



## Certificate of Analysis

Near Jyoti Ltd, BIDD Gorwa Estate, Vadodara, Gujarat 390016

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<b>Product Name</b>	85:15Poly(D,L-lactide-co-glycolide)Acid terminated		
<b>Batch No</b>	DLG85W001		
<b>Item code</b>	DLG852A	<b>HSN Code</b>	29181110
<b>CAS No</b>	26780-50-7	<b>Specification No</b>	DLG852AFP001
<b>Mfg. date:</b>	Mar-23	<b>Retest Date</b>	Mar-25
Sr No.	Description	Specification	Results
1	Appearance	White powder.	Complies
2	FT NMR (PROTON)	Should comply	Conform to the structure.
3	Polymer Composition: Lactide	85±2%	86.5%
4	Polymer Composition: Glycolide	15±2%	13.5%
5	Inherent Viscosity (1% in CHCl <sub>3</sub> )	Between 0.16 - 0.24dL/g	0.23dl/g
6	Residual monomer DL-Lactide	≤ 0.5 %	0.25%
7	Residual monomer Glycolide	≤ 0.5 %	Not detected
8	Residual Solvent DMSO	≤ 0.5 %	0.24%
9	Residual solvent Toluene	≤ 890 PPM	Not Detected
10	Acid number	≤8-15 mg KOH/g	8.70
11	Residual Tin	≤ 50 PPM	Not Detected
12	Water content	≤ 0.5%	0.31%
13	Residue on Ignition (Sulfated Ash)	≤ 0.1%	Complies
14	Total Aerobic Microbial Count	≤ 100 CFU/g	Complies
15	Total Yeast and Molds	≤ 100 CFU/g	Complies
16	Bacterial Endotoxins	≤ 0.1 EU/mg	Complies

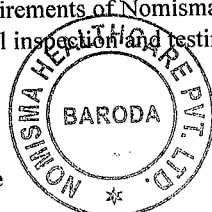
For all other Class 1, Class 2, and Class 3 elemental impurities, this product is in compliance with the limit requirements in General Chapters <232> Elemental Impurities and the ICH Q3D Guideline for Elemental Impurities.

The polymer remains stable when stored in -25° to 8 C for 24 months in the original unopened containers. The polymer can be requalified for an additional 24 months (up to a maximum of 48 months from the manufacturing date) by reanalysis of inherent viscosity.

The product conforms to the requirements of Nomisma Healthcare, including ISO 9001:2015. However, the customer is still responsible for conducting careful inspection and testing of incoming products.

Released By:

Quality Assurance



Milanj

04-05-2023

Signature by QA signifies that the batch record has been reviewed and that the above values accurately reflect the results obtained.