

Enabling extremely narrow product specifications

A process technology for custom excipients

Resomer®
Precise



Unrivalled precision and accuracy for your drug product performance

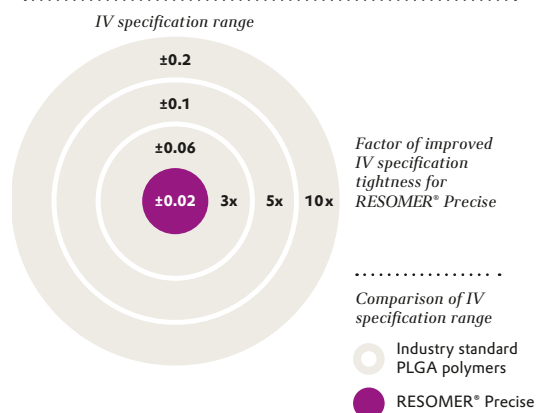
As complex parenterals continue to become more specialized and regulatory agencies increase their focus on quality and safety, it is increasingly important to ensure the excipients you select can consistently meet the precise specifications required for your final product.

Evonik has leveraged decades of expertise in polymerization processes to create RESOMER® Precise, a best-in-class process technology for customized excipients that can be validated to consistently meet even the most extreme product specifications.

RESOMER Precise provides you with the following advantages:

- Extremely tight product specifications such as:
 - inherent viscosity (IV) range of ± 0.02 dl/g
 - Precise control of glycolate block length
 - Very low residual monomer content
- Ability to perform process validation according to the defined product specifications
- Guaranteed product stability verified by stability studies and defined storage conditions
- Supports faster regulatory approval for your drug products through
 - Increased control of release profiles
 - Reduced formulation development times
 - Lower risk of delays in clinical trials

Enabling specifications up to 10 times tighter than standard PLGA polymers



A highly flexible platform available from our U.S. and EU sites

RESOMER® Precise is a customization option available with all Poly(D,L-lactide) and Poly(D,L-lactide-co-glycolide) types of RESOMER® polymers that are used for parenteral controlled release applications. These customized polymer solutions can be supplied from either of our GMP facilities in the U.S. and Germany to ensure you have the benefit of dual sourcing for security of supply.

Quality-by-Design (QbD) sampling, analytical and regulatory support and other excipient formulation development and manufacturing services are also available to further streamline your path to market.

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Evonik Nutrition & Care GmbH
Health Care Business Line
Pharma Polymers & Services

resomer@evonik.com
www.evonik.com/resomer