

Poly(lactide-co-glycolide) (PLGA) 75:25

Specification and Test Methods

Chemical Name	Poly(DL-lactide-co-glycolide) or Propanoic acid 2-hydroxypolymer with hydroxyacetic acid
CAS No.	26780-50-7
Ratio of La and Ga	75% Lactide and 25% Glycolide

1 Commercial form

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

Polymer Identity	I.V range / Mw in kDa
DLG 75-2A	0.08-0.21 / 5-20
DLG 75-5A	0.38-0.64 / 37-84
DLG 75-7A	0.60-0.70 / 65-85
DLG 75-8A	0.70-0.90 / 76-130
DLG 75-10A	0.80-1.10 / 110-166

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

Polymer Identity	I.V range / Mw in kDa
DLG 75-2E	0.08-0.21 / 5-20
DLG 75-5E	0.38-0.64 / 37-84
DLG 75-7E	0.60-0.70 / 65-85
DLG 75-8E	0.70-0.90 / 76-130
DLG 75-10E	0.80-1.10 / 110-166

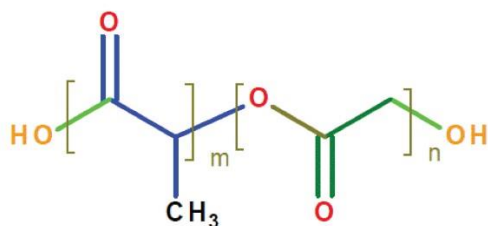
Poly L-lactic-co-glycolic acid (Hydroxy terminated)

Polymer Identity	I.V range / Mw in kDa
LG 75-2A	0.08-0.21 / 5-20
LG 75-5A	0.38-0.64 / 37-84
LG 75-7A	0.60-0.70 / 65-85
LG 75-8A	0.70-0.90 / 76-130
LG 75-10A	0.80-1.10 / 110-166

MOQ-25g,

2 Chemical structure

PLGA 75:25 is copolymer based on Lactide and Glycolide with a ratio of 75:25.



The monomers are randomly distributed along the copolymer chain.

3 Characters

Description

PLGA 75:25 is White to Tan colored solid powder

Solubility

Freely soluble in methylene chloride, Acetone, Ethyl acetate etc.

Insoluble in water.

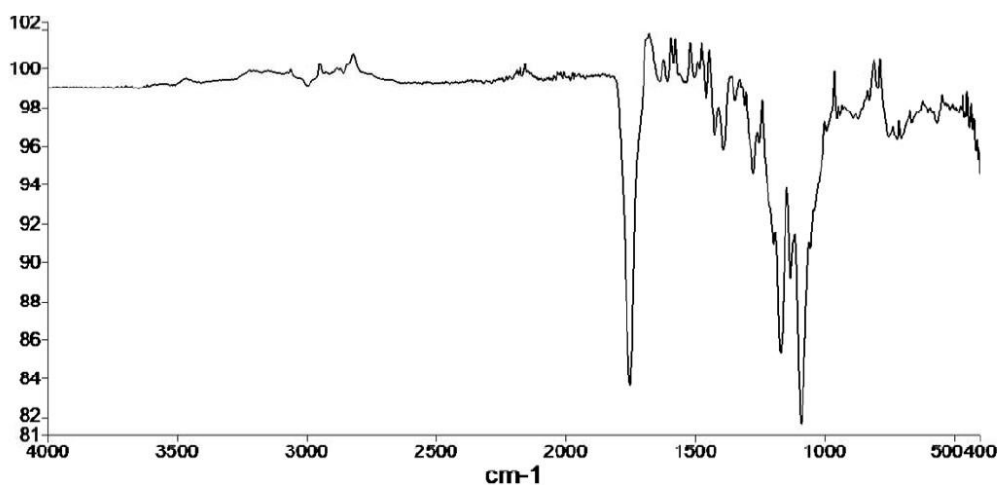
(Reference: USP, BP, Ph.Eur.,IP)

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.

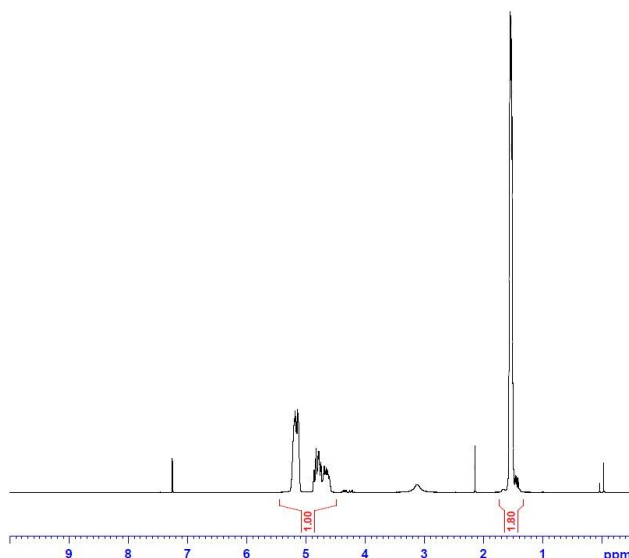
(Reference: USP <197K> Ph. Eur. 2.2.24, BP Appendix IIA)



