

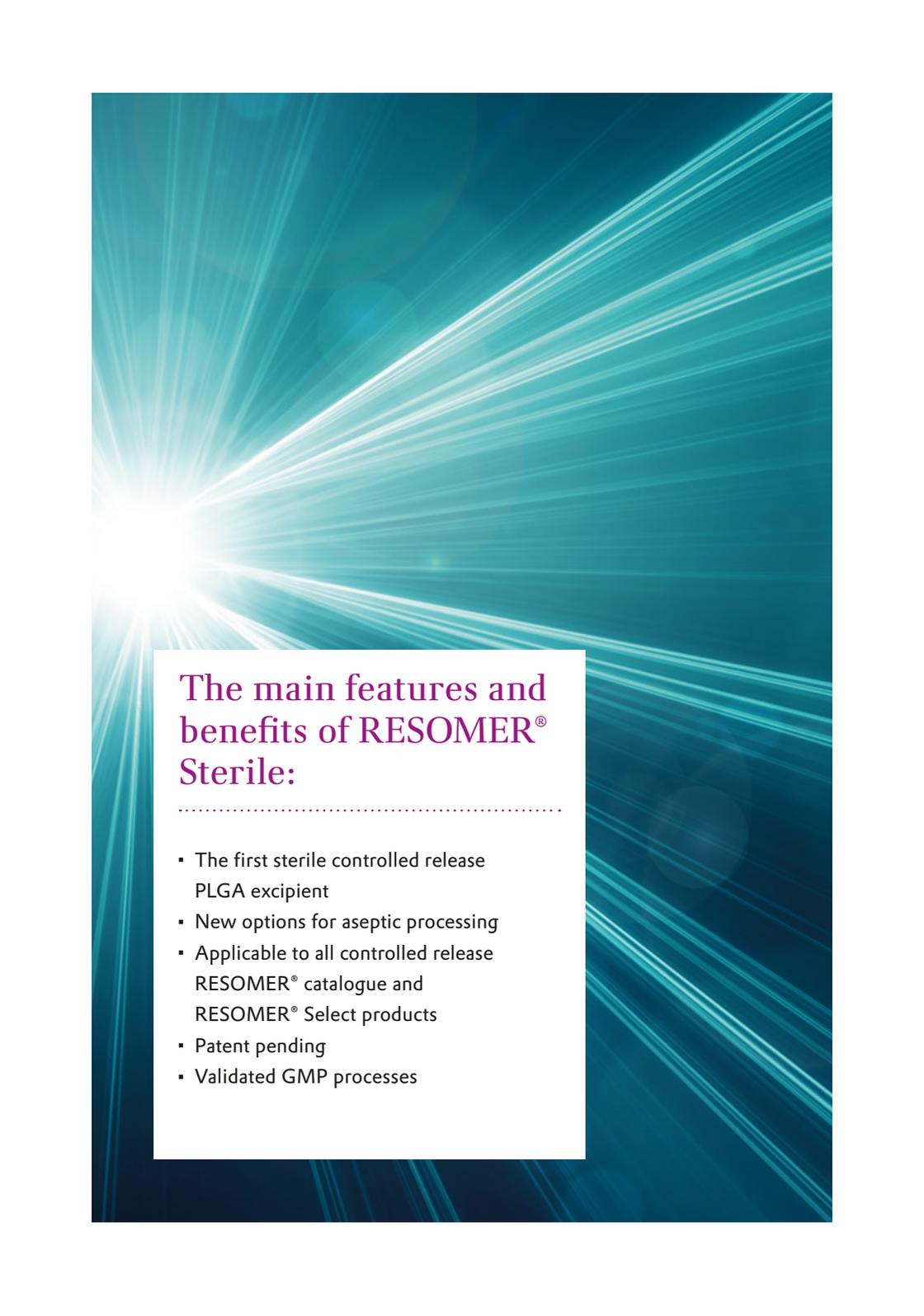
Ready. Sterile. Go.

Creating new manufacturing options and reduced steps for aseptic processing

Resomer® Sterile



 **EVONIK**
POWER TO CREATE

The background of the slide is a vibrant teal color with a dynamic pattern of light rays emanating from a bright white point on the left side, creating a sense of energy and focus.

The main features and benefits of RESOMER® Sterile:

- The first sterile controlled release PLGA excipient
- New options for aseptic processing
- Applicable to all controlled release RESOMER® catalogue and RESOMER® Select products
- Patent pending
- Validated GMP processes

RESOMER® Sterile is the first and only sterile controlled release poly (lactic-co-glycolic) (PLGA) excipient. New options are now enabled for the manufacturing of parenteral drugs, improved process controls and streamlined steps for aseptic processing. RESOMER® Sterile is manufactured using a proprietary GMP (Good manufacturing Practice) process. Polymer bulk density is tuned for easy handling during formulation.

Aseptic processing avoids possible detrimental effects on polymer, API and drug products as compared to terminal sterilization. Evonik developed RESOMER® Sterile to allow more options for aseptic processing, especially for formulations that cannot be sterilized by filtration, e.g., powder processing. RESOMER® Sterile can benefit drug formulations using terminal sterilization as it is a premium excipient with minimized bioburden level.

RESOMER® Sterile versions are available on a made to order basis for any controlled release RESOMER® catalogue product or RESOMER® Select custom-made product. The polymers are designed to meet high SAL (sterility assurance level) of 10^{-6} while preserving the proven reliability and quality of RESOMER® products.



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RESOMER® = reg. trademark of Evonik Industries AG and its subsidiaries

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