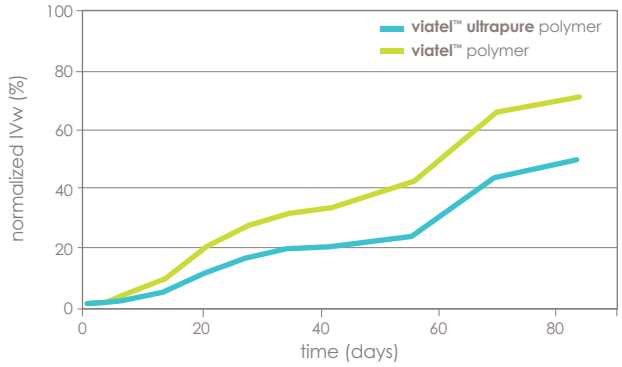


figure 6: *in-vitro* release profile comparing viatel™ polymer versus viatel™ ultrapure polymer



specifications table

Viatel™ Ultrapure polymer is tested to meet the following limits:

characteristic	test method	acceptance criteria
appearance	visual inspection	white to light brown solid granules, powder, flake, or other suitable form
polymer identification	1H-NMR spectroscopyas per USP <761>	conforms to 1H-NMR reference spectrum
co-polymer ratio		ratio of monomers ± 3 (mole %)
inherent viscosity	Ubbelohde viscometry (0.1 or 0.5 wt%*, 25 °C, CHCl3) as per USP <911> Method 1	grade dependent tailored IV ranges available
molecular weight	gel permeation chromatography (35 °C, THF, PS standard)	as reported *for indication only*
residual monomer	gas chromatography (FID-detector) as per USP <621> and <467>	≤ 0.5 % combined D,L-lactide and glycolide
residual solvents		max. 0.1 % total
water content	Karl Fischer as per USP <921>	≤ 0.5 wt%
acid number	titration as per USP <541>	determine and report
tin content	ICP-MS as per USP <730>	≤ 150 ppm Sn
solubility	visual inspection after dissolution in CHCl3, DCM at 15 – 30 °C	clear homogenous solution with no observable fibres, particles, or other impurities
****bioburden (optional)**	USP <61>, <62> or Ph. Eur. 2.6.12 and 2.6.13	TAMC ≤ 100 CFU/g TYMC ≤ 100 CFU/g
****endotoxin (optional)**	USP <85> method A (gel clot method) or Ph. Eur. 2.6.14	≤ 0.5 EU/g

*0.1 wt% concentration used for IV specs > 0.4 dl/g, 0.5 wt% concentration used for IV specs ≤ 0.4 dl/g.

**Outsourced lab is used for these tests when required.

packaging

available in triple layered 100 g or 1 kg packaging

- PA/PE bag (primary), heat sealed under inert conditions
- PET/Foil pouch (secondary), heat sealed
- PE bag (tertiary), heat sealed

Ashland offers shipping of Viatel™ products under controlled conditions, with a validated shipping system, to maintain 2 – 8 °C for 5 days.

manufacturing and quality:

Viatel™ bioresorbable polymers are produced in an ISO 14644-1 Class 8 cleanroom environment and 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.

Ashland holds a type IV excipient drug master file (DMF) with the FDA for Viatel™ bioresorbable polymers (DMF number 33847) and holds a China Excipient DMF with National Medical Products Administration (NMPA) for PLGA 5050, PLGA 7525 and PLGA 8515. During 2020-2024, Ashland manufactures these materials at a state-of-the-art GMP manufacturing and R&D facility located in Mullingar, Ireland.

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