

# SEQENS

CDMO



## DRUG DELIVERY

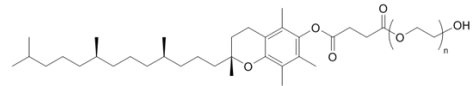
*Over 20 years leading in PLA & PLGA manufacturing*

### Biodegradable Polymers

- EXPANSORB® portfolio: PLA/PLGA and **PCL\*New** copolymers are ideal functional excipients for controlled release applications
  - Excellent biocompatibility, controllable biodegradability
  - Several commercial using PLA/PLGA
  - Currently approved by the FDA as an excipient in drug delivery systems (implants, parenterals) of injectable APIs, i.e peptides...
- EXPANSORB® Catalog polymers available from SEQENS' exclusive distributor: **Merck KGaA**
- Custom cGMP polymers on request

### Vitamin E TPGS

- Water soluble derivative of Vitamin E
  - multirole Excipient
  - Solubilizer of poorly soluble drug substance
- Manufactured under GMP - FDA site approved
- Seqens's DMF type IV: 034015



- Improving Drug Bioavailability
  - Surfactant, enhance solubilization of poorly water soluble drug
  - Stabilization of amorphous drug
  - Enhances drug permeability by P-glycoprotein efflux inhibition.
- Emulsion vehicle
- Functional Ingredient in self-emulsifying formulations
- Thermal binder in melt granulation/extrusion processing
- Reducing drug sensitivity on skin or tissues
- Carrier for wound care and treatment

## MEDICAL MATERIAL

*Polymers for Biomedical applications*

### cGMP

- Resorbable polymers
- Purification media for therapeutics proteins
- Chemicals for diabetes monitoring

### Medical Grade

- PEKK a thermoplastic poly-Ether-Ketone-ketone Polymer for durable medical use: dental, permanent implants, 3D printing... (catalog on demand)

## CAPABILITIES & SERVICES

- Dedicated polymers workshop unit
- From Kg to large scale capacity under GMP
- Standard and Ultrapure\* PLGA/PLA polymers (\*Low monomers content)
- Active US DMF type IV (Excipients)

# EXPANSORB® polymers: catalog and bulk specifications

Poly (D/L-Lactide) or PLA			
L/DL Lactide	IV (dl/g)	Mw (kDa)	Expansorb®
100	0.05-0.20	04-20	10P006
100	0.15-0.30	10-25	10P005
100	0.40-0.60	40-75	10P018
100	0.60-0.80	65-110	10P036
100	0.15-0.30	10-25	10P014
10	1.30-1.70	200-250	10P039
Poly (D/L-Lactide-co-Glycolide) or PLGA			
L/G	IV (dl/g)	MW (KDa)	Expansorb®
45/55	n/a	15-30	10P032
50/50 E	0.40-0.35	42-65	10P001
50/50	0.65-0.90	80-130	10P012
50/50	0.25-0.40	15-40	10P017
50/50	0.15-0.25	05-20	10P019
50/50	0.47-0.53	50-60	10P028
50/50	0.55-0.65	60-85	10P034
50/50 E	0.60-0.70	70-100	10P016
50/50 E	0.50-0.65	60-85	10P022
50/50 E	0.15-0.25	05-20	10P024
55/45	0.40-0.50	42-65	10P031
65/35	0.50-0.65	45-85	10P013
65/35	0.25-0.35	15-40	10P030
65/35 E	0.50-0.65	45-85	10P010
75/25	0.38-0.48	40-55	10P042
75/25	0.38-0.64	39-80	10P002
75/25	0.60-0.90	70-130	10P003
75/25	0.80-1.10	100-166	10P004
75/25	0.08-0.21	05-20	10P015
75/25	0.60-0.70	65-85	10P021
75/25 E	0.66-0.80	80-115	10P011
75/25 E	0.75-1.00	100-150	10P027
75/25 E	0.15-0.30	10-25	10P033
75/25 E	0.30-0.50	25-60	10P035
85/15	1.00-1.30	ND	10P040
85/15	0.55-0.75	65-95	10P008
85/15	0.25-0.35	14-26	10P038
85/15	0.15-0.25	10-20	10P020
85/15 E	0.25-0.35	14-26	10P044
85/15 E	0.55-0.75	65-95	10P009
85/15 E	1.00-1.30	150-220	10P043
90/10	0.35-0.55	30-70	10P007
90/10	0.60-0.70	60-95	10P029
95/5	0.15-0.25	05-20	10P023
95/5	0.25-0.50	25-60	10P025
Copolymer PLA-PEG or PLGA-PEG			
L/G	IV (dl/g)	MW (KDa)	Expansorb®
50/50 P	0.71-0.86	77-118	10P026
50/50 P	0.55-0.70	36-77	10P037
100 P	0.33-0.58	30-60	10P045
100 P	0.59-0.84	55-115	10P047
75/25 P	0.50-0.70	45-80	10P046
75/25 P	0.70-0.90	80-125	10P048

Additional specs: Bacterial Endotoxins (<5IU/g); TAMC (≤100 CFU/g); TYMC (≤50 CFU/g)  
 DMF: Drug Master File type IV available - IV: Inherent Viscosity - MW: Molecular Weight (kDa) - E: Ester - PEG: polyethylene glycol - PLA: poly (D/L, L) lactide - PLGA: poly (D/L-lactide-co-glycolide).



Poly(ε-caprolactone)  
 PCL  
 Expansorb®  
 10P201 (IV: 2,15-2,40)  
 10P202 (IV: 1,35-1,65)  
 10P203 (IV: 1,00-1,25)  
 10P204 (IV: 0,40-0,65)



## Custom polymers services

- Specific developments under CDA
- Full development capacity in house: from kilolab to industrial scale
- Large scale capacity (FDA inspected sites)
- Analytical resources and manufacturing units operate according to ICHQ7 and cGMP guidelines
- Full regulatory support: IMPD, DMF filling
- Long term storage (Expansorb®): below -15°C, under dry inert atmosphere

## Project management

Project leader and regular reporting  
 Confidentiality and strict respect of customer's IP

# SEQENS

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