Nomisma Healthcare

Certificate of Analysis

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

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Product :	**DLG757E**	**Inherent viscosity (IV): 0.66-0.80 dL/g**	**HSN Code : 29181110**
Certificate for	**Poly DL-lactic-co-glycolic acid (C3H4O2)x(C2H2O2)y_70kDa**	**Polymer Ratio: PLGA 75/25**	**CAS No: 26780-50-7**
		End group: Ester	**Specification No.:DLG757EFP01**

Batch No : DLG757EV0306 **Manufacturing date: Mar-22**

Expiry Date: Mar-24

Sr No.	Description	Specification	Results
1	Appearance	White to tan solid	Complies
2	FT NMR (PROTON)	Should comply	Conform to the structure.
3	Polymer Composition: lactide	75±2%	75.0%
4	Polymer Composition: Glycolide	25±2%	25.0%
5	Inherent Viscosity (0.5% in CHCl3)	Between 0.75-1.00 dL/g	0.69 dl/g
6	Residual monomer DL-Lactide	≤ 2 %	0.55%
7	Residual monomer Glycolide	≤ 2 %	Not detected
8	Residual solvent acetone	≤ 0.1 %	Not Detected
9	Residual solvent toluene	≤ 890 PPM	Not Detected
10	Totel Residual solvent	≤ 1000 PPM	Not detected
11	Acid number	≤ 6 mg KOH/g	4.1
12	Residual Tin	≤ 200 PPM	185 PPM
13	Water content	≤ 0.5%	0.41%
14	Residue on Ignition (Sulfated Ash)	≤ 0.1%	Complies
15	Total Aerobc Microbal Count	≤ 2000 CFU/g	Complies
16	Total Yeast and Molds	≤ 200 CFU/g	Complies
17	Bacterial Endotoxins	≤ 6 EU/g	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 ICH Q3D Guideline for Elemental Impurities.

The polymer is stable when stored in a freezer (s -10° C) for 24 months in the original unopened containers. The polymer may be requalified for an additional 24 months (to a maximum of 48 months from the manufacture date) by reanalysis of inherent viscosity.

The Product conforms to the requirements of Nomisma Healthcare, including ISO 9001:2015. The customer is not released from the obligation to conduct careful inspection and testing of incoming products.

GMP Compliance:
The product is manufactured according to current Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients as published by IPEC-PQG.

Released By:

Date : 18 March 2022

Quality Assurance

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