Poly(lactide-co-glycolide) (PLGA) 50:50

Specification and Test Methods

Chemical Name	Poly (DL-lactide-co-glycolide) Ester Terminated
CAS No.	26780-50-7
Ratio of La and Ga	50% Lactide and 50% Glycolide

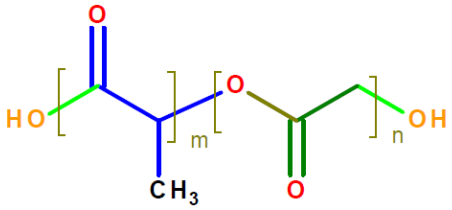
1 Commercial form

Poly DL-lactic-co-glycolic acid (Ester terminated)

Polymer Identity	I.V range (dl/g) / Mw in KDa
DLG50-6E	0.50-0.65/ 60-85

2 Chemical structure

PLGA 50:50 is a co-polymer based on Lactide and Glycolide with a ratio of 50:50.



The monomers are randomly distributed along the copolymer chain.

3 Characteristic

Description

PLGA 50:50 is White to Tan colored solid powder

Solubility

Freely soluble in methylene chloride, Acetone, Ethyl acetate.

Insoluble in water.

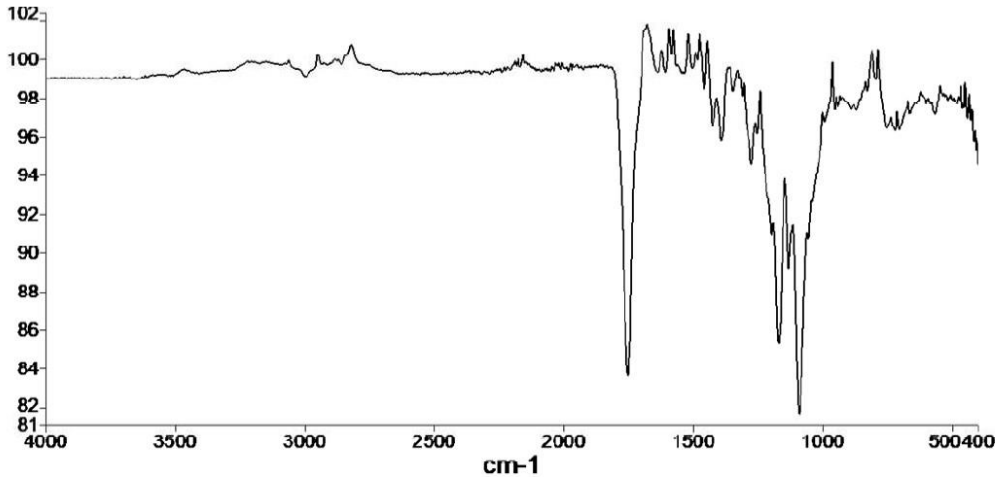
(Reference: USP, BP, Ph.Eur.,IP)

4 Identification

Identification by FT-IR

The transmission minima (absorption maxima) in the spectrum obtained with the substance correspond in position and relative size to those in spectrum obtained with the working standard.

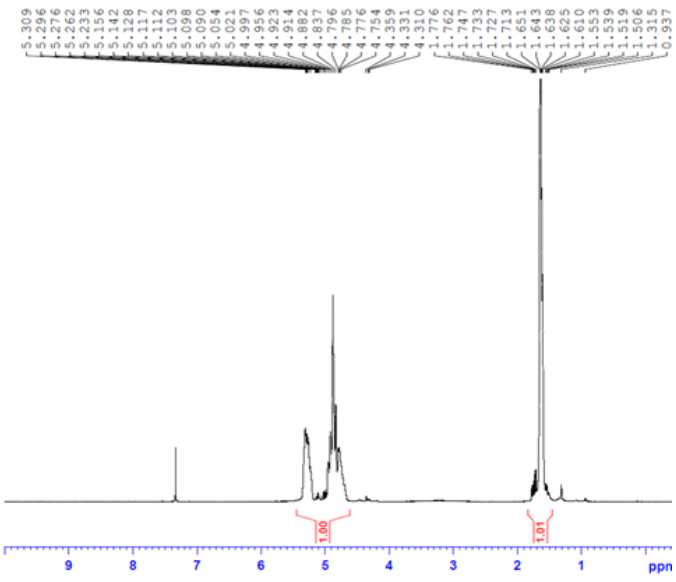
(Reference: USP <197K> Ph. Eur. 2.2.24, BP Appendix IIA)



