Ashland™

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: 8828405/000060** **Delivery: 852698293/000050** **Date Shipped: October 31, 2023** **Sold To Number: 700479**

VIATEL DLG 7505 A BAG 100GM
Viatel(TM) DLG 7505 A Poly(D,L-lactide-co-glycolide) (PLGA)
Ashland Material Number: 946861

Batch: 0002640537

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)	72.0 - 78.0	74.1
Co-polymer Ratio – Glycolide, mol % (1H-NMR)	22.0 - 28.0	25.9
Inherent Viscosity, dl/g (U-tube)	0.40 - 0.60	0.51
Molecular Weight – Mn, kDa (GPC)	Determine/Report	25.2
Molecular Weight – Mw, kDa (GPC)	Determine/Report	51.1
Polydispersity (GPC)	Determine/Report	2.0
Residual Monomer – D,L-lactide, wt%. (GC)	Determine/Report	1.89
Residual Monomer – Glycolide, wt%. (GC)	Determine/Report	0.06
Residual Monomer – total, wt%. (GC)	<= 3.00	2.05
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 7505 A BAG 100GM
Viatel(TM) DLG 7505 A Poly(D,L-lactide-co-glycolide) (PLGA)
Ashland Material Number: 946861

Batch: 0002640537

Characteristics	Specification	Results
Date of Manufacture		October 11, 2023
Expiry Date		October 10, 2028
Shipped Quantity		100.000 G

Notes:

Packaging:
This product is not sterilized and is packaged in PET/FOIL/PE heat sealed packaging under inert conditions.

Test Methods:

· Polymer identification and co-polymer ratio is determined via 1H-NMR spectroscopy in deuterated chloroform as per USP <761>.

· Inherent viscosity is determined via ubbelohde capillary viscometry in chloroform at 25 °C at a concentration of 0.1 wt% for IV specs greater than 0.40 dl/g and at a concentration of 0.5 wt% for IV specs less than or equal to 0.40 dl/g as per USP <911> method 1.

· Molecular weight and polydispersity are determined via gel permeation chromatography at 35 °C using THF or 30 °C using chloroform as the eluent and polystyrene standards.

· Residual monomer is determined via gas chromatography with FID detector as per USP <621> or via 1H-NMR spectroscopy as per USP <761>.

· Water content is determined via Karl Fischer (oven method) as per USP <921>.

· Acid number is determined via potentiometric titration as per USP <541>.

· Solubility is performed by visual inspection after polymer dissolution in CHCl3, DCM at 15 to 30 °C. Pass criteria for solubility is a clear homogenous solution with no observable fibers, particles, or other impurities.

· Tin content is determined via inductively coupled plasma-mass spectroscopy as per USP <730>, after samples were prepared by microwave digestion.

· Microbiological testing is carried out as per customer request. Bioburden testing is done as per USP <61>, <62> or Ph. Eur. 2.6.12 and 2.6.13. Endotoxin testing is carried out as per USP <85> method A (gel clot method) or Ph. Eur. 2.6.14.

The manufacturing and quality control records associated with the above referenced lot of

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VIATEL DLG 7505 A BAG 100GM
Viatel(TM) DLG 7505 A Poly(D,L-lactide-co-glycolide) (PLGA)
Ashland Material Number: 946861

Batch: 0002640537

Characteristics	Specification	Results

Viatel product have been reviewed and found to be complete. The quality control testing of the lot complies with specifications 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 ISO 13485:2016 requirements. This lot is released for distribution.

Storage Conditions: When stored in the original packaging, at <-15C, recommended shelf life is five 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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Printed: October 31, 2023 11:21:10