

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: 8828405/000080 Delivery: 852698293/000070 Date Shipped: October 31, 2023

Sold To Number: 700479

VIATEL L 18 E BAG 100GM

Viatel(TM) L 18 E Poly(L-lactide) (PLLA)

Ashland Material Number: 946890

Batch: 0002648943

	Baccii: 0002040743	
Characteristics	Specification	Results
Appearance	PASS	PASS
(Pass = White to light tan		
solid granules, powder, flake		
or other suitable form as		
agreed with the Customer)		
Molar Mass (Inherent	1.60 - 2.00	1.64
Viscosity), dl/g		
Polymer Identification (Pass =	PASS	PASS
Conforms to 1H-NMR reference		
spectrum)		
Residual Monomer (L-lactide),	<= 3.00	2.44
%wt.		
Tin Content, ppm	<= 150	135
Solubility (Pass = Clear	PASS	PASS
homogenous solution in		
Chloroform or Dichloromethane)		
Date of Manufacture		May 10, 2023
Next Retest Date		May 09, 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.
- 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.

Printed: October 31, 2023 11:22:28



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Characteristics Specification Results

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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