Identification by NMR

Analytical methods for determination mole ratio of monomers, block structure characterization, end group analysis by NMR spectroscopy technique are developed.

Ref: Polylactic-Co-Glycolic Acid (PLGA), Konstantinos Avgoustakis, Laboratory of Pharmaceutical Technology, Department of Pharmacy, University of Patras, Rio, Greece



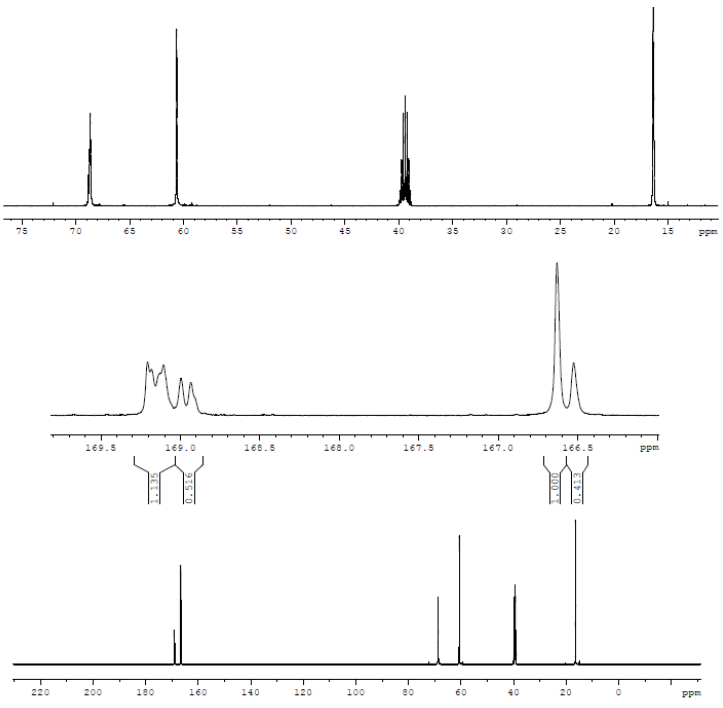
The spectra were used to determine lactic acid and glycolic acid ratio. The integrated areas of the peak at 5.2 ppm (1H) and at 4.8 ppm (2H) were compared directly to confirm the lactic acid and glycolic acid ratio of PLGA. The mole fraction (ML) of lactide was calculated using the integrated area of the peaks of lactide and glycolide

Calculation:

A=Integral Value of 1.57ppm	1.01
B=Integral Value of 4.2ppm+5.5ppm	1.00
m=Mole Fraction of Lactic Acid=A/3	0.337
n=Mole Fraction of Glycolic Acid=(B-m)/2	0.332
(m+n)=	0.668
% Mole Ratio of Lactic acid=(m/m+n)*100	50.4 i.e.~50%
% Mole Ratio of Glycolic acid=(n/m+n)*100	49.6 i.e.~ 50%

Polymer Blockiness and End Group

The monomer sequence distribution i.e. glycolide –glycolide (G-G) or glycolide-lactide (G-L) block length and End group of polymers i.e., Ester terminated is determined by 13C NMR spectroscopy. (Typical reference spectra as per below)



5 Purity

Sulphated ash / Residue on ignition

Max. 0.1 %
The test is performed according to Ph. Eur. 2.4.14 or USP <281>.

