

## Certificate of Analysis

<b>AKINA INC</b> <b>COA CONTACT</b> <b>3495 KENT AVENUE</b> <b>WEST LAFAYETTE IN 47906</b>	<b>Customer Order: 230925DTERD</b>  <b>Shipped Quantity: 100.000 G</b> <b>Shipped From: ASIE IE MULLINGAR PLT</b> <b>Order Number: 8828405/000040</b> <b>Delivery: 852698293/000030</b> <b>Date Shipped: October 31, 2023</b> <b>Sold To Number: 700479</b>
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VIATEL DLG 5005 E BAG 100GM  
 Viatel(TM) DLG 5005 E Poly(D,L-lactide-co-glycolide) (PLGA)  
 Ashland Material Number: 946855

Batch: 0002615160

Characteristics	Specification	Results
Colour (Visual Inspection) Spec: White to light brown	Determine/Report	BEIGE
Form (Visual Inspection) Spec: Granules, powder, flake or other suitable form as agreed with the customer	Determine/Report	GRANULES
Polymer Identification (1H -NMR Spectroscopy)	PASS	PASS
Co-polymer Ratio - D,L-lactide, mol % (1H -NMR)	47.0 - 53.0	51.0
Co-polymer Ratio - Glycolide, mol % (1H-NMR)	47.0 - 53.0	49.0
Inherent Viscosity, dl/g (U-tube)	0.40 - 0.60	0.59
Molecular Weight - Mn, kDa (GPC)	Determine/Report	42.4
Molecular Weight - Mw, kDa (GPC)	Determine/Report	76.7
Polydispersity (GPC)	Determine/Report	1.8
Residual Monomer - D,L-lactide, wt%. (GC)	Determine/Report	0.92
Residual Monomer - Glycolide, wt%. (GC)	Determine/Report	0.11
Residual Monomer - total, wt%. (GC)	<= 3.00	1.18
Water Content, %wt. (Karl Fischer)	<= 0.50	0.20
Acid Number, mgKOH/g (Titration)	Determine/Report	0.20
Solubility (Visual inspection)	PASS	PASS
Tin Content, ppm (ICP-MS)	<= 150	135
Bioburden-TYMC, cfu/g (PASS=<100 cfu/g)	Determine/Report	PASS
Bioburden-TAMC, cfu/g (PASS= <100 cfu/g)	Determine/Report	PASS
Endotoxin Testing, EU/g (Using LAL gel clot) (PASS=NMT 0.5 EU/g)	Determine/Report	PASS

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VIATEL DLG 5005 E BAG 100GM  
 Viatel(TM) DLG 5005 E Poly(D,L-lactide-co-glycolide) (PLGA)  
 Ashland Material Number: 946855

Batch: 0002615160

Characteristics	Specification	Results
Date of Manufacture		August 17, 2022
Expiry Date		August 16, 2027
Shipped Quantity		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.
  
- 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.

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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: 8828405/000040 Delivery: 852698293/000030 Date Shipped: October 31, 2023 Sold To Number: 700479	
VIATEL DLG 5005 E BAG 100GM Viatel(TM) DLG 5005 E Poly(D,L-lactide-co-glycolide) (PLGA) Ashland Material Number: 946855		
Batch: 0002615160		
<b>Characteristics</b>	<b>Specification</b>	<b>Results</b>

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

Contact:  
 MATEUSZ WALENCIAK  
 Phone: +48223955322  
 Email: Mateusz.Walenciak@ashland.com