

SynBiosys based sustained release formulations

"SynBiosys® is a safe, versatile, biodegradable polymer platform applicable for sustained release formulations of API's from days to months"

The SynBiosys polymers are multi-block copolymers composed of building blocks lactide, glycolide, ε-caprolactone and polyethylene glycol.

Original compound	Degradation products	Excreted as
Lactide	Lactic acid	CO ₂ and H ₂ O
Glycolide	Glycolic acid	CO ₂ and H ₂ O
Caprolactone	Hydroxy hexanoic acid	Hydroxy hexanoic acid
Polyethylene glycol (PEG)	PEG	PEG
Butanediisocyanate (BDI)	Butanediamine (putrescine), CO ₂ and H ₂ O	Butanediamine, CO ₂ and H ₂ O
Butanediol (BDO)	Butanediol	Butanediol

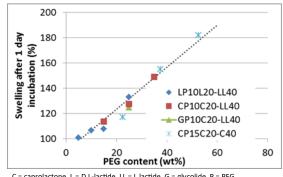
- ✓ Safe to use polymers
- ✓ Well known building blocks
- ✓ Biodegradable
- **✓** Urinary excretion

"SynBiosys® has endless versatility"

- ✓ Ample choice of building blocks in the multi-block copolymer
- ✓ Endless possibilities to fine tune water-swellability, polymer degradation and API release
- ✓ SynBiosys is designed to fit the purpose

Example SynBiosys structure:

Robust, linear swelling independent of polymer type:



C = caprolactone, L = D,L-lactide, LL = L,lactide, G = glycolide, P = PEG

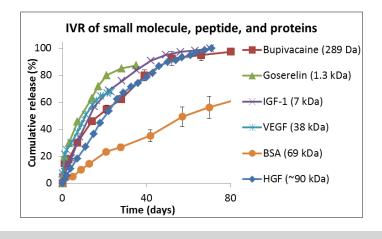


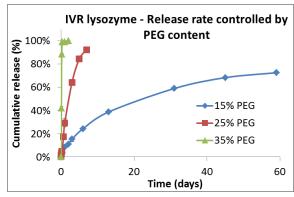
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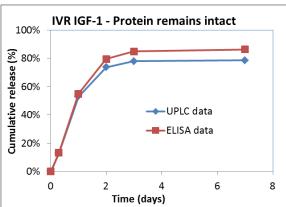
"SynBiosys® shows excellent release performance"

SynBiosys' versatility and water-swellability enable sustained release.

- ✓ From days to months
- ✓ Supporting small molecules, peptides and specially proteins
- ✓ By diffusion, thus without lag phase
- **✓** Limited or no burst of API







References

- Stankovic et al., European journal of pharmaceutics and biopharmaceutics, 2014, Volume: 87, Issue: 2, Pages: 329-337
- Stankovic et al., European journal of pharmaceutical sciences, 2013, Volume: 49, Issue: 4, Pages: 578-587
- Ramazani et al., European journal of pharmaceutics and biopharmaceutics, 2015, Volume: 95, Pages: 368-377, Part: B
- Gillisen et al., Journal of controlled release, 2006, Volume: 116, Issue: 2, Pages: E90-E92
- Steendam et al., Journal of controlled release, 2006, Volume: 116, Issue: 2, Pages: E94-E95
- WO2004-007588, Biodegradable phase separated MBCPs
- WO2005-068533, Amorphous MBCP
- WO2012-005594, Biodegradable, phase separated, segmented multi-block copolymers and release of biologically active polypeptides
- WO2013-015685, Biodegradable, semi-crystalline, phase-separated, thermoplastic multi-block copolymers for