Heavy metals

Max. 20 ppm
The test is performed according to Ph. Eur. 2.4.8 method C or USP <231> method II.

Monomers

Total of monomers: < 2000 ppm
The test is performed by GC or Limit test by Q-NMR.

Acid number

Acid number is a measure of the acid content in the polymer, is directly related to the number of free carboxylic acid functionalities and it is determined by titration.

≤ 5 mg KOH/g

Residual Solvents

Small amounts of Dimethyl sulphoxide is present in the product within the specified limit. The concentration remains below 0.5 %.
The test is performed according to Ph. Eur. 2.4.24 sample preparation 2 or USP <467>.

Microbial count

Total aerobic microbial count (TAMC): max. 10^3 CFU / g
Total combined yeasts and moulds count (TYMC): max. 10^2 CFU / g
(Acceptance criteria according to Ph. Eur. 5.1.4 / USP <1111>) The test is performed according to Ph. Eur. 2.6.12 or USP <61>.

Water content

Not more than 0.5%
The test is performed according to USP<921>,Ph.Eur.2.5.12,BP Appendix IXC,IP 2.3.43

Viscometry (Inherent Viscosity)

The inherent viscosity (iv) of polymer samples is determined in a capillary Oc in chloroform

at 25°C.

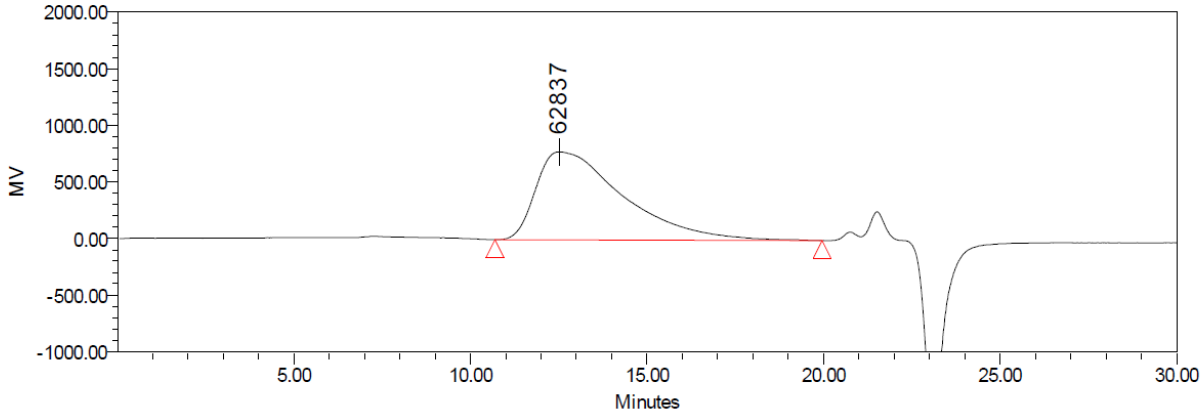
Potency by Q-NMR

Not less than 98.0%
The Potency of Polymer is calculated by Acetanilide Internal standard concerning -CH_3 peak of polylactide.

GPC Analysis

Gel permeation chromatography is analyzed with respect to Polystyrene Molecular weight

Standards. (Typical reference chromatogram as per below)



6 Storage

PLGA Protect from warm temperatures (USP, General Notices). Protect from moisture. Any storage between 8°C and 25°C fulfils this requirement. PLGA tends to form lumps at warm temperatures (≥ 30°C). This has no influence on the quality. The lumps are easily broken up again.

7 Stability

Minimum stability dates are given on the product labels and batch-related Certificates of Analysis. Storage Stability data are available upon request.

Nomisma Healthcare pvt.ltd
J-63 BIDC, Gorwa ,Vadodara, Gujarat, India
PHONE +919773134699, info@nomismahealthcare.com, www.nomismahealthcare.com