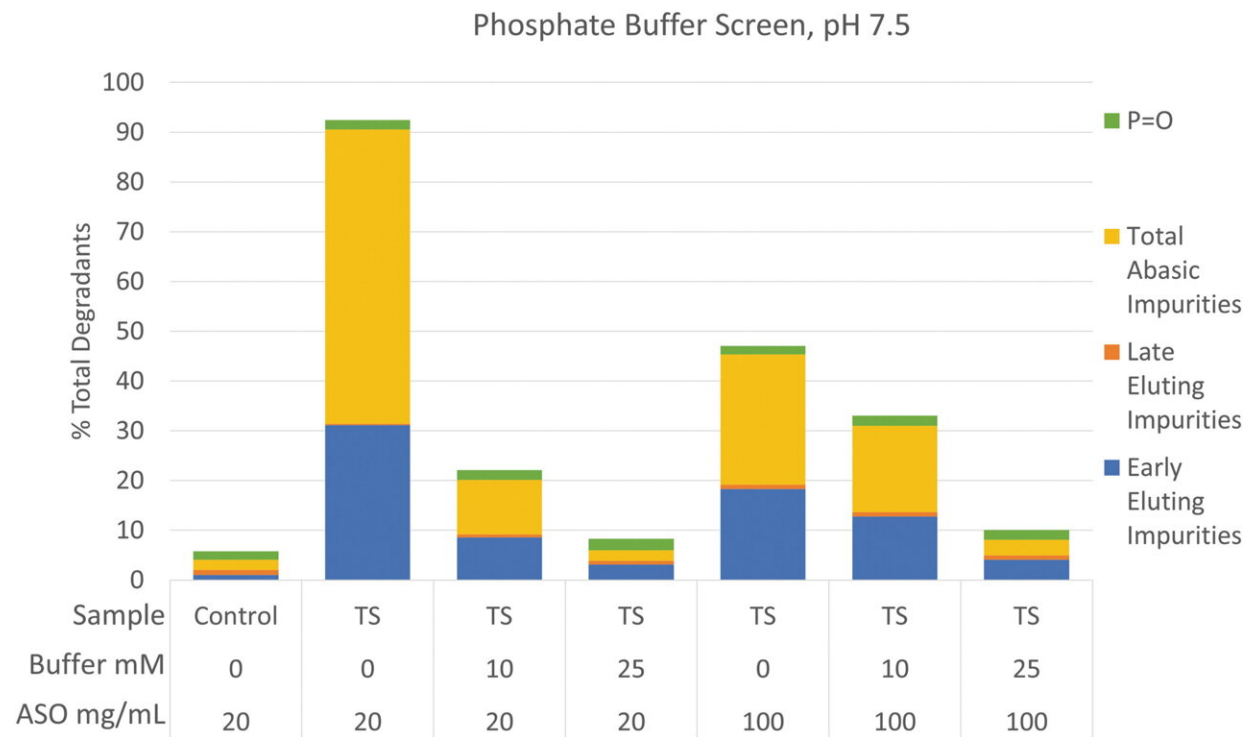


# Terminal sterilization of oligonucleotide drug products

February 22 2023



The effect of formulation buffer on the stability of a model oligonucleotide during terminal sterilization at 115°C for 15 min. Credit: *Nucleic Acid Therapeutics* (2023). DOI: 10.1089/nat.2022.0073

A new report, coauthored by several major pharmaceutical companies, reviews the current state of sterile oligonucleotide drug product processing. The article, which provides recommendations to aid in the

evaluation and development of terminal sterilization processes, is published in *Nucleic Acid Therapeutics*.

All marketed oligonucleotide products are delivered as sterile preparations for parenteral delivery. The two most common methods for sterilizing parenteral drug products are terminal sterilization and membrane sterilization. Terminal sterilization provides greater sterility assurance than membrane sterilization, but not all drug products are amenable to terminal sterilization, which usually involves exposure to high heat or ionizing radiation.

Regarding the terminal sterilization of oligonucleotides, the authors provide recommendations for formulation development, assessing changes in the purity and impurity profile after terminal sterilization, and selecting the correct container closure.

"As the field continues to advance, commercial and [academic researchers](#) alike look to *Nucleic Acid Therapeutics* to provide the community with clear, detailed guidance on candidate therapeutic development and processing," says Executive Editor Graham C. Parker, Ph.D., Department of Pediatrics, Wayne State University School of Medicine, Detroit, MI.

**More information:** Daniel Paul DeCollibus et al, Considerations for the Terminal Sterilization of Oligonucleotide Drug Products, *Nucleic Acid Therapeutics* (2023). [DOI: 10.1089/nat.2022.0073](https://doi.org/10.1089/nat.2022.0073)

Provided by Mary Ann Liebert, Inc

Citation: Terminal sterilization of oligonucleotide drug products (2023, February 22) retrieved 21 June 2024 from

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