Identification by NMR

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

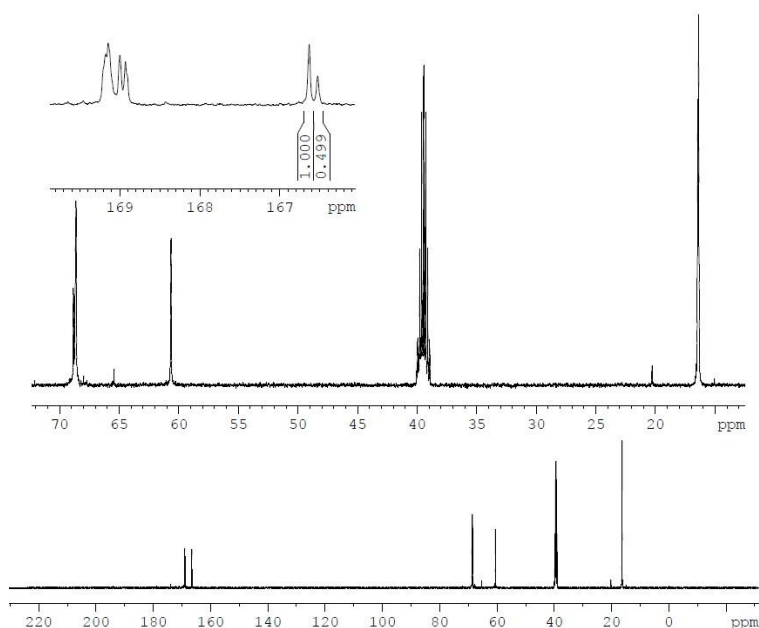
Ref: Polylactic-Co-Glycolic Acid (PLGA), Konstantinos Avgoustakis, Laboratory of Pharmaceutical Technology, Department of Pharmacy, University of Patras, Rio, Greece



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 to directly 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

Polymer Block length 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., Acid Terminated, 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.

Zinc content

Max 0.1% w/w

The test is performed according to IS:7874 (part-II) – 1975

Monomers

Total of monomers: < 2000 ppm

The test is performed by GC or Limit test by Q-NMR.

Residual Solvents

Small amounts of Dimethyl sulphoxide in the product within the minimum stability period. 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 4.0%

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

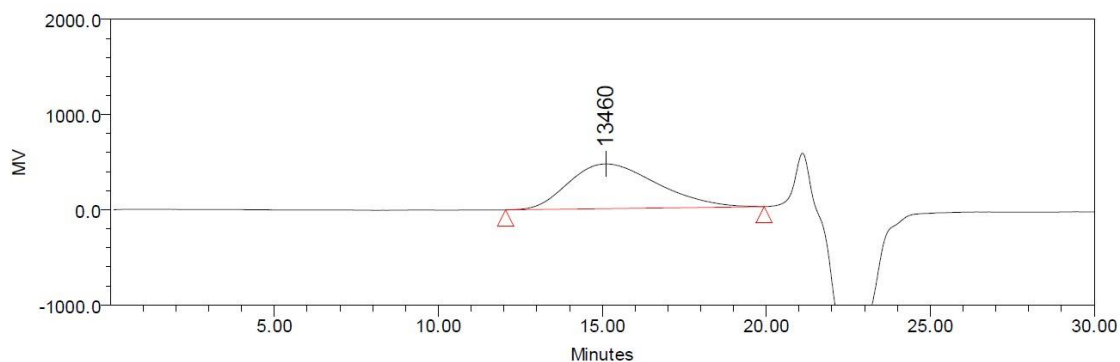
Not less than 98.0%

The Potency of Polymer is calculated by Acetanilide Internal standard concerning -CH₃ peak of polylactide.

Polydispersity and GPC Analysis

Polydispersity Between 1.2 and 2.2

Gel permeation chromatography analyzed with respect to Polystyrene Molecular weight Standards. (Typical reference chromatogram as per below)



GPC Results

	Retention Time (min)	Mn	Mw	MP	Mz	Mz+1	Poly dispersity
1	15.118	8065	13583	13460	19428	25263	1.68

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 ($\geq 30^\circ\text{C}$). 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.

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