

Certificate of Analysis

AKINA INC COA CONTACT 3495 KENT AVENUE WEST LAFAYETTE IN 47906 Customer Order: 230925DTERD

Shipped Quantity: 100.000 G Shipped From: ASIE IE MULLINGAR PLT Order Number: 8828405/000020 Delivery: 852698293/000010 Date Shipped: October 31, 2023 Sold To Number: 700479

VIATEL DLG 5003 A BAG 100GM Viatel(TM) DLG 5003 A Poly(D,L-lactide-co-glycolide) (PLGA) Ashland Material Number: 946848

		Batch: 0002533975
Characteristics	Specification	Results
Appearance	PASS	PASS
(Pass = White to light tan		
solid granules, powder, flake		
or other suitable form as		
agreed with the Customer)	0.00.0.10	
Molar Mass (Inherent	0.20 - 0.40	0.28
Viscosity), dl/g		
Polymer Identification (Pass =	PASS	PASS
Conforms to 1H-NMR reference		
spectrum)		
Co-polymer ratio (Ratio of	47.0 - 53.0	49.3
D,L-lactide), mole %		
Co-polymer ratio (Glycolide),	47.0 - 53.0	50.7
mole %		1.05
Residual Monomer (Combined	<= 3.00	1.85
D,L-lactide and glycolide), %wt.	150	150
Tin Content, ppm	<= 150	150
Solubility (Pass = Clear	PASS	PASS
homogenous solution in		
Chloroform or Dichloromethane)		
Date of Manufacture		May 19, 2021
Next Retest Date		May 18, 2026
Shipped Quantity	<u>l</u>	100.000 G

Notes:

- Packaging: This product is not sterilized and is packaged in PET/Foil/PE heat sealed packaging.

- Test Methods: Inherent viscosity is determined via Ubbelohde capillary viscometry (type Oc) in chloroform (0.1 g/dl) as per USP <911> Method 1. Polymer identification, co-polymer molar ratio and residual monomer content are determined via 1H-NMR spectroscopy as per USP <761>. Tin content is advised based on the amount of catalyst added during synthesis.

- The manufacturing and quality control records associated with above referenced lot of Viatel product have been reviewed and found to be complete. The Quality control testing of the lot complies with specification established by Ashland Specialties Ireland Ltd. The batch was produced in compliance with current USP/NF <1078> Good Manufacturing Practices for Bulk Pharmaceutical Excipients and ISO13485:2016 requirements. This lot is released for distribution.



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Characteristics Specification Results	

- Storage Conditions: When stored in the original packaging at low temperatures <-15°C, recommended shelf life is three years. Allow the material to reach room temperature before opening the packaging.

This COA is printed from a secure computer system ensuring the batch was properly released by the Quality Department and is valid without signature.

Manufactured by: ASHLAND SPECIALTIES IRELAND LTD. AFFILIATE OF ASHLAND Dublin Road, Petitswood MULLINGAR, CO. WESTMEATH N91 F6PD IRELAND

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