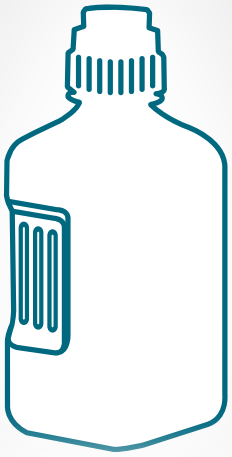
thermo scientific

Thinking beyond sterile

Within the biopharmaceutical manufacturing industry, sterility and contamination are common, serious concerns. Particulate contamination can render products unusable and causing losses of investment as well as time.

Choosing Thermo Scientific™ Nalgene™ Certified Clean and Platinum Clean Bottles and Carboys can help you avoid these losses by minimizing risk of product contamination.



USP <788> describes the amounts of particulate based on size and count allowed in injections and parenteral preparations.

41% **of industry professionals* are not familiar with USP <788>**

92% of industry professionals* are concerned about particulate contamination in their final product

48% of industry professionals* track the level of particulate contamination throughout the manufacturing process

Particulate levels can compound throughout manufacturing steps, with risk of contamination arising from various sources

	Extrinsic contamination 33%	Inherent contamination 19%	Intrinsic contamination 48%
Contamination risk factors perceived by industry professionals			
Potential contamination source	Material from the external environment	Expected from Active Pharmaceutical Ingredients (API) and formulation components	From sources related to the product, packaging, or process
Risk mitigation strategies compliant with USP <788>	Always work in the correct clean room environment	Use product release criteria that are a two-third fraction of USP <788> to accommodate for assay error and batch variation	Throughout the manufacturing process, ensure the use of the cleanest product containers available

* According to the 2019 Thermo Scientific Bioprocessing Particulate Contamination Survey.

Find out more at **thermofisher.com/uspclean**

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