



## Certificate of Analysis

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


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Sr No.	Description	Specification	Methods
1	Appearance	White powder.	As per USP/EP
2	FT NMR (PROTON)	Should comply	As per USP/EP
3	Polymer Composition: Lactide	±2% of Reported value	Proton NMR
4	Polymer Composition: Glycolide	±2% of Reported value	Proton NMR
5	Inherent Viscosity (1% in CHCl <sub>3</sub> )	±10% of Reported value	ubbelohde viscometer
6	Residual monomer DL-Lactide	≤ 0.5 %	GC
7	Residual monomer Glycolide	≤ 0.5 %	GC
8	Residual Solvent DMSO	≤ 0.5 %	GC
9	Residual solvent Toluene	≤ 890 PPM	GC
10	Acid number	Acid Terminated 8-15 mg KOH/g Ester Terminated ≤6 mg KOH/g	Auto titrator
11	Residual Tin	≤ 50 PPM	As per USP/EP
12	Water content	≤ 0.5%	As per USP/EP
13	Residue on Ignition (Sulfated Ash)	≤ 0.1%	As per USP/EP
14	Total Aerobic Microbial Count	≤ 100 CFU/g	As per USP/EP
15	Total Yeast and Molds	≤ 100 CFU/g	As per USP/EP
16	Bacterial Endotoxins	≤ 0.1 EU/mg	As per USP/EP

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.

  
27-10-2023

