

ABSTRACT

Laboratory Plan and Data Recording

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The first of two laboratory sessions is designed to provide participants with a practical experience on the important aspects in making Dose Content Uniformity (DCU) determinations, both for a metered-dose inhaler (MDI) and for a dry-powder inhaler (DPI). This testing includes setting the sampling flow rate, extracting the active drug product from the test filter, and obtaining a liquid sample suitable for quantification with ultraviolet spectrometry. Students will compare results to the label claim of the registered drug products.

In the second laboratory session, participants will measure the size of particles emitted by an MDI using both a full-resolution impactor and an abbreviated impactor. Participants will also test a nasal spray with the typical glass chamber attached to an abbreviated impactor. Once samples from these experiments have been obtained, students will analyze them for drug content and record the data for a following session on data analysis. When not actively involved in either of these activities, students will be given a demonstration in particle size analysis using Laser Diffraction.

The laboratory component of the school will allow students to approach confidently the measurement of critical metrics of inhaler performance by conducting the same measurements required by Pharmacopeial methods or those that would be carried out in their own company's quality control environment.