

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: 8828405/000030 Delivery: 852698293/000020 Date Shipped: October 31, 2023 Sold To Number: 700479
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VIATEL DLG 5005 A BAG 100GM
 Viatel(TM) DLG 5005 A Poly(D,L-lactide-co-glycolide) (PLGA)
 Ashland Material Number: 946849

Batch: 0002648016

Characteristics	Specification	Results
Colour (Visual Inspection) Spec: White to light brown	Determine/Report	OFF WHITE
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	50.0
Co-polymer Ratio - Glycolide, mol % (1H-NMR)	47.0 - 53.0	50.0
Inherent Viscosity, dl/g (U-tube)	0.40 - 0.60	0.46
Molecular Weight - Mn, kDa (GPC)	Determine/Report	24.8
Molecular Weight - Mw, kDa (GPC)	Determine/Report	50.3
Polydispersity (GPC)	Determine/Report	20.0
Residual Monomer - D,L-lactide, wt%. (GC)	Determine/Report	0.08
Residual Monomer - Glycolide, wt%. (GC)	Determine/Report	0.00
Residual Monomer - total, wt%. (GC)	<= 3.00	0.08
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
Date of Manufacture		May 03, 2023
Expiry Date		May 02, 2028
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.

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VIATEL DLG 5005 A BAG 100GM Viatel(TM) DLG 5005 A Poly(D,L-lactide-co-glycolide) (PLGA) Ashland Material Number: 946849	Batch: 0002648016
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Characteristics	Specification	Results
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- 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.

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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