

Special Considerations for Measuring the Particle Size Distributions of Liquid Aerosols

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Abstract

Liquid aerosols are problematic to characterize accurately as they can change size if they are not in equilibrium with their environment. Nebulizers humidify the air passing through the nebulizer by evaporation from the droplets which cools the aerosol exiting the nebulizer. If an impactor is at ambient temperature, the aerosol will be warmed by the impactor, and droplets will evaporate causing an underestimation of the true particles size distribution (PSD). Using laser diffraction is a good option for research and development, but the measurements are not recognized by regulatory agencies as they do not directly measure the distribution of drug in the PSD. Validating your impactor method at ambient temperature is also not recommended due to potential conflicts between data used for scientific purposes and those used in promotion of the drug product. Working with cooled impactors is recommended for generating data for regulatory submissions.