Guidance document: 110-14

Adopted: December 9, 2019

Effective:

## VIRGINIA BOARD OF PHARMACY

## Statistically Valid Sample Size for Pharmaceutical Processors

The Board deems that a sample size consistent with the sampling requirements found in the United States Pharmacopeia Chapter < 561> Articles of Botanical Origin will satisfy the requirement in Regulation 18VAC110-60-300 for a "statistically valid sample."

## 18VAC110-60-300. Laboratory requirements; testing.

B. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.