

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: 8828405/000110
Delivery: 852698300/000010
Date Shipped: October 31, 2023

Sold To Number: 700479

VIATEL DLG 5002 A BAG 100GM

Viatel(TM) DLG 5002 A Poly(D,L-lactide-co-glycolide) (PLGA)

Ashland Material Number: 952401

		Batch: 0002650007
Characteristics	Specification	Results
Appearance	PASS	PASS
(Pass = White to light tan		
solid granules, powder, flake		
or other suitable form as		
agreed with the Customer)	0.10	0.15
Molar Mass (Inherent	0.10 - 0.30	0.15
Viscosity), dl/g	PASS	PASS
Polymer Identification (Pass = Conforms to 1H-NMR reference	PASS	PASS
spectrum)		
Co-polymer ratio (Ratio of	47.0 - 53.0	50.2
D,L-lactide), mole %	17.0 33.0	30.2
Co-polymer ratio (Glycolide),	47.0 - 53.0	49.8
mole %		
Residual Monomer (Combined	<= 3.00	2.48
D,L-lactide and glycolide), %wt.		
Tin Content, ppm	<= 150	135
Solubility (Pass = Clear	PASS	PASS
homogenous solution in		
Chloroform or Dichloromethane)		
Date of Manufacture		May 19, 2023
Next Retest Date		May 18, 2028
Shipped Quantity	L	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 0c) 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.

Printed: October 31, 2023 11:23:13



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Ashland Material Number: 952401

Batch: 0002650007

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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