



Ashland announces compliance of viatel™ lactide/glycolide polymers versus upcoming LG polymer USP-NF monographs.

February 5, 2025

WILMINGTON, Del., February 5, 2025, – Ashland, a premier specialty materials company, is pleased to announce compliance with the upcoming Lactide (or lactic acid) and Glycolide (or glycolic acid) (LG) polymer USP-NF monographs. The announcement came during a joint [webinar](#) with Ashland and Oakwood laboratories on scale-up of long-acting injectables. Ashland has been actively involved in the development of USP-NF monographs, general chapters and reference standards for LG Polymers. Patrick Duffy, PhD, R&D team leader, Ashland, serves as an expert advisor to USP's joint sub-committee working on LG polymer monographs.

The USP–NF combines the United States Pharmacopeia (USP) and the National Formulary (NF) and contains more than 5,000 public quality standards for chemical and biologic medicines, active pharmaceutical ingredients (APIs), dietary ingredients and dietary supplements, and excipients. It also maintains standards for various analytical testing methods, medicine storage and distribution, compounded medicines, prescription labeling and many other aspects of medical product development, manufacture and use.

Regulatory evaluation of LG polymer-containing drug products remains challenging due to the complexities of LG polymers, their characterization and testing, and use in formulations. The USP developed a suite of solutions to help formulators meet the regulatory expectations and characterization challenges associated with these polymers. Refer to www.usp.org/excipients/lg-polymers. This work included the development of a series of NF monographs – which are used to articulate the quality expectations for a medicine. Expectations are included for a drug's identity, strength, purity, and performance. Monographs also describe tests needed to validate the medicine and its ingredients meet expected criteria.

The first three LG polymer monographs have now been published in USP-NF 2025, Issue 1 and will be official as of May 1, 2025.

- DL-Lactide and Glycolide (50:50) Copolymer 12000 Acid
- DL-Lactide and Glycolide (50:50) Copolymer 12000 Ethyl Ester
- DL-Lactide and Glycolide (50:50) Copolymer 46000 Acid

Ashland has completed verification testing of corresponding grades from the viatel™ portfolio of LG polymers (DLG 5002 A UP, DLG 5002 E UP, DLG 5005 A UP) in order to certify compliance with these recently published NF monographs. Today, the company announced its viatel™ portfolio of products meet the stringent quality standards associated with the upcoming monographs.

For more information about the Ashland [viatel™](#) portfolio, visit www.ashland.com/industries/pharmaceutical/parenteral-dosage/viatel-bioresorbable-polymers

About Ashland

Ashland Inc. (NYSE: ASH) is a global additives and specialty ingredients company with a conscious and proactive mindset for environmental, social and governance (ESG). The company serves customers in a wide range of consumer and industrial markets, including architectural coatings, construction, energy, food and beverage, personal care and pharmaceutical. Approximately 3,200 passionate, tenacious solvers thrive on developing practical, innovative and elegant solutions to complex problems for customers in more than 100 countries. Visit ashland.com and ashland.com/ESG to learn more